TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

NOTE: Under IC 16-1-1-6, the name of the Indiana State Board of Health is changed to Indiana State Department of Health, effective January 1, 1992.

ARTICLE 1. COMMUNICABLE DISEASE CONTROL

Rule 1. Immunization of School Children

410 IAC 1-1-1 Immunization requirements

Authority: IC 20-8.1-7-9.5
Affected: IC 20-8.1-7

Sec. 1. Immunization Requirements. For those diseases listed in IC 20-8.1-7 (diphtheria, tetanus, whooping cough, poliomyelitis, measles, and rubella), the adequately immunizing doses and the child's age for administering each vaccine shall be those recommended in the current Report of the Committee on Infectious Diseases of the American Academy of Pediatrics ("Red Book") or those currently recommended by the United States Public Health Service Advisory Committee on Immunization Practices. *(Indiana State Department of Health; Reg HCD 32,Sec 1; filed Aug 12, 1976, 10:09 am: Rules and Regs. 1977, p. 217; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-1-2 Immunization history; parental statement

Authority: IC 20-8.1-7-9.5
Affected: IC 20-8.1-7

Sec. 2. Statement of Immunization History. When a child enrolls for the first time in a school corporation the parents shall furnish to the governing body of that corporation an adequately documented statement of the child's immunizations which shall show that the child has received at least the minimum number of doses for his age as recommended by the official bodies named in Section 1 *[410 IAC 1-1-1]*. The statement shall also show whether the child has been tested for sickle cell anemia or for lead poisoning and the results of any such testing. *(Indiana State Department of Health; Reg HCD 32,Sec 2; filed Aug 12, 1976, 10:09 am: Rules and Regs. 1977, p. 217; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-1-3 Documentation of immunization history

Authority: IC 20-8.1-7-9.5
Affected: IC 20-8.1-7

Sec. 3. Documentation. Adequate documentation of an immunization history shall consist of:
(a) a physician's certificate, if available; or
(b) immunization records forwarded from another school corporation; or
(c) a record maintained by the parent showing the month and year during which each dose of vaccine was administered.
(Indiana State Department of Health; Reg HCD 32,Sec 3; filed Aug 12, 1976, 10:09 am: Rules and Regs. 1977, p. 218; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-1-4 Report forms submitted by school corporations

Authority: IC 20-8.1-7-9.5
Affected: IC 20-8.1-7

Sec. 4. Reports of Immunization and Testing to the State Board of Health. All reports required to be made to the State Board of Health by school corporations shall be submitted on forms prescribed and provided by the Board for those purposes. *(Indiana State Department of Health; Reg HCD 32,Sec 4; filed Aug 12, 1976, 10:09 am: Rules and Regs. 1977, p. 218; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. Communicable Disease Reporting and Control (Repealed)

(Repealed by Indiana State Department of Health; filed Jul 27, 1988, 2:50 pm: 11 IR 4098)

Rule 2.1. Disease Reporting and Control (Repealed)

(Repealed by Indiana State Department of Health; filed Sep 11, 2000, 1:36 p.m.: 24 IR 369)

Rule 2.2. Notification of Person at Risk

410 IAC 1-2.2-1 "Carrier" defined

Authority: IC 16-41-7-4
Affected: IC 16-41-7

Sec. 1. As used in this rule, "carrier" means a person infected with human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) or tested positive for Hepatitis B surface antigen. *(Indiana State Department of Health; 410 IAC 1-2.2-1; filed Mar 21, 1994, 5:00 p.m.: 17 IR 1882; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-2.2-2 "Department" defined

Authority: IC 16-41-7-4
Affected: IC 16-41-7

Sec. 2. As used in this rule, "department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 1-2.2-2; filed Mar 21, 1994, 5:00 p.m.: 17 IR 1882; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-2.2-3 "High risk activity" defined

Authority: IC 16-41-7-4
Affected: IC 16-41-7

Sec. 3. As used in this rule, "high risk activity" means sexual or needle sharing contact that has been demonstrated epidemiologically to transmit a dangerous communicable disease, such as human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), or Hepatitis B. *(Indiana State Department of Health; 410 IAC 1-2.2-3; filed Mar 21, 1994, 5:00 p.m.: 17 IR 1882; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-2.2-4 "Person at risk" defined

Authority: IC 16-41-7-4
Affected: IC 16-41-7

Sec. 4. As used in this rule, "person at risk" means an individual who, in the best judgment of a physician, has engaged in high risk activity or is in imminent danger of engaging in high risk activity. *(Indiana State Department of Health; 410 IAC 1-2.2-4; filed Mar 21, 1994, 5:00 p.m.: 17 IR 1882; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-2.2-5 Reports to local health officer

Authority: IC 16-41-7-4
Affected: IC 16-41-7

Sec. 5. (a) If a health officer is notified in writing by a physician of a patient for whom the physician has medical verification that the patient is a carrier, and who, in the best judgment of the physician, is a serious and present danger to the health of others, the health officer shall make an investigation of the carrier to determine whether the environmental conditions surrounding the carrier or the conduct of the carrier requires the intervention by the health officer or designated health official to prevent the spread of disease to others. This investigation shall include the following:

(1) A determination of the environmental conditions or specific conduct of the carrier that pose a risk of spreading the disease.

(2) A determination of the epidemiological significance of the risk of spreading disease caused by the environmental conditions or the conduct of the carrier.

(b) If it is determined, following the investigation, that the condition or conduct warrants further intervention, this action shall be handled by the local health officer or referred to the department for further action. *(Indiana State Department of Health; 410 IAC 1-2.2-5; filed Mar 21, 1994, 5:00 p.m.: 17 IR 1882; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-2.2-6 Contact by department

Authority: IC 16-41-7-4
Affected: IC 16-41-7-3

Sec. 6. (a) If the department is requested in writing by a physician who has complied with IC 16-41-7-3(b)(2) to notify a person at risk, the department shall contact the physician to determine that the physician:

(1) has medical verification that the patient is a carrier;

(2) knows the identity of the person at risk and has a reasonable belief of a significant risk of harm to the identified person at risk;

(3) has reason to believe the identified person at risk has not been informed and will not be informed of the risk by the patient or another person; and

(4) has made reasonable efforts to inform the carrier of the physician's intent to make or cause the department to make a disclosure to the person at risk.

(b) The department shall notify the person at risk unless, in the opinion of the department, the person at risk:

(1) has already been notified;

(2) will be notified; or

(3) will otherwise be made aware that they are a person at risk.

(Indiana State Department of Health; 410 IAC 1-2.2-6; filed Mar 21, 1994, 5:00 p.m.: 17 IR 1883; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-2.2-7 Confidentiality of notice

Authority: IC 16-41-7-4
Affected: IC 16-41-7

Sec. 7. All notifications of persons at risk shall be conducted confidentially and in person by trained public health disease intervention specialists (DIS). All identified persons at risk shall receive information about counseling and be offered serologic testing. *(Indiana State Department of Health; 410 IAC 1-2.2-7; filed Mar 21, 1994, 5:00 p.m.: 17 IR 1883; errata filed Apr 14, 1994, 5:00 p.m.: 17 IR 2080; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-2.2-8 Registry

Authority: IC 16-41-7-4
Affected: IC 16-41-7

Sec. 8. The department shall establish a confidential registry of all persons submitting written requests pursuant to section 6 of this rule. The registry shall include the following information about the physician:

(1) Full name.

(2) Street address.

(3) City.

(4) Zip code.

(5) County.

(6) Telephone number.

(Indiana State Department of Health; 410 IAC 1-2.2-8; filed Mar 21, 1994, 5:00 p.m.: 17 IR 1883; errata filed Apr 14, 1994, 5:00 p.m.: 17 IR 2080; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 2.3. Disease Reporting and Control

410 IAC 1-2.3-1 Applicability
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 1-2.3-1; filed Sep 11, 2000, 1:36 p.m.: 24 IR 334)*

410 IAC 1-2.3-2 "Active surveillance" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 2. "Active surveillance" means taking measures to identify all cases of an infectious disease by the local health officer or department, including, but not limited to, calling or otherwise contacting:
(1) physicians;
(2) hospitals;
(3) clinics;
(4) laboratories; and
(5) others who might be aware of cases of disease.
(Indiana State Department of Health; 410 IAC 1-2.3-2; filed Sep 11, 2000, 1:36 p.m.: 24 IR 334)

410 IAC 1-2.3-3 "Airborne precautions" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 3. "Airborne precautions" means transmission-based precautions for health care facilities designed to reduce the risk of airborne transmission of infectious agents. Requirements for airborne precautions are presented in Guidelines for Isolation Precautions in Hospitals, Infection Control and Hospital Epidemiology, Volume 17, No. 1, January 1996. *(Indiana State Department of Health; 410 IAC 1-2.3-3; filed Sep 11, 2000, 1:36 p.m.: 24 IR 334)*

410 IAC 1-2.3-4 "Bloodborne pathogens" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 4. "Bloodborne pathogens" means pathogenic micro-organisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, the following:
(1) HBV.
(2) HCV.
(3) HIV.
(Indiana State Department of Health; 410 IAC 1-2.3-4; filed Sep 11, 2000, 1:36 p.m.: 24 IR 334)

410 IAC 1-2.3-5 "Carrier" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 5. "Carrier" means a person who harbors a specific infectious agent without discernible clinical disease and serves as a potential source of infection. *(Indiana State Department of Health; 410 IAC 1-2.3-5; filed Sep 11, 2000, 1:36 p.m.: 24 IR 334)*

410 IAC 1-2.3-6 "Case" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 6. "Case" means a person who harbors a communicable disease, usually in the presence of discernible clinical disease, symptoms, or signs and may serve as a potential source of infection. Specific case definitions are defined in the Centers for Disease Control and Prevention publication Case Definitions for Infectious Conditions Under Public Health Surveillance, MMWR, Recommendations and Reports, May 2, 1997, Volume 46, No. RR-10 and by reference are incorporated into this rule. *(Indiana State Department of Health; 410 IAC 1-2.3-6; filed Sep 11, 2000, 1:36 p.m.: 24 IR 334)*

410 IAC 1-2.3-7 "Case ascertainment" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 7. "Case ascertainment" means collecting clinical, laboratory, and epidemiological information for the purpose of determining whether a reported case of disease met the standard clinical or laboratory case definition for the disease, or both. *(Indiana State Department of Health; 410 IAC 1-2.3-7; filed Sep 11, 2000, 1:36 p.m.: 24 IR 334)*

410 IAC 1-2.3-8 "Case management" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 8. "Case management" means systematic monitoring and quality assurance of diagnosis, treatment, control, and prevention strategies performed by public health employees, including, but not limited to, local health officers and their designees. *(Indiana State Department of Health; 410 IAC 1-2.3-8; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)*

410 IAC 1-2.3-9 "Cleaning" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 9. "Cleaning" means the removal by scrubbing and washing, as with water and soap or suitable detergent, or by vacuum cleaning of infectious agents and of organic matter from surfaces on which and in which infectious agents may find favorable conditions for surviving or multiplying. *(Indiana State Department of Health; 410 IAC 1-2.3-9; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)*

410 IAC 1-2.3-10 "Commissioner" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 10. "Commissioner" means the state health commissioner or authorized officers, employees, or agents of the department. *(Indiana State Department of Health; 410 IAC 1-2.3-10; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)*

410 IAC 1-2.3-11 "Communicable disease" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 11. "Communicable disease" means an illness due to a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal, or inanimate reservoir to a susceptible host, either directly or indirectly, through an intermediate plant or animal host, vector, or the inanimate environment. *(Indiana State Department of Health; 410 IAC 1-2.3-11; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)*

410 IAC 1-2.3-12 "Concurrent disinfection" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 12. "Concurrent disinfection" means the application of disinfective measures including use of an EPA approved disinfectant cleaning agent as soon as possible after the discharge of infectious material from the body of an infected person or after the soiling of articles with such infectious discharges. *(Indiana State Department of Health; 410 IAC 1-2.3-12; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)*

410 IAC 1-2.3-13 "Contact" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 13. "Contact" means a person or animal that has been in association with an infected person or animal, or a contaminated environment that is likely to provide an opportunity to acquire the infection. *(Indiana State Department of Health; 410 IAC 1-2.3-13; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)*

410 IAC 1-2.3-14 "Contact precautions" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 14. "Contact precautions" means procedures in addition to standard precautions to prevent transmission in health care facilities of diseases or conditions which are spread primarily by direct or indirect contact. Direct contact transmission involves skin-to-skin contact and physical transfer of micro-organisms to a susceptible host from an infected or colonized person. For details of the precautions see Guideline for Isolation Precautions in Hospitals, Infection Control and Hospital Epidemiology, Volume 17, No. 1, January 1996. *(Indiana State Department of Health; 410 IAC 1-2.3-14; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)*

410 IAC 1-2.3-15 "Contact tracing" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 15. "Contact tracing" means the use of epidemiological methods to confidentially locate, counsel, and refer for medical evaluation and possible treatment of person or persons who have been in contact with someone with a communicable disease in a manner that might provide an opportunity to acquire the disease. *(Indiana State Department of Health; 410 IAC 1-2.3-15; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)*

410 IAC 1-2.3-16 "Contaminated sharp" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 16. (a) "Contaminated sharp" means an object that meets the following conditions:
(1) Is capable of cutting or penetrating the skin.
(2) Has been in contact with blood or other potentially infectious materials.
(b) The term includes, but is not limited to, the following:
(1) Hypodermic or suture needle.
(2) Scalpel blade.
(3) Pipette.
(4) Lancet.
(5) Broken glass.
(Indiana State Department of Health; 410 IAC 1-2.3-16; filed Sep 11, 2000, 1:36 p.m.: 24 IR 335)

410 IAC 1-2.3-17 "Contamination" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 17. "Contamination" means the presence of an infectious agent:
(1) on a body surface;
(2) in clothes;
(3) in bedding;
(4) on toys;
(5) on surgical instruments or dressings; or
(6) in or on other inanimate articles or substances, including water and food.
(Indiana State Department of Health; 410 IAC 1-2.3-17; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)

410 IAC 1-2.3-18 "Control measures" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 18. "Control measures" means those measures to reduce the threat of disease transmission from a case of communicable disease. *(Indiana State Department of Health; 410 IAC 1-2.3-18; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-19 "Counseling and testing site" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 19. "Counseling and testing site" means a place that has been designated, approved, and registered with the department to counsel and test individuals anonymously or confidentially, or both, for HIV. *(Indiana State Department of Health; 410 IAC 1-2.3-19; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-20 "Day care center" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 20. "Day care center" means a day nursery that is any institution operated for the purpose of providing care and maintenance to children separated from their parent, guardian, or custodian during a part of the day for two (2) or more consecutive weeks, except a school or other bona fide educational institution. *(Indiana State Department of Health; 410 IAC 1-2.3-20; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-21 "Decontamination" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 21. "Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne and other pathogens on a surface or item that does not require sterilization, thus rendering the item safe for handling, use, or disposal. *(Indiana State Department of Health; 410 IAC 1-2.3-21; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-22 "Department" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 22. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 1-2.3-22; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-23 "Droplet precautions" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 23. "Droplet precautions" means measures to reduce the risk of droplet transmission of infectious agents. Droplet transmission involves contact of the conjunctivae or the mucous membranes of the nose or mouth of a susceptible person with large-particle droplets (larger than five (5) micrometers in size) containing micro-organisms generated from a person who has a clinical disease or who is a carrier of the micro-organism. For complete description, see Guideline for Isolation Precautions in Hospitals, Infection Control and Hospital Epidemiology, Volume 17, No. 1, 1996. *(Indiana State Department of Health; 410 IAC 1-2.3-23; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-24 "Food handler" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 24. "Food handler" means an individual who works with unpackaged food, food equipment or utensils, or food contact surfaces. *(Indiana State Department of Health; 410 IAC 1-2.3-24; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-25 "Hand washing procedures" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 25. "Hand washing procedures" means vigorous washing of hands using soap and running water from an approved water supply, followed by drying hands using clean paper or single use cloth toweling or air drying devices. An alcohol-based hand rinse/foam may be used when hands are not visibly soiled and in accordance with manufacturer's guidelines. *(Indiana State Department of Health; 410 IAC 1-2.3-25; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-26 "HBV" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 26. "HBV" means hepatitis B virus. *(Indiana State Department of Health; 410 IAC 1-2.3-26; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-27 "HCV" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 27. "HCV" means hepatitis C virus. *(Indiana State Department of Health; 410 IAC 1-2.3-27; filed Sep 11, 2000, 1:36 p.m.: 24 IR 336)*

410 IAC 1-2.3-28 "Health care facility" defined

Authority: IC 16-41-2-1
Affected: IC 12-25; IC 16-21-2; IC 16-24-1; IC 16-28; IC 16-41-2

Sec. 28. "Health care facility" includes the following:

(1) Hospitals licensed under IC 16-21-2, private mental health institutions licensed under IC 12-25, and tuberculosis hospitals established under IC 16-24-1.

(2) Health facilities licensed under IC 16-28.

(3) Rehabilitation facilities and kidney disease treatment centers.

(Indiana State Department of Health; 410 IAC 1-2.3-28; filed Sep 11, 2000, 1:36 p.m.: 24 IR 337)

410 IAC 1-2.3-29 "Health care worker" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 29. "Health care worker" means a person who provides services whether as an individual health care provider, volunteer, or student at or employee of a health care facility. *(Indiana State Department of Health; 410 IAC 1-2.3-29; filed Sep 11, 2000, 1:36 p.m.: 24 IR 337)*

410 IAC 1-2.3-30 "HIV" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 30. "HIV" means human immunodeficiency virus. *(Indiana State Department of Health; 410 IAC 1-2.3-30; filed Sep 11, 2000, 1:36 p.m.: 24 IR 337)*

410 IAC 1-2.3-31 "HIV infection/disease" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 31. "HIV infection/disease" means a condition that meets the criteria of one (1) of the following:
(1) Persons who meet the Centers for Disease Control and Prevention (CDC) definition of AIDS, as found in Morbidity and Mortality Weekly Report, Volume 41, Recommendations and Reports No. RR-17, December 18, 1992.
(2) Persons who have serologic evidence of HIV infection.
(3) Other persons with signs or symptoms, or both, that cause the attending physician to strongly suspect HIV infection.
(4) Infants born to mothers with HIV infection/disease and who have not been determined to be a seroreverter as defined in the Morbidity and Mortality Weekly Report Volume 43, No. RR-12, 1994 Revised Classified System for Human Immunodeficiency Virus Infection in Children Less Than 13 Years of Age.
(5) Children under thirteen (13) years of age who meet the CDC definition of HIV infection or AIDS, or both, as found in Morbidity and Mortality Weekly Report Volume 43, No. RR-12, 1994 Revised Classified System for Human Immunodeficiency Virus Infection in Children Less Than 13 Years of Age.
(6) Persons who meet the CDC Revised Surveillance Case Definition for HIV Infection, as found in Morbidity and Mortality Weekly Report, Vol. 48, No. RR-13, 1999, CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome.
(Indiana State Department of Health; 410 IAC 1-2.3-31; filed Sep 11, 2000, 1:36 p.m.: 24 IR 337)

410 IAC 1-2.3-32 "Intervention or prevention activities" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 32. "Intervention or prevention activities" means:
(1) the promotion of health by personal or community-wide efforts;
(2) early detection to correct deviations from good health; and
(3) the reduction of impairments and disabilities caused by existing departures from good health.
(Indiana State Department of Health; 410 IAC 1-2.3-32; filed Sep 11, 2000, 1:36 p.m.: 24 IR 337)

410 IAC 1-2.3-33 "Invasive disease" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 33. "Invasive disease" means disease:
(1) in association with positive bacterial cultures from:
(A) blood;
(B) cerebrospinal fluid;
(C) pleural fluid;
(D) pericardial fluid;

(E) synovial fluid; or
(F) other usually sterile body fluid; or
(2) such as epiglottitis or necrotizing fasciitis, in association with positive bacterial cultures from those sites.
(Indiana State Department of Health; 410 IAC 1-2.3-33; filed Sep 11, 2000, 1:36 p.m.: 24 IR 337)

410 IAC 1-2.3-34 "Local health officer" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 34. "Local health officer" means the county/city health officer or authorized officers, employees, or agents of the county/city health department. *(Indiana State Department of Health; 410 IAC 1-2.3-34; filed Sep 11, 2000, 1:36 p.m.: 24 IR 337)*

410 IAC 1-2.3-35 "Medical laboratory" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 35. "Medical laboratory" means an entity that engages in the biological, microbiological, serological, chemical, immunohematological, radioimmunological, hematological, cytological, pathological, or other examination of materials derived from the human body for the detection, diagnosis, prevention, or treatment of any disease, infection, or impairment, or the assessment of human health. *(Indiana State Department of Health; 410 IAC 1-2.3-35; filed Sep 11, 2000, 1:36 p.m.: 24 IR 337)*

410 IAC 1-2.3-36 "Other potentially infectious materials" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 36. "Other potentially infectious materials" means:
(1) semen;
(2) vaginal secretions;
(3) cerebrospinal fluid;
(4) synovial fluid;
(5) pleural fluid;
(6) pericardial fluid;
(7) peritoneal fluid;
(8) amniotic fluid;
(9) saliva in dental procedures;
(10) any body fluid that is visibly contaminated with blood;
(11) all body fluids where it is difficult or impossible to differentiate between body fluids;
(12) any unfixed tissue or organ (other than intact skin) from a human, living or dead;
(13) any HIV-containing cell or tissue cultures, organ cultures and HIV-containing or HBV-containing culture medium; or
(14) blood, organs, or other tissues from experimental animals infected with HIV, HBV, or HCV.
(Indiana State Department of Health; 410 IAC 1-2.3-36; filed Sep 11, 2000, 1:36 p.m.: 24 IR 338)

410 IAC 1-2.3-37 "Outbreak" defined
Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 37. "Outbreak" means cases of disease occurring in a community, region, or particular population at a rate clearly in excess of that which is normally expected. *(Indiana State Department of Health; 410 IAC 1-2.3-37; filed Sep 11, 2000, 1:36 p.m.: 24 IR 338)*

410 IAC 1-2.3-38 "Quarantine" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 38. "Quarantine" means the restriction of the activities or confinement of well persons or animals who have, or may have been exposed to a case of communicable disease during its period of communicability to prevent disease transmission during the incubation period, if infection should occur. *(Indiana State Department of Health; 410 IAC 1-2.3-38; filed Sep 11, 2000, 1:36 p.m.: 24 IR 338)*

410 IAC 1-2.3-39 "Restriction of activities" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 39. "Restriction of activities" means limitations placed on the activities of persons with disease or infection to prevent transmission of communicable diseases to other individuals. *(Indiana State Department of Health; 410 IAC 1-2.3-39; filed Sep 11, 2000, 1:36 p.m.: 24 IR 338)*

410 IAC 1-2.3-40 "Serious and present danger to health" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-7-1; IC 16-41-9-1

Sec. 40. "Serious and present danger to health", as used in IC 16-41-9-1 and this rule, means one (1) or more of the following:

(1) Failure to comply with the measures specified under this rule.

(2) Repeated behavior by a carrier or case that has been demonstrated epidemiologically to transmit, or evidences a careless disregard for the transmission of the disease to others.

(3) A substantial likelihood that a carrier or case will repeatedly transmit the disease to others as is evidenced by that individual's past behavior, or by statements of the individual that are credible indicators of the individual's intention.

(4) Affirmative misrepresentation by a carrier of his or her carrier status prior to engaging in any behavior that has been epidemiologically demonstrated to transmit the disease.

(5) Failure or refusal to carry out the carrier's or case's duty to warn under IC 16-41-7-1.

(Indiana State Department of Health; 410 IAC 1-2.3-40; filed Sep 11, 2000, 1:36 p.m.: 24 IR 338)

410 IAC 1-2.3-41 "Sexually transmitted disease" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 41. "Sexually transmitted disease" means local or systemic communicable diseases due to infectious agents, generally transmitted person-to-person by sexual intercourse on genital mucosal contact, including, but not limited to, the following:

(1) HIV.
(2) HBV.
(3) HCV.
(4) Gonorrhea.
(5) Chlamydia.
(6) Syphilis.
(7) Chancroid.
(8) Granuloma inguinale.

(Indiana State Department of Health; 410 IAC 1-2.3-41; filed Sep 11, 2000, 1:36 p.m.: 24 IR 338)

410 IAC 1-2.3-42 "Standard precautions" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 42. "Standard precautions" means measures used for all patients to prevent the nosocomial spread of micro-organisms in hospitals. Requirements of standard precautions are presented in Guideline for Isolation Precautions in Hospitals, Infection Control and Hospital Epidemiology, Volume 17, No. 1, January 1996. *(Indiana State Department of Health; 410 IAC 1-2.3-42; filed Sep 11, 2000, 1:36 p.m.: 24 IR 339)*

410 IAC 1-2.3-43 "Sterilize" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 43. "Sterilize" means the use of physical or chemical procedures to destroy all microbial life, including highly resistant bacterial endospores. *(Indiana State Department of Health; 410 IAC 1-2.3-43; filed Sep 11, 2000, 1:36 p.m.: 24 IR 339)*

410 IAC 1-2.3-44 "Suspect case" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 44. "Suspect case" means a person whose medical history, signs, and symptoms suggest that this person may be incubating or may be actively infected with some communicable disease. *(Indiana State Department of Health; 410 IAC 1-2.3-44; filed Sep 11, 2000, 1:36 p.m.: 24 IR 339)*

410 IAC 1-2.3-45 "Terminal cleaning" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 45. "Terminal cleaning" means routine cleaning to remove dust, soil, and microbial contamination on inanimate surfaces and is done after a patient has been removed by death or transfer, or has ceased to be a source of infection, or after isolation or other practices/precautions have been discontinued. *(Indiana State Department of Health; 410 IAC 1-2.3-45; filed Sep 11, 2000, 1:36 p.m.: 24 IR 339)*

410 IAC 1-2.3-46 "Universal precautions" defined

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 46. "Universal precautions" means an approach to infection control in which all human blood and certain body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens. *(Indiana State Department of Health; 410 IAC 1-2.3-46; filed Sep 11, 2000, 1:36 p.m.: 24 IR 339)*

410 IAC 1-2.3-47 Reporting requirements for physicians and hospital administrators

Authority: IC 16-41-2-1
Affected: IC 4-22-2-37.1; IC 16-21; IC 16-41-2-8; IC 25-22.5

Sec. 47. (a) It shall be the duty of each physician licensed under IC 25-22.5, and each administrator of a hospital licensed under IC 16-21, or the administrator's representative, to report all cases, and suspected cases of the diseases listed in subsection (d). Reporting of specimen results by a laboratory to health officials does not nullify the physician's or administrator's obligations to report said case.

(b) The report required by subsection (a) shall be made to the local health officer in whose jurisdiction the patient was examined at the time the diagnosis was made or suspected. If the patient is a resident of a different jurisdiction, the local health jurisdiction receiving the report shall forward the report to the local health jurisdiction where the patient resides. If a person who is required to report is unable to make a report to the local health officer within the time mandated by this rule, a report shall be made directly to the department within the time mandated by this rule.

(c) Any reports of diseases required by subsection (a) shall include the following:

(1) The patient's:
(A) full name;
(B) street address;
(C) city;
(D) zip code;
(E) county of residence;
(F) telephone number;
(G) age or date of birth;
(H) sex; and
(I) race and ethnicity, if available.
(2) Date of onset.
(3) Diagnosis.
(4) Definitive diagnostic test results (for example, culture, IgM, serology, or Western Blot).
(5) Name, address, and telephone number of the attending physician.
(6) Other epidemiologically necessary information requested by the local health officer or the commissioner.
(7) Persons who are tested anonymously at a counseling and testing site cannot be reported using personal identifiers; rather, they are to be reported using a numeric identifier code. Age, race, sex, risk factors, and county of residence shall also be reported.
(8) Name, address, and telephone number of person completing report.

(d) The dangerous communicable diseases and conditions described in this subsection shall be reported within the time specified. Diseases or conditions that are to be reported immediately to the local health officer shall be reported by telephone or other instantaneous means of communication on first knowledge or suspicion of the diagnosis. Diseases that are to be reported within seventy-two (72) hours shall be reported to the local health officer within seventy-two (72) hours of first knowledge or suspicion of the diagnosis by telephone, electronic data transfer, other confidential means of communication, or official report forms furnished by the department. During evening, weekend, and holiday hours, those required to report should report diseases required to be immediately reported to the after-hours duty officer at the local health department. If unable to contact the after-hours duty officer locally, or one has not been designated locally, those required to report shall file their reports with the after-hours duty officer at the department at (317) 233-1325 or (317) 233-8115.

DANGEROUS COMMUNICABLE DISEASES AND CONDITIONS

Disease	When to Report (from probable diagnosis)	Disease Intervention Methods (section in this rule)
Acquired immunodeficiency syndrome	See HIV Infection/Disease	Sec. 76
Animal bites	Within 24 hours	Sec. 52
Anthrax	Immediately	Sec. 53
Babesiosis	Within 72 hours	Sec. 54
Botulism	Immediately	Sec. 55
Brucellosis	Within 72 hours	Sec. 56
Campylobacteriosis	Within 72 hours	Sec. 57
Chancroid	Within 72 hours	Sec. 58
Chlamydia trachomatis, genital infection	Within 72 hours	Sec. 59
Cholera	Immediately	Sec. 60
Cryptosporidiosis	Within 72 hours	Sec. 61
Cyclospora	Within 72 hours	Sec. 62
Diphtheria	Immediately	Sec. 63
Ehrlichiosis	Within 72 hours	Sec. 64

Encephalitis, arboviral, Calif, EEE, WEE, SLE, West Nile	Immediately	Sec. 65
Escherichia coli, infection (including E. coli 0157:H7 and other enterohemorrhagic types)	Immediately	Sec. 66
Gonorrhea	Within 72 hours	Sec. 67
Granuloma inguinale	Within 72 hours	Sec. 68
Haemophilus influenzae invasive disease	Immediately	Sec. 69
Hansen's disease (leprosy)	Within 72 hours	Sec. 70
Hantavirus pulmonary syndrome	Immediately	Sec. 71
Hemolytic uremic syndrome, postdiarrheal	Immediately	Sec. 66
Hepatitis, viral, Type A	Immediately	Sec. 72
Hepatitis, viral, Type B	Within 72 hours	Sec. 73
Hepatitis, viral, Type B, pregnant woman (acute and chronic), or perinatally exposed infant	Immediately (when discovered at or close to time of birth)	Sec. 73
Hepatitis, viral, Type C (acute)	Within 72 hours	Sec. 74
Hepatitis, viral, Type Delta	Within 72 hours	Sec. 73
Hepatitis, viral, unspecified	Within 72 hours	
Histoplasmosis	Within 72 hours	Sec. 75
HIV infection/disease	Within 72 hours	Sec. 76
HIV infection/disease, pregnant woman, or perinatally exposed infant	Immediately (when discovered at or close to time of birth)	Sec. 76
Legionellosis	Within 72 hours	Sec. 77
Leptospirosis	Within 72 hours	Sec. 78
Listeriosis	Within 72 hours	Sec. 79
Lyme disease	Within 72 hours	Sec. 80
Lymphogranuloma venereum	Within 72 hours	Sec. 81
Malaria	Within 72 hours	Sec. 82
Measles (rubeola)	Immediately	Sec. 83
Meningitis, aseptic	Within 72 hours	Sec. 84
Meningococcal disease, invasive	Immediately	Sec. 85
Mumps	Within 72 hours	Sec. 86
Pertussis	Immediately	Sec. 88
Plague	Immediately	Sec. 89
Poliomyelitis	Immediately	Sec. 90
Psittacosis	Within 72 hours	Sec. 91
Q Fever	Immediately	Sec. 92
Rabies in humans or animals (confirmed and suspect animal with human exposure)	Immediately	Sec. 93
Rabies, postexposure treatment	Within 72 hours	Secs. 93 and 52
Rocky Mountain spotted fever	Within 72 hours	Sec. 94
Rubella (German measles)	Immediately	Sec. 95

Rubella congenital syndrome	Immediately	Sec. 95
Salmonellosis, other than typhoid fever	Within 72 hours	Sec. 96
Shigellosis	Immediately	Sec. 97
Staphylococcus aureus, Vancomycin resistance level of MIC ≥ 8 μg/mL	Immediately	Sec. 98
Streptococcus pneumoniae, invasive disease, and antimicrobial resistance pattern	Within 72 hours	Sec. 99
Streptococcus, Group A, invasive disease	Within 72 hours	Sec. 100
Streptococcus, Group B, invasive disease	Within 72 hours	Sec. 101
Syphilis	Within 72 hours	Sec. 102
Tetanus	Within 72 hours	Sec. 103
Toxic shock syndrome (streptococcal or staphylococcal)	Within 72 hours	Sec. 104
Trichinosis	Within 72 hours	Sec. 105
Tuberculosis, cases and suspects	Withing *[sic.]* 72 hours	Sec. 106
Tularemia	Immediately	Sec. 107
Typhoid fever, cases and carriers	Immediately	Sec. 108
Typhus, endemic (flea borne)	Within 72 hours	Sec. 109
Varicella, resulting in hospitalization or death	Within 72 hours	Sec. 110
Yellow fever	Within 72 hours	Sec. 111
Yersiniosis	Within 72 hours	Sec. 112

DANGEROUS BUT NOT COMMUNICABLE DISEASES AND CONDITIONS OF PUBLIC HEALTH SIGNIFICANCE

Disease and Condition	When to Report (from probable diagnosis)	Disease Intervention Methods
Pediatric venous blood lead ≥ 10 μg/dl in children less than or equal to 6 years of age	Within 1 week	Sec. 87

(e) Reporting of HIV infection/disease shall include classification as defined in the CDC Morbidity and Mortality Weekly Report, Volume 41, No. RR-17, 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS among Adolescents and Adults. Reporting of HIV infection/disease in children less than thirteen (13) years of age shall include classification as defined in the CDC Morbidity and Mortality Weekly Report, Volume 43, No. RR-12, 1994 Revised Classification System for Human Immunodeficiency Virus Infection in Children Less Than 13 Years of Age. Supplemental reports shall be provided by the physician when an individual's classification changes. The CD4+ T-lymphocyte count and percentage, or viral load count, or both, shall be included with both initial and supplemental reports.

(f) The department, under the authority of IC 4-22-2-37.1, may adopt emergency rules to include mandatory reporting of emerging infectious diseases. Reports shall include the information specified in section 47(c) of this rule *[subsection (c)]*.

(g) Outbreaks of any of the following shall be reported immediately upon suspicion:

(1) Any disease required to be reported under this section.

(2) Diarrhea of the newborn (in hospitals or other institutions).

(3) Foodborne or waterborne diseases in addition to those specified by name in this rule.

(4) Streptococcal illnesses.

(5) Conjunctivitis.

(6) Impetigo.

(7) Nosocomial disease within hospitals and health care facilities.

(8) Influenza-like illness.

(9) Unusual occurrence of disease.

(10) Any disease (that is, anthrax, plague, tularemia, Brucella species, smallpox, or botulinum toxin) or chemical illness that is considered a bioterrorism threat, importation, or laboratory release.

(h) Failure to report constitutes a Class A infraction as specified by IC 16-41-2-8. *(Indiana State Department of Health; 410 IAC 1-2.3-47; filed Sep 11, 2000, 1:36 p.m.: 24 IR 339)*

410 IAC 1-2.3-48 Laboratories; reporting requirements

Authority: IC 16-41-2-1
Affected: IC 16-41-2-8

Sec. 48. (a) Each director, or the director's representative, of a medical laboratory in which examination of any specimen derived from the human body yields microscopic, bacteriologic, immunologic, serologic, or other evidence of infection by any of the organisms or agents listed in section 48(d) of this rule *[subsection (d)]* shall report such findings and any other epidemiologically necessary information requested by the department. HIV serologic results of tests performed anonymously in conjunction with the operation of a counseling and testing site registered with the department shall not be identified by name of patient, but by a numeric identifier code; for appropriate method to report such results, see subsection (b).

(b) The report required by subsection (a) shall, at a minimum, include the following:

(1) Name, date, results of test performed, the laboratory's normal limits for that test, and the laboratory's interpretation of the test results.

(2) Name of person and date of birth or age from whom specimen was obtained.

(3) Name, address, and telephone number of attending physician, hospital, clinic, or other specimen submitter.

(4) Name, address, and telephone number of the laboratory performing the test.

(c) This subsection does not preclude laboratories from testing specimens, which, when submitted to the laboratory, are identified by a numeric identifier code and not by name of patient. If testing of such a specimen, identified by numeric code, produces results that are required to be reported under this rule, the laboratory shall submit a report that includes the following:

(1) Numeric identifier code, date, and results of tests performed.

(2) Name and address of attending physician, hospital, clinic, or other.

(3) Name and address of the laboratory performing the test.

(d) Laboratory findings demonstrating evidence of the following infections, diseases, or conditions shall be reported at least weekly to the department:

(1) Arboviruses, including, but not limited to, the following:
- (A) St. Louis.
- (B) California group.
- (C) Eastern equine.
- (D) Western equine.
- (E) West Nile.
- (F) Japanese B.
- (G) Yellow fever.

(2) Babesia species.
(3) Bacillus anthracis.
(4) Bordetella pertussis.
(5) Borrelia burgdorferi.
(6) Brucella species.
(7) Calymmatobacterium granulomatis.
(8) Campylobacter species.
(9) Chlamydia psittaci.
(10) Chlamydia trachomatis.
(11) Clostridium botulinum.
(12) Clostridium perfringens.
(13) Clostridium tetani.
(14) Corynebacterium diphtheriae.
(15) Coxiella burnetii.

(16) Cryptococcus neoformans.
(17) Cryptosporidium parvum.
(18) Cyclospora cayetanensis.
(19) Ehrlichia chaffeensis.
(20) Ehrlichia phagocytophila.
(21) Enteroviruses (coxsackie, echo, polio).
(22) Escherichia coli infection (including E. coli 0157:H7 and other enterohemorrhagic types).
(23) Francisella tularensis.
(24) Haemophilus ducreyi.
(25) Hantavirus.
(26) Hepatitis viruses:
(A) anti-HAV IgM;
(B) HbsAg or HbeAg or anti-HBc IgM;
(C) RIBA or RNA or Anti-HCV, or any combination
(D) Delta.
(27) Haemophilus influenzae, invasive disease.
(28) Histoplasmosis capsulatum.
(29) HIV and related retroviruses.
(30) Influenza.
(31) Kaposi's sarcoma (biopsies).
(32) Legionella species.
(33) Leptospira species.
(34) Listeria monocytogenes.
(35) Measles virus.
(36) Mumps virus.
(37) Mycobacterium tuberculosis.
(38) Neisseria gonorrhoeae.
(39) Neisseria meningitidis, invasive.
(40) Pediatric blood lead tests (capillary and venous) equal to or greater than 10 µg/dl on children less than or equal to six (6) years of age.
(41) Plasmodium species.
(42) Pneumocystis carinii.
(43) Rabies virus (animal or human).
(44) Rickettsia species.
(45) Rubella virus.
(46) Salmonella species.
(47) Shigella species and antimicrobial resistance pattern.
(48) Staphylococcus aureus, Vancomycin resistance equal to or greater than 8 µg/mL.
(49) Streptococcus pneumoniae, invasive disease, and antimicrobial resistance pattern.
(50) Streptococcus Group A (Streptococcus pyogenes), invasive disease.
(51) Streptococcus Group B, invasive disease.
(52) Treponema pallidum.
(53) Trichinella spiralis.
(54) Vibrio species.
(55) Yersinia species, including pestis, enterocolitica, and pseudotuberculosis.

(e) Laboratories may also report to the local health officer, but any such local report shall be in addition to reporting to the department. A laboratory may report by electronic data transfer, telephone, or other confidential means of communication. In lieu of electronic data transfer or reporting by telephone, a laboratory may submit a legible copy of the laboratory report, provided that the information specified in subsection (b) appears thereon. Whenever a laboratory submits a specimen, portion of a specimen, or culture to the department laboratory resource center for confirmation, phage typing, or other service, these reporting requirements will be deemed to have been fulfilled, provided that the minimum information specified in subsection (b) accompanies the specimen

or culture.

(f) Laboratories shall submit all isolates of the following organisms to the department's microbiology laboratory for further evaluation:

(1) Haemophilus influenzae, invasive disease.

(2) Neisseria meningitidis, invasive disease.

(3) E. coli 0157:H7 or sorbital-negative E. coli isolates.

(4) Staphylococcus aureus, Vancomycin resistance equal to or greater than 8 μg/mL.

(5) Mycobacterium tuberculosis.

(6) Listeria monocytogenes.

(7) Salmonella from any site.

(g) Quarterly report the total number of blood lead test (capillary and venous) performed on children six (6) or less years of age.

(h) Reporting by a laboratory, as required by this section, shall not:

(1) constitute a diagnosis or a case report; and

(2) be considered to fulfill the obligation of the attending physician or hospital to report.

(i) Failure to report constitutes a Class A infraction as specified by IC 16-41-2-8. *(Indiana State Department of Health; 410 IAC 1-2.3-48; filed Sep 11, 2000, 1:36 p.m.: 24 IR 342)*

410 IAC 1-2.3-49 Disease intervention measures; responsibility to investigate and implement

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 49. (a) Case reports submitted to the local health department or the department may be used for epidemiological investigation or other disease intervention activities as warranted. Prior approval from a patient is not required before releasing medical or epidemiological information to the local health department or the department.

(b) Unless otherwise indicated, the local health department in the jurisdiction where the patient is a resident is responsible for performing any epidemiological investigation required and instituting control measures.

(c) Upon receiving a communicable disease report, local health officers must investigate the report within a reasonable time frame, immediately for diseases that shall be reported immediately, but usually not more than seventy-two (72) hours after the report is received for other diseases.

(d) Investigation shall include obtaining laboratory and clinical data necessary for case ascertainment. Investigation efforts should identify all potential means for disease acquisition, risk factors, and any potential public health threats posed by the case. Findings of the investigation shall be used to institute control measures to minimize or abrogate the risk of disease spread.

(e) The results of the investigation shall be documented, in writing, with a copy maintained at the local health department, and a copy forwarded to the department communicable disease section. Local health departments that do not have the necessary security to maintain complete confidentiality of HIV/AIDS patients may defer the storage of all copies to the department.

(f) The department may request and obtain epidemiological information on cases of communicable disease or diseases of public health importance, including diseases caused by drug-resistant organisms and emerging infectious diseases.

(g) Medical or epidemiological information, wherever maintained, concerning reportable cases, shall be made available to the commissioner or the commissioner's designee. *(Indiana State Department of Health; 410 IAC 1-2.3-49; filed Sep 11, 2000, 1:36 p.m.: 24 IR 342)*

410 IAC 1-2.3-50 Confidentiality of medical and epidemiological information

Authority: IC 16-41-2-1
Affected: IC 16-18-2; IC 16-41; IC 34-43-1-12

Sec. 50. (a) All information obtained pursuant to this rule, whether from patient records or other sources, is confidential as specified by IC 16-41-8-1(a).

(b) Except as provided in subsection (a), a person responsible for recording, reporting, or maintaining information required to be reported under IC 16-41-2 who recklessly, knowingly, or intentionally discloses or fails to protect medical or epidemiological information classified as confidential under this section commits a Class A misdemeanor.

(c) In addition to subsection (b), a public employee who violates this section is subject to discharge or other disciplinary action under the personnel rules of the agency that employs the employee.

(d) Release shall be made of the medical records concerning an individual to the individual or to a person authorized in writing by the individual to receive the medical records.

(e) An individual may voluntarily disclose information about the individual's communicable disease.

(f) The provisions of this section regarding confidentiality apply to information obtained under IC 16-41-1 through IC 16-41-16. For purposes of compliance with the confidentiality provisions of IC 34-43-1-12, only the following diseases and conditions shall be defined as dangerous communicable diseases:

(1) Acquired immunodeficiency syndrome.
(2) Gonorrhea.
(3) Hepatitis, viral.
(4) HIV infection/disease.
(5) Syphilis.
(6) Chancroid.
(7) Chlamydial (genital) infections.
(8) Lymphogranuloma venereum.
(9) Information regarding all other diseases and conditions listed in section 47 of this rule, and not listed in this subsection, may be released as authorized by IC 34-43-1-12.

(Indiana State Department of Health; 410 IAC 1-2.3-50; filed Sep 11, 2000, 1:36 p.m.: 24 IR 343; errata filed Aug 29, 2001, 2:50 p.m.: 25 IR 106)

410 IAC 1-2.3-51 General control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 51. General control measures are as follows:

(1) A local health officer or the commissioner, upon being notified of the existence of any communicable disease covered by a specific control measure in this section shall ensure that the procedures required under the rule for the specific disease are carried out.

(2) A local health officer or the commissioner, upon learning or being notified of communicable diseases that are not covered by any specific control measures in this section, shall place such restrictions upon the movements of cases or carriers and their contacts as may be reasonably necessary to prevent the spread of disease. Specific control measures for the selected diseases or conditions are listed in sections 52 through 112 of this rule. For control measures for diseases or conditions not listed insofar as applicable, the procedures prescribed in the Control of Communicable Diseases Manual, 17th Edition, 2000, a publication of the American Public Health Association, shall be followed to the extent that they are not in conflict with the laws of Indiana or this rule. In addition, the procedures implemented by the local health officer or the commissioner shall include provisions for proper hand washing procedures and universal precautions as defined in this rule.

(3) A local health officer, upon notification of the occurrence of a disease that is required by sections 47 and 48 of this rule to be reported immediately, shall in turn notify the department immediately by telephone or other instantaneous means of communication.

(4) A local health officer, in receipt of reports required by sections 47 and 48 of this rule to be reported in either seventy-two (72) hours or one (1) week, shall, on each Friday, or if Friday is a holiday, the previous business day, forward to the department electronic or paper copies of reports received during the previous seven (7) days and not yet forwarded. Upon suspicion of an outbreak, the local health officer shall notify the department immediately, by telephone or other instantaneous means of communication. More frequent reports shall be furnished during an outbreak as required by the department.

(5) A local health officer in receipt of a report of a disease that is potentially dangerous to the public health, or of national or international significance not listed as a reportable disease in section 47 or 48 of this rule, shall notify the department immediately by telephone or other confidential means of communication to establish reporting requirements for additional reports of that disease that subsequently may be received by the local health officer.

(6) The local health officer or the commissioner shall make an attempt to seek cooperation of cases, carriers, contacts, or suspect cases to implement the least restrictive, but medically necessary, procedures to protect the public health. Those

procedures may include, but not be limited to:

(A) participate in a designated education, counseling, or treatment program;

(B) undergo confirmatory testing;

(C) undergo medically accepted tests or treatments that are consistent with standard medical practice as necessary to make the case or carrier noninfectious;

(D) notify or appear before designated health officials for verification of disease status at periodic times;

(E) cease and desist conduct that constitutes a health threat to others;

(F) be monitored by an electronic monitoring device to prevent activities that constitute a health threat to others;

(G) live part time or full time in a supervised setting;

(H) be confined to an appropriate hospital, home, apartment, or other institutional facility or residential setting; or

(I) comply with any combination of the remedies under this subdivision considered appropriate by the health officer.

(Indiana State Department of Health; 410 IAC 1-2.3-51; filed Sep 11, 2000, 1:36 p.m.: 24 IR 344)

410 IAC 1-2.3-52 Animal bites; specific control measures

Authority: IC 16-41-2-1
Affected: IC 15-2.1-6-11; IC 16-41-2; IC 16-41-9

Sec. 52. (a) The specific control measures for animal bites are as follows:

(1) Every case of a human bitten by a domestic or wild mammal shall be reported promptly to the local health officer or his or her designee having jurisdiction. If a physician is in attendance, such physician shall report the bite. If no physician is in attendance and the person bitten is a child, it shall be the duty of the parent or the guardian to make such a report immediately. If the person bitten is an adult, such person shall make the report or, if incapacitated, the bite shall be reported by whoever is caring for the person bitten. It shall be the duty of the local health officer to report information concerning the bite on the prescribed form. The report shall include requested information on postexposure rabies prophylaxis if it is being administered to the bite victim. Each reported bite shall be investigated immediately by the local health officer or a designee. This investigation shall be conducted with the purpose of determining the need for postexposure rabies prophylaxis of the bite victim and either:

(A) imposing a ten (10) day observation period on the biting animal (dog, cat, or ferret only) to determine if the animal was capable of transmitting rabies at the time of the biting incident; or

(B) submission of the head, if the biting animal is a potential rabies vector, to the department laboratory to determine if it was infected with rabies.

(2) Isolation is not necessary.

(3) Concurrent disinfection is not necessary.

(4) Quarantine shall be applied as follows:

(A) Any apparently healthy dog, cat, or ferret that has bitten a person, or any dog, cat, or ferret suspected of being rabid shall be confined and held in observation for the period specified in IC 15-2.1-6-11 (not less than ten (10) days) or humanely killed at once for laboratory examination. Such confinement shall be under the supervision of the state veterinarian or a licensed, accredited veterinarian, or other person designated by the official quarantining the animal, and at the expense of the owner.

(B) Any illness in the confined dog, cat, or ferret shall be reported immediately to the local health department. Animals under confinement shall not be immunized against rabies during the observation period. The head of any such dog, cat, or ferret that dies during the period of observation, or is killed subsequent to having bitten a person or another animal, shall be removed, packed in an iced container, but not frozen, and forwarded immediately to the laboratory of the department for rabies testing.

(C) Any stray, unwanted, or unhealthy dog, cat, or ferret that has bitten a person shall be humanely killed immediately for laboratory examination. The animal's owner shall be responsible for having the unwanted or unhealthy animal euthanized, head removed, and shipped to the department for rabies examination. In the case of a stray animal or an animal whose owner cannot be found, the local health department or its designee shall assume this responsibility.

(D) Any potentially rabid wild mammal that has bitten a human or a domestic animal, or is suspected of being rabid, shall not be placed under observation, but shall be humanely killed at once in a manner that does not cause trauma to the head or brain. The head shall be refrigerated, but not frozen, and submitted within forty-eight (48) hours to the

laboratory of the department. Wild mammals include, but are not limited to, the following:

(i) Wild animals kept as pets.

(ii) Wild mammals crossbred to domestic dogs and cats.

(E) The bite victim shall be notified after a dog, cat, or ferret has passed the ten (10) day observation period in a healthy state or after the results of a laboratory test are available.

(F) Any person bitten or scratched by a wild carnivorous mammal or bat not available for rabies testing should be regarded as having been potentially exposed to rabies. The following chart provides information on quarantine and disposition of biting animals.

Animal Type	Evaluation and Disposition of Animal	Postexposure Prophylaxis Recommendation
Dogs, cats, and ferrets	Healthy and available for 10 day observation[1]	Should not begin prophylaxis unless animal develops symptoms of rabies[2]
	Rabid or suspected rabid	Immediate postexposure prophylaxis
	Unknown	Consult public health officials
Skunks, raccoons, bats[3], foxes, and most other carnivores; woodchucks and wild animals kept as pets	Regard as rabid unless geographic area is known to be free of rabies or until animal proven negative by laboratory testing[4]	Immediate postexposure prophylaxis or if animal available for testing, as soon as positive result is observed
Livestock, rodents, and lagomorphs (rabbits and hares)	Consider individually	Consult public health officials. Bites of squirrels, hamsters, guinea pigs, gerbils, chipmunks, rats, mice, other rodents, rabbits, and hares almost never require antirabies treatment.

[1]Stray dogs and cats may be euthanized immediately and their heads submitted to the rabies laboratory.

[2]Postexposure prophylaxis should be started if a veterinarian identifies an animal as being symptomatic. Symptomatic animals should be euthanized and tested immediately.

[3] What appears to be insignificant contact with bats may result in rabies transmission, even without clear evidence of a bite. Postexposure prophylaxis is recommended for all persons with bite, scratch, or mucous membrane exposure to a bat unless the bat is available for testing and is negative for rabies. Postexposure prophylaxis is appropriate even in the absence of bite, scratch, or mucous membrane exposure in situations in which there is a reasonable probability that such contact occurred (for example, a sleeping individual awakes to find a bat in the room, an adult witnesses a bat in the room with a previously unattended child, mentally challenged person, or intoxicated person) and rabies cannot be ruled out by testing the bat.

[4]The animal should be killed and tested as soon as possible. Holding for observation is not recommended as time lapse from virus secretion in saliva until clinical symptoms appear have not been determined for species other than a dog, cat, and ferret. Consult with the department veterinary epidemiologist for information on presence or absence of rabies in particular species.

(b) All bite wounds should be treated immediately in the following steps:

(1) Clean and flush wound as first aid.

(2) Thorough wound cleansing under medical supervision.

(3) Evaluation of need for postexposure prophylaxis.

(4) Tetanus prophylaxis and antibacterial treatment as required.

(c) If the decision is made to provide postexposure prophylaxis to the individual, the following protocols must be followed, and a decision to provide postexposure prophylaxis must be reported to the department:

Guidelines for Postexposure Prophylaxis

Vaccination Status	Treatment	Regimen*
Not previously vaccinated	Local wound cleaning	All postexposure treatment should begin with immediate thorough cleansing of all wounds with soap and water.

	Human rabies immune globulin (HRIG)	20 IU/kg body weight. If anatomically feasible, the full dose should be infiltrated around the wound or wounds. Any remaining volume should be administered intramuscularly at a site distant from vaccine inoculation.
	Vaccine	Human diploid cell vaccine (HDCV), purified chick embryo cell vaccine (PCEC), or rabies vaccine adsorbed (RVA), 1.0 ml, IM (deltoid[1]), 1 each on days 0, 3, 7, 14, and 28.
Previously vaccinated[2]	Local wound cleaning	All postexposure treatment should begin with immediate thorough cleansing of all wounds with soap and water.
	HRIG	Should not be administered.
	Vaccine	HDCV, PCEC, or RVA, 1.0 ml IM (deltoid[1]), 1 each on days 0 and 3.

*These regimens are applicable for all age groups, including children.

[1] The deltoid area is the only acceptable site of vaccination for adults and older children. For younger children, the outer aspect of the thigh may be used. The vaccine should never be administered in the gluteal area.

[2]Any person with a history of preexposure vaccination with HDCV or RVA; prior postexposure prophylaxis with HDCV or RVA; or previous vaccination with any other type of rabies vaccine and a documented history of antibody response to the prior vaccination.

(Indiana State Department of Health; 410 IAC 1-2.3-52; filed Sep 11, 2000, 1:36 p.m.: 24 IR 345)

410 IAC 1-2.3-53 Anthrax; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 53. The specific control measures for anthrax (infectious agent: Bacillus anthracis) are as follows:

(1) Immediate investigation by the local health officer shall be accomplished to determine the source of exposure. History of exposure to animals and animal products (wool, hair, or raw leather), and travel to endemic anthrax areas shall be fully investigated.

(2) Standard precautions for isolation of hospitalized patients shall be followed.

(3) Discharges from lesions and articles contaminated with discharges require disinfection. An infectious agent is a spore former that will survive in environment for long periods. Disinfection requires sporicidal agent.

(4) Quarantine is not necessary.

(5) If exposure occurred in an occupational/industrial setting, a review of industrial hygiene practices shall be made to reduce risk of other cases.

(Indiana State Department of Health; 410 IAC 1-2.3-53; filed Sep 11, 2000, 1:36 p.m.: 24 IR 346)

410 IAC 1-2.3-54 Babesiosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2-1

Sec. 54. The specific control measures for babesiosis (infectious agent: Babesia species) are as follows:

(1) The local health officer shall perform an investigation within seventy-two (72) hours. The investigation shall focus on source of exposure to infected ticks or recent blood transfusions. Travel history for the previous six (6) months to include the most recent summer months is essential.

(2) Isolation is not required.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(5) Immunizations are not available. Household contacts or traveling companions with similar exposures should also be evaluated for infection. If the patient donated blood while incubating the disease, the blood collecting agency should be notified.

(Indiana State Department of Health; 410 IAC 1-2.3-54; filed Sep 11, 2000, 1:36 p.m.: 24 IR 347)

410 IAC 1-2.3-55 Botulism; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2-1

Sec. 55. The specific control measures for botulism (infectious agent: Clostridium botulinum) are as follows:

(1) An investigation shall be performed immediately. The purpose of the investigation shall be case ascertainment, assurance of availability of polyvalent (equine ABE) antitoxin, and identification of infection source. The local health officer shall obtain a five (5) day food history of those ill, in addition to a fourteen (14) day wound history. The local health officer shall also recover all suspected foods for appropriate testing and disposal. If suspicion is high that the source is a commercial food product or a product served in a restaurant, the local health officer shall perform active surveillance to identify additional cases.

(2) Isolation is not required.

(3) Implicated food shall be detoxified by boiling before discarding, or containers broken and buried deeply to prevent ingestion by animals. Contaminated environmental surfaces shall be sterilized by boiling, or by chlorine disinfection to inactivate any remaining toxin. Feces from infant cases may be disposed of in a sanitary sewer. Terminal cleaning shall also be followed.

(4) Polyvalent (equine ABE) antitoxin may be given to asymptomatic individuals within one (1) to two (2) days of consuming implicated foods, but must be weighed against the risk of adverse reaction and sensitization to horse serum.

(Indiana State Department of Health; 410 IAC 1-2.3-55; filed Sep 11, 2000, 1:36 p.m.: 24 IR 347)

410 IAC 1-2.3-56 Brucellosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 56. The specific control measures for brucellosis (infectious agent: Brucella species) are as follows:

(1) An investigation to trace infection to the common or individual source, usually:

(A) infected dogs, domestic goats, swine, or cattle; or

(B) unpasteurized milk or dairy products (cheese) from cows and goats;

shall be conducted by the local health officer. Occupational exposures from slaughterhouses or others working with infected animal tissues or products should be considered. Animals suspected of being infected shall be managed according to requirements of the Indiana state board of animal health.

(2) Standard precautions for hospitalized patients shall be taken.

(3) Concurrent disinfection of purulent discharges shall be followed.

(4) Quarantine is not required.

(5) Protection or immunization of contacts is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-56; filed Sep 11, 2000, 1:36 p.m.: 24 IR 347)

410 IAC 1-2.3-57 Campylobacteriosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 57. The specific control measures for Campylobacter enteritis (infectious agent: Campylobacter species) are as follows:

(1) An investigation by the local health officer shall include a five (5) day food history and history of exposure to pets, farm animals, or infected infants.

(2) Contact precautions shall be followed for diapered or incontinent individuals or children less than six (6) years of age, otherwise use standard precautions. For others, the following guidelines apply:

(A) Symptomatic persons shall be excluded from employment involving food handling, or direct care of children or hospitalized or institutionalized patients.

(B) Asymptomatic food handlers, day care workers, or health care workers may be released to return to work provided

the following activities have taken place prior to that person's return to work:

(i) The local health officer or his or her designee discusses with the asymptomatic worker his or her symptoms and determines that he or she is indeed asymptomatic and that the worker is further counseled about measures, such as hand washing, that shall be followed to prevent transmission of disease.

(ii) The local health officer or his or her designee contacts the employer to reemphasize the need to comply with local and state rules requiring proper hand washing facilities for all employees, and to correct any observed lapses in hygienic measures of any employees.

(C) Symptomatic persons shall be excluded from schools and day care centers. Asymptomatic persons may be released to return to school or day care after the local health officer or his or her designee has discussed with the appropriate school or day care center staff the need for proper hand washing and other infection control practices, and the need to comply with all local and state rules pertaining to prevention of infectious diseases.

(D) If an outbreak of the infection occurs among staff or attendees in a day care center, all attendees may be required to submit stool specimens for examination. In addition, all asymptomatic attendees and staff who are infected with Campylobacter may need to be isolated from other attendees and staff in the same day care center and admission of all new attendees suspended while the outbreak continues.

(3) Concurrent disinfection of feces and soiled articles is required. Feces may be discharged in a sanitary sewer without prior disinfection.

(4) Quarantine is not required.

(5) Protection/immunization is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-57; filed Sep 11, 2000, 1:36 p.m.: 24 IR 347)

410 IAC 1-2.3-58 Chancroid; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2-1

Sec. 58. The specific control measures for chancroid (infectious agent: Haemophilus ducreyi) are as follows:

(1) An investigation shall be accomplished by the local health officer and shall be focused on identifying sexual partners who were at risk for transmitting to, or contracting the infection from the case. Case and contacts shall be fully evaluated and treated as recommended in the MMWR 1998 Guidelines for Treatment of Sexually Transmitted Diseases, January 23, 1998, Volume 47/RR1.

(2) Standard precautions are required. Avoid sexual contact until all lesions are healed.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(5) Sexual contacts shall receive prophylactic treatment. Immunization is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-58; filed Sep 11, 2000, 1:36 p.m.: 24 IR 348)

410 IAC 1-2.3-59 Chlamydial infections, genital; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 59. The specific control measures for chlamydial infections, genital, (infectious agent: Chlamydia trachomatis) (See Psittacosis for infections caused by Chlamydia psittaci) are as follows:

(1) An investigation shall be accomplished by the local health officer and shall be focused on identifying sexual partners who were at risk for transmitting to, or contacting the infection from the case. Case and contacts shall be fully evaluated and treated as recommended in the MMWR 1998 Guidelines for Treatment of Sexually Transmitted Diseases, January 23, 1998, Volume 47/RR1.

(2) For hospital patients, standard precautions shall be followed. Appropriate antibiotic therapy renders discharges noninfectious; patients shall refrain from sexual intercourse until treatment is completed.

(3) Careful disposal of articles contaminated with urethral and vaginal discharges is required.

(4) Quarantine is not required.

(5) Immunization is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-59; filed Sep 11, 2000, 1:36 p.m.: 24 IR 348)

410 IAC 1-2.3-60 Cholera; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 60. The specific control measures for Cholera (infectious agent: Vibrio cholerae) are as follows:

(1) Immediate investigation by the local health officer shall include food and water consumption history for patients for five (5) days prior to illness, as well as travel history. Interview individuals who consumed food and water with the patient to identify additional cases, and determine the contaminated food or water source. If suspicion centers on water, a commercial food product, or a restaurant as a potential source, active surveillance shall be carried out to identify additional cases.

(2) For hospitalized individuals, standard precautions shall be followed with the addition of contact precautions for diapered or incontinent children less than six (6) years of age for duration of illness.

(3) Feces, vomitus, and articles soiled by feces or vomitus, or both, shall receive concurrent disinfection. Feces and vomitus can be discharged directly in a sanitary sewer system.

(4) Quarantine is not required.

(5) Observe individuals who consume food and drink from the same sources as the patient for five (5) days from the last exposure. In household where secondary transmission is highly likely, antimicrobial therapy with either tetracycline or doxycycline should be provided. Immunization of contacts is not beneficial.

(Indiana State Department of Health; 410 IAC 1-2.3-60; filed Sep 11, 2000, 1:36 p.m.: 24 IR 348)

410 IAC 1-2.3-61 Cryptosporidiosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 61. The specific control measures for cryptosporidiosis, (infectious agent: Cryptosporidium species) are as follows:

(1) The local health officer shall determine if the case is a food handler, day care worker, or health care worker or day care attendee. Additional investigation shall include a seven (7) day food history, history of exposure to day care or preschool children, pets or domestic animals, or exposure to surface water. If suspicion centers on a commercial food product, restaurant, or public water supply, active surveillance shall be instituted to identify additional cases.

(2) For hospitalized individuals, standard precautions shall be followed with the addition of contact precautions for diapered or incontinent children less than six (6) years of age for the duration of the illness. For others, the following instructions apply:

(A) Symptomatic persons shall be excluded from employment involving food handling or the direct care of children or hospitalized or institutionalized patients.

(B) Asymptomatic food handlers, day care workers, or health care workers may be released to return to work, providing the following activities have taken place prior to that person's return to work:

(i) The local health officer or his or her designee discusses with the asymptomatic worker his or her symptoms and determines that he or she is indeed asymptomatic, and that the worker is further counseled about measures, such as hand washing, that shall be followed to prevent transmission of the disease.

(ii) The local health officer or his or her designee contacts the employer to:

(AA) reemphasize the need to comply with local and state rules requiring proper hand washing facilities for all employees; and

(BB) correct any observed lapses in hygienic measures of any employees.

(C) Symptomatic persons shall be excluded from schools and day care centers.

(D) Asymptomatic persons may be released to return to school or day care after the local health officer or his or her designee has discussed with appropriate school or care center staff the need:

(i) for proper hand washing and other infection control practices; and

(ii) to comply with all local and state rules pertaining to prevention of infectious diseases.

If an outbreak of the infection occurs in a day care center, all attendees may be required to submit stool specimens for examination. In addition, all asymptomatic attendees and staff who are infected with Cryptosporidium may need to be isolated from other attendees and staff in the same center, and admission of all new attendees suspended while the

outbreak continues.

(3) Concurrent disinfection of feces and feces soiled articles is required. Feces may be disposed of in a sanitary sewer system.

(4) Quarantine is not required.

(5) Vaccination is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-61; filed Sep 11, 2000, 1:36 p.m.: 24 IR 349)

410 IAC 1-2.3-62 Cyclospora species; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 62. The specific control measures for Cyclospora species are as follows:

(1) Within seventy-two (72) hours of receiving the report, the local health officer shall investigate the case to include a seven (7) day food history, exposure to water, and travel. Use individual case investigation to detect outbreaks and identify potential sources. If a commercial food source is suspected, active surveillance shall be undertaken.

(2) For hospitalized individuals, standard precautions shall be followed with the addition of contact precautions for diapered or incontinent children less than six (6) years of age for the duration of the illness. For others, the following instructions apply:

(A) Symptomatic persons shall be excluded from employment involving food handling or the direct care of children or hospitalized or institutionalized patients.

(B) Asymptomatic food handlers, day care workers, or health care workers may be released to return to work, provided the following activities have taken place prior to that person's return to work:

(i) The local health officer or his or her designee discusses with the asymptomatic worker his or her symptoms and determines that he or she is indeed asymptomatic, and that the worker is further counseled about measures, such as hand washing, that shall be followed to prevent transmission of disease.

(ii) The local health officer or his or her designee contacts the employer to:

(AA) reemphasize the need to comply with local and state rules requiring proper hand washing facilities for all employees; and

(BB) correct any observed lapses in hygienic measures of any employees.

(C) Symptomatic persons shall be excluded from schools and day care centers.

(D) Asymptomatic persons may be released to return to school or day care after the local health officer or his or her designee has discussed with appropriate school or care center staff the need:

(i) for proper hand washing and other infection control practices; and

(ii) to comply with all local and state rules pertaining to prevention of infectious diseases.

If an outbreak of the infection occurs in a day care center, all attendees may be required to submit stool specimens for examination. In addition, all asymptomatic attendees and staff who are infected with Cyclospora may need to be isolated from other attendees and staff in the same center, and admission of all new attendees suspended while the outbreak continues.

(3) Concurrent disinfection of feces and feces soiled articles is required. Feces may be disposed of in a sanitary sewer.

(4) Quarantine is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-62; filed Sep 11, 2000, 1:36 p.m.: 24 IR 349)

410 IAC 1-2.3-63 Diphtheria; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 63. The specific control measures for diphtheria (infectious agent: Corynebacterium diphtheriae) shall be implemented immediately and are as follows:

(1) A trained immunization field representative of the department, in cooperation with local health officers, shall perform an investigation and case management of diphtheria cases. All investigation activities shall be performed immediately and shall include (at a minimum) determination of immunization status of the index case or suspect case. Culture shall be obtained for organism identification. A complete list of contacts shall be generated. Contacts are defined as all individuals in the household, all individuals with a history of habitual, close contact, and all individuals directly exposed to throat and nasal secretions of

the patient.

(2) For hospitalized patients, institute droplet precautions for pharyngeal diphtheria and contact precautions for cutaneous diphtheria. Continue precautions until the patient is off antibiotics and two (2) cultures taken twenty-four (24) hours apart are negative.

(3) Concurrent disinfection is required for:

(A) articles in contact with the patient; and

(B) all articles soiled by the patient's discharges.

(4) Contacts who are food handlers, child care providers, or health care workers shall be excluded from work until bacteriologic examination proves them not to be carriers.

(5) Close contacts, regardless of immunization status shall be observed for seven (7) days for signs, symptoms of disease, cultured for C. diphtheriae, and treated prophylactically with oral erythromycin (forty (40) to fifty (50) milligram *[sic., milligrams]* per kilogram per day (mg/kg/day) for seven (7) days, two (2) grams per day (gm/day) maximum), or given a single intramuscular (IM) dose of benzathine penicillin G (six hundred thousand (600,000)) units (U) for those less than thirty (30) kg and one million two hundred thousand (1,200,000) U for older children and adults). For individuals who are culture positive, repeat cultures after completion of therapy. Previously immunized asymptomatic close contacts should receive a booster dose of diphtheria toxoid if five (5) years have lapsed since the last immunization. Individuals incompletely immunized or with unknown immunization status should start an active immunization series with a diphtheria toxoid preparation appropriate for age.

(6) Treatment of individuals suspected of having diphtheria should not be delayed awaiting culture results. Diphtheria antitoxin should be given based on clinical diagnosis. Antitoxin dosage is dependent on length and severity of the disease. Antimicrobial therapy is essential to eliminate organism, and to prevent the spread of the disease, as follows:

(A) Erythromycin (forty (40) to fifty (50) mg/kg/day, maximum two (2) grams per day (gm/d)) given orally or parenterally for fourteen (14) days.

(B) Penicillin G given parenterally (aqueous crystalline, one hundred thousand (100,000) to one hundred fifty thousand (150,000) units per kilogram per day (U/kg/day), in four (4) divided doses intravenous (IV)).

(C) Aqueous procaine penicillin, (twenty-five thousand (25,000) to fifty thousand (50,000) U/kg/day, maximum one million two hundred thousand (1,200,000) units intramuscular (IM) in two (2) divided doses) for fourteen (14) days are the recommended therapy.

(D) Penicillin V per os (PO) (one hundred twenty-four (124) to two hundred fifty (250) mg four (4) times daily) for fourteen (14) days.

(Indiana State Department of Health; 410 IAC 1-2.3-63; filed Sep 11, 2000, 1:36 p.m.: 24 IR 350)

410 IAC 1-2.3-64 Ehrlichiosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 64. The specific control measures for ehrlichiosis, (infectious agent: Ehrlichia chaffeensis or other Ehrlichia species) are as follows:

(1) Interview the patient to determine exposure to ticks and the location of exposure for the previous four (4) weeks. Information gathered is useful in identifying foci of infected environments and public education campaigns on prevention.

(2) Standard precautions are required.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-64; filed Sep 11, 2000, 1:36 p.m.: 24 IR 350)

410 IAC 1-2.3-65 Encephalitis, arboviral; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 65. The specific control measures for arboviral encephalitis (California, eastern equine encephalitis, western equine encephalitis, and St. Louis encephalitis) are as follows:

(1) The local health officer shall investigate immediately for the purpose of identifying location and presence of vector mosquitoes. Active surveillance shall be instituted. The local health department shall identify areas in the community where there is a need for vector control. Identification of cases in horses, birds, or humans, or both provides evidence of virus presence and amplification in the community environment.

(2) Use contact precautions until enterovirus meningoencephalitis is eliminated from list of possible diagnoses.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(5) Protection or immunization of contacts is not required for individuals. Fogging or spraying insecticides have been effectively used to abort urban epidemics and may be recommended by the department.

(Indiana State Department of Health; 410 IAC 1-2.3-65; filed Sep 11, 2000, 1:36 p.m.: 24 IR 351)

410 IAC 1-2.3-66 E. coli infection (including E. coli 0157:H7) and hemolytic uremic syndrome; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 66. The specific control measures for diarrhea and hemolytic uremic syndrome associated E. coli infection (including E. coli 0157:H7), (infectious agent: Escherichia coli (including serotype 0157:H7)) are as follows:

(1) An investigation by the local health officer shall be accomplished immediately to determine if the affected individual is part of an outbreak and if he or she is a food handler, day care attendant, health care worker, day care attendee, or attendee at a school or other institution. Further investigation shall be performed to determine a seven (7) day food consumption history with an emphasis on the consumption of beef products and raw vegetables, unpasteurized fruit juices or milk, or exposure to potentially contaminated water, either by swimming or consumption. Interview meal companions for additional cases and if a commercial food product or restaurant is suspected, conduct active surveillance for additional cases. Medical evaluation, including adequate laboratory examination of feces of contacts should be limited to food handlers, child care attendants, health care workers, or other situations where outbreaks may occur.

(2) For hospitalized individuals, standard precautions shall be followed with the addition of contact precautions for diapered or incontinent patients for the duration of the illness and until two (2) successive stool cultures taken no less than twenty-four (24) hours apart and no sooner than forty-eight (48) hours after the cessation of antibiotic therapy are negative for the presence of E. coli 0157:H7 organisms. For others, the following steps shall be taken:

(A) Symptomatic persons shall be excluded from employment involving food handling or the direct care of children or hospitalized or institutionalized patients.

(B) Asymptomatic food handlers, day care workers, and health care workers may return to work, provided the following have taken place prior to that person's return to work:

(i) The local health officer discusses with the asymptomatic worker his or her symptoms and determines that he or she is indeed asymptomatic, and that the worker is further counseled about measures, such as hand washing, that shall be followed to prevent transmission of disease.

(ii) The local health officer contacts the employer to reemphasize the need to comply with local and state rules requiring proper hand washing facilities for all employees, and to correct any observed lapses in hygiene measures of any employees.

In addition, asymptomatic food handlers will be restricted from working with exposed food, clean equipment, utensils, linens, unwrapped single-service, and single-use articles until two (2) successive stool cultures taken no less than twenty-four (24) hours apart and no sooner than forty-eight (48) hours after the cessation of antibiotic therapy are negative for the presence of E. coli 0157:H7 organisms.

(C) Infected children shall be excluded from any day care setting (including, but not limited to, babysitting groups and preschools) until two (2) successive stool cultures taken no less than twenty-four (24) hours apart and no sooner than forty-eight (48) hours after the cessation of antibiotic therapy are negative for the presence of E. coli 0157:H7 organisms. It is imperative that parents of infected children understand the potential consequences of this disease, its modes of transmission, and the absolute necessity for strict attention to personal hygiene. It is imperative that excluded children not be transferred to another child care setting until such time as they are determined to be clear of organisms.

(D) If an outbreak occurs in a day care center or preschool, all attendees and staff may be required to submit stool

specimens for examination. Rather than expulsion until stool-negative, the day care administrator may consider isolation of asymptomatic infected attendees from other attendees. This alternative can only be considered if the physical structure and staff organization of the center can accommodate isolation of various groups from one another. If this alternative is selected, increased emphasis on hand washing and environmental cleaning is necessary. Day care centers shall be closed to new admissions until such time as health officials determine that the outbreak is over.

(E) Symptomatic children shall be excluded from school until asymptomatic and the following activities have taken place prior to the student's return to school:

(i) The local health officer discusses with the asymptomatic student and parents his or her symptoms and determines that he or she is indeed asymptomatic, and that the student is further counseled about measures, such as hand washing, that shall be followed to prevent transmission of disease.

(ii) The local health officer contacts the local school administration to reemphasize the need to comply with local and state rules requiring proper hand washing facilities and the need to emphasize good hand washing practices of the students.

(3) Concurrent disinfection of feces and fecal soiled articles is required. Feces may be disposed of directly in a sanitary sewage system.

(4) Quarantine is not required.

(5) Protection or immunization of contacts is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-66; filed Sep 11, 2000, 1:36 p.m.: 24 IR 351)

410 IAC 1-2.3-67 Gonorrhea; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 67. The specific control measures for gonorrhea (infectious agent: Neisseria gonorrhoeae) are as follows:

(1) Investigation shall be accomplished by the local health officer and shall be focused on identifying sexual partners who were at risk for transmitting to, or contacting the infection from, the case. Case and contacts shall be fully evaluated and treated as recommended in the MMWR 1998 Guidelines for Treatment of Sexually Transmitted Diseases, January 23, 1998, Volume 47/RR1.

(2) Standard precautions shall be instituted for hospitalized individuals. Infected persons shall not engage in sexual activities involving the exchange of body fluids until therapy is completed and they no longer have symptoms. Treated persons shall also refrain from sexual activities involving the exchange of body fluids with untreated previous sexual partners to avoid reinfection. Cases should be examined serologically for syphilis.

(3) Concurrent disinfection is required for articles contaminated with discharges.

(4) Quarantine is not required.

(5) Immunization is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-67; filed Sep 11, 2000, 1:36 p.m.: 24 IR 352)

410 IAC 1-2.3-68 Granuloma inguinale; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 68. The specific control measures for Granuloma inguinale (infectious agent: Calymmatobacterium granulomatis) are as follows:

(1) An investigation shall be accomplished by the local health officer and shall be focused on identifying sexual partners who were at risk for transmitting to, or contacting the infection from, the case. Case and contacts shall be fully evaluated and treated as recommended in the MMWR 1998 Guidelines for Treatment of Sexually Transmitted Diseases, January 23, 1998, Volume 47/RR1.

(2) Standard precautions for hospitalized patients are required. Patients shall refrain from sexual activities until treatment is complete and lesions are healed. Patients shall refrain from sexual activities with untreated previous sexual partners.

(3) Concurrent disinfection is required for discharges from lesions and articles soiled by those discharges.

(4) Quarantine is not required.

(5) No immunization is available. Prompt treatment of contacts upon recognition or suspicion of disease is required.
(Indiana State Department of Health; 410 IAC 1-2.3-68; filed Sep 11, 2000, 1:36 p.m.: 24 IR 352)

410 IAC 1-2.3-69 Haemophilus influenzae invasive disease; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 69. The specific control measures for Haemophilus influenzae Type B invasive disease (including bacteremia, meningitis, epiglottitis, septic arthritis, cellulitis, pericarditis, endocarditis, and osteomyelitis), (infectious agent: Haemophilus influenzae) are as follows:

(1) An investigation and case management shall be performed immediately by department-trained immunization field representatives in cooperation with the local health officer. The investigation shall include an immunization history of the index case, and identification of all contacts under four (4) years of age. Contacts are defined as household, child care, and nursery school contacts, or individuals who spent four (4) or more hours with the index case for at least five (5) of the seven (7) days preceding the onset of the illness.

(2) Droplet precautions shall be followed for twenty-four (24) hours after the start of chemotherapy.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(5) With the exception of pregnant females, rifampin prophylaxis (orally once daily for four (4) days in twenty (20) mg/kg dose, maximal dose six hundred (600) mg/day) should be administered to the following:

(A) All members of a household where there is one (1) or more children younger than twelve (12) months should receive prophylaxis.

(B) All members of a household where there are contacts under forty-eight (48) months of age with incomplete immunization status should receive prophylaxis.

(C) Attendees and supervisory personnel in a child care facility where unvaccinated or incompletely vaccinated children are in attendance, and where two (2) cases of invasive Haemophilus influenzae have occurred within sixty (60) days.

(D) Prophylaxis of a single case in child care facilities is controversial; consult current recommendations.

(E) The index case should receive rifampin prior to discharge if he or she was not treated with cefotaxime or ceftriaxone.

(F) Parents and child care providers of contacts should be educated about signs and symptoms of Haemophilus influenzae disease.

(Indiana State Department of Health; 410 IAC 1-2.3-69; filed Sep 11, 2000, 1:36 p.m.: 24 IR 352)

410 IAC 1-2.3-70 Hansen's disease; specific control measures

Authority: IC 16-41-2
Affected: IC 16-41-2; IC 16-41-9

Sec. 70. The specific control measures for Hansen's disease (infectious agent: Mycobacterium leprae) are as follows:

(1) The local health officer shall assure that initial and periodic examination of household contacts occur at twelve (12) month intervals for at least five (5) years after the last contact with infectious patient.

(2) Standard precautions for hospitalized patients are required.

(3) Concurrent disinfection is required for nasal discharges and articles soiled with nasal discharges from patients considered infectious.

(4) Household contact of patients with borderline or lepromatous leprosy who are less than twenty-five (25) years of age should be treated prophylactically with dapsone for three (3) years at the same doses as for treatment.

(Indiana State Department of Health; 410 IAC 1-2.3-70; filed Sep 11, 2000, 1:36 p.m.: 24 IR 353)

410 IAC 1-2.3-71 Hantavirus; specific control measures

Authority: IC 16-41-2
Affected: IC 16-41-2; IC 16-41-9

Sec. 71. The specific control measures for hantavirus are as follows:

(1) An investigation shall be immediately conducted by the local health officer for the purpose of case ascertainment and identification of the source of infection. The investigation shall be to identify the source of exposure to rodent feces and urine. Exterminate rodents at suspected site of infection, and disinfect environmental surfaces.

(2) Standard precautions are required.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(5) Protection/immunization of contacts is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-71; filed Sep 11, 2000, 1:36 p.m.: 24 IR 353)

410 IAC 1-2.3-72 Hepatitis, viral, Type A; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 72. The specific control measures for hepatitis, viral, Type A (infectious agent: Hepatitis A virus) are as follows:

(1) An investigation shall be performed by the local health officer immediately to determine whether the case is a food handler, day care or health care worker, or day care attendee, and worked or attended while having diarrhea. Investigator shall prepare a list of all contacts. Contacts are defined as household members, day care center attendees in same room, sexual partners, and persons eating food prepared by the case during the infectious period. The infectious period is defined as from seven (7) days before to fourteen (14) days after onset of symptoms if no jaundice occurred; otherwise, the infectious period is defined as from fourteen (14) days prior to seven (7) days after the onset of jaundice. The investigation shall also include a food history, history of exposure to undercooked food items, and a history of sexual exposure during the fifteen (15) to fifty (50) day period prior to onset of illness. In the event that a common source foodborne outbreak is suspected, the local health officer must initiate active surveillance immediately to identify additional cases.

(2) Contact precautions as follows:

(A) For diapered or incontinent patients less than three (3) years of age for the duration of the illness.

(B) In children three (3) to fourteen (14) years of age, until two (2) weeks after the onset of the symptoms.

(C) In others for two (2) weeks after the onset of the symptoms or one (1) week after the onset of jaundice.

Infected children shall be excluded from schools and day care centers, and adults from employment involving food handling, direct care of children, or hospitalized or institutionalized patients during the infectious period.

(3) Sanitary disposal of feces, vomitus, and blood is required. Disposal through the sanitary system is acceptable.

(4) Quarantine is not required.

(5) Passive immunization with immune globulin (IG) should be given as soon as possible after exposure, but within two (2) weeks to all household and sexual contacts. In a day care center, IG should be given to all classroom contacts. If the day care center admits children in diapers, IG should be given to all children and staff in the center. If a food handler is diagnosed with hepatitis A, IG should be administered to other food handlers (unless the employee is immune due to vaccination or past infection) at the same location. Any susceptible food handler who refuses IG prophylaxis is to be restricted from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles for fifty (50) days. IG should not routinely be given to contacts in the usual office, school, or factory situation. When hepatitis A occurs in a food handler, IG shall be considered for food establishment patrons in the establishment only if the following three (3) events occurred:

(A) The food handler worked while infectious, and directly handled uncooked foods or foods after cooking.

(B) Deficiencies in personal hygiene are noted, or the food handler worked while ill with diarrhea.

(C) IG may be given within two (2) weeks after the last exposure.

(Indiana State Department of Health; 410 IAC 1-2.3-72; filed Sep 11, 2000, 1:36 p.m.: 24 IR 353)

410 IAC 1-2.3-73 Hepatitis, viral, Type B and Type D; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 73. The specific control measures for hepatitis, viral, Type B (infectious agent: Hepatitis B virus) and Type D (infectious

agent: Delta Hepatitis, occurs only in individuals with acute or chronic hepatitis B virus infection) are as follows:

(1) An investigation and case management duties are assigned as follows:

(A) An Investigation and case management of infants born to HBsAg (+) pregnant women shall begin immediately (when infection is identified at or close to the time of birth) and shall be performed by trained department immunization representatives in cooperation with the local health officer or trained local health department staff for the purpose of assuring that infants receive the complete HBIG and HBV vaccine series.

(B) The local health officer shall perform investigation and case management of all others, including household and sexual contacts of HBsAg (+) pregnant women. Investigators shall identify a complete list of contacts. Contacts are defined as sexual partners, household members, individuals with whom needles have been shared, and others who have been exposed to infectious body fluids. In addition, the investigation shall focus on history of surgery, transfusion or other blood product exposures, hemodialysis, employment as a health care worker, and other contacts with blood or other potentially infectious materials during the incubation period. When two (2) or more cases occur in association with some common exposure, a search for additional cases shall be conducted. If transfused blood or blood products is implicated in transmission, the lot shall be withdrawn from use and reasonable steps taken to ensure that no further donations from the infected donor are utilized.

(C) Hepatitis B immunization history shall be obtained on all cases of hepatitis B.

(2) Standard precautions for hospitalized patients and universal precautions for others where exposure to blood or other potentially infectious materials, or both, is a possibility. Infected persons shall not engage in sexual activities involving the exchange of body fluids without first informing their partner of their disease status. Restrictions on sexual activities shall be removed when the previously infected person is serologically confirmed to be noninfectious. The infected persons shall not:

(A) share needles or syringes with other persons without first notifying those persons of their disease status;

(B) donate blood, plasma, or organs for transplantation; or

(C) donate semen for artificial insemination.

(3) Equipment contaminated with blood or other potentially infectious body fluids, or both, shall be appropriately disinfected or when required, sterilized prior to reuse.

(4) Quarantine is not required.

(5) Protection/immunization of contacts shall be accomplished as follows:

(A) Infants of HBsAg(+) pregnant women shall be given the appropriate dosage of HBIG IM and of hepatitis B vaccine within twelve (12) hours of birth unless medically contraindicated. Additional doses of vaccine should be given at one (1) month and six (6) months of age. Infants should be tested for anti-HBs and HBsAg one (1) to three (3) months after completing the vaccine series.

(B) Potentially susceptible sexual partners should be tested for HBsAG, HBsAB, and anti-HBc; if negative, they should be given the appropriate dosage of HBIG IM and the first dose of hepatitis B vaccine IM within fourteen (14) days of the last sexual contact. Sexual contacts should complete the hepatitis B immunization series.

(C) If the index case is the mother or primary care provider of a susceptible infant less than twelve (12) months of age, the infant should receive the appropriate dosage of HBIG and hepatitis B vaccine according to vaccine manufacturer's directions.

(D) Other susceptible household contacts of the index case should receive the appropriate dosage of HBIG IM and initiate and complete hepatitis B vaccine if they have had identifiable blood exposures to the index case, such as sharing toothbrushes or razors.

(E) If the index case becomes a hepatitis B carrier, all household contacts should complete the hepatitis B vaccine series.

(Indiana State Department of Health; 410 IAC 1-2.3-73; filed Sep 11, 2000, 1:36 p.m.: 24 IR 354)

410 IAC 1-2.3-74 Hepatitis C infection; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 74. The specific control measure for hepatitis C (acute) are as follows:

(1) An investigation shall be performed within seventy-two (72) hours by the local health officer for the purpose of determining risk factors for infection.

(2) Standard for hospitalized patients and universal precautions for others, where exposure to blood or other potentially infectious materials, or both, is a possibility. Infected persons shall not:

(A) share needles or syringes with other persons;

(B) donate blood, plasma, or organs for transplantation; or

(C) donate semen for artificial insemination.

(3) Equipment contaminated with blood or other infectious body materials, or both, shall be appropriately disinfected or sterilized prior to reuse.

(4) Quarantine is not required.

(5) HCV-positive individuals shall not share razors or toothbrushes with others. Infants twelve (12) months of age or older born to infected mothers should be screened for anti-HCV. Health care workers with percutaneous or permucosal exposure to HCV shall have baseline and six (6) month follow-up serologic testing for anti-HCV and alanine aminotransferase activity.

(Indiana State Department of Health; 410 IAC 1-2.3-74; filed Sep 11, 2000, 1:36 p.m.: 24 IR 355)

410 IAC 1-2.3-75 Histoplasmosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 75. The specific control measure for histoplasmosis (infectious agent: Histoplasma capsulatum) are as follows:

(1) A local health officer shall investigate cases of infection to potential sources of exposure. The investigation shall evaluate the potential for occupational exposure, and in the event of two (2) or more cases for evidence of infection from a common environmental source.

(2) Standard precautions for hospitalized patients shall be instituted. No isolation is required for others.

(3) Concurrent disinfection is required for sputum and equipment and articles soiled with sputum. Terminal cleaning is also required.

(4) Quarantine is not required.

(5) Protection/immunization of contacts is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-75; filed Sep 11, 2000, 1:36 p.m.: 24 IR 355)

410 IAC 1-2.3-76 Human immunodeficiency virus infection/disease; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 76. The specific control measures for HIV are as follows:

(1) An investigation shall be performed by trained public health disease intervention specialists who shall conduct any contact tracing. Persons who are tested anonymously at a counseling and testing sites cannot be reported using personal identifiers; rather, they are to be reported using a numeric identifier code. Age, race, sex, risk factors, and county of residence shall also be reported. HIV infected persons are required to warn contacts of their disease status and the need to seek health care, such as counseling and testing. All identified contacts should receive counseling and be offered serologic testing. Until their status with regard to infection has been determined, contacts shall refrain from sexual activities involving the exchange of body fluids. All contacts shall not share needles and syringes with other persons without first notifying the other persons of their disease status.

(2) Standard precautions shall be used in hospitalized patients. Universal precautions shall be used for all other medical settings. Infected persons shall not:

(A) engage in sexual activities involving exchange of body fluids without first informing their partner of their disease status;

(B) share needles or syringes with other persons without first notifying the other persons of their disease status; or

(C) donate blood, plasma, organs for transplantation, or semen for artificial insemination.

(3) Concurrent disinfection is required for equipment and articles contaminated by blood or other potentially infectious material.

(4) Quarantine is not required.

(5) An investigation of HIV positive women, perinatally exposed infant and pediatric HIV cases will be performed by HIV

surveillance and disease intervention specialist staff members, who will obtain information epidemiologically necessary to protect the life of named parties.

(Indiana State Department of Health; 410 IAC 1-2.3-76; filed Sep 11, 2000, 1:36 p.m.: 24 IR 355)

410 IAC 1-2.3-77 Legionellosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 77. The specific control measures for legionellosis (infectious agent: Legionella species) are as follows:

(1) An investigation shall be performed by the local health officer in the event that a single nosocomial case is identified or in the event that two (2) or more cases not associated with a health care facility are identified. A definite noscomial case is a laboratory confirmed case who has spent ten (10) days or more continuously in a health care facility. A possible noscomial case is a laboratory case that occurs two (2) to nine (9) days after discharge from a health care facility. The investigation shall focus on environmental sources for the exposure in the health care facility for nosocomial cases, or places of common exposure for those infections not associated with a health care facility. Active surveillance for additional cases shall be undertaken.

(2) Standard precautions for hospitalized patients is required.

(3) Equipment contaminated with blood or infectious body fluids, or both, shall be appropriately disinfected or sterilized prior to reuse.

(4) Quarantine is not required.

(5) Protection/immunization of contacts is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-77; filed Sep 11, 2000, 1:36 p.m.: 24 IR 356)

410 IAC 1-2.3-78 Leptospirosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 78. The specific control measure for leptospirosis (infectious agent: Leptospira species) are as follows:

(1) An investigation by the local health officer shall be conducted for case ascertainment and to identify potential sources of the infection, such as contaminated water, occupational exposure, including handling of infected animals.

(2) Standard precautions are required.

(3) Quarantine is not required.

(4) Protection for contacts is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-78; filed Sep 11, 2000, 1:36 p.m.: 24 IR 356)

410 IAC 1-2.3-79 Listeriosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 79. The specific control measure for listeriosis (infectious agent: Listeria monocytogenes) are as follows:

(1) An investigation by the local health officer shall include a twenty-one (21) day food history, exposure to soil, and farm animals. Food history should include history of consuming raw milk, soft cheese, raw vegetables, and ready-to-eat meats. Surveillance data should be analyzed for clusters, and clusters for common source exposures.

(2) Standard precautions for hospitalized patients are required.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(5) Protection/immunization of contacts is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-79; filed Sep 11, 2000, 1:36 p.m.: 24 IR 356)

410 IAC 1-2.3-80 Lyme disease; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 80. The specific control methods for lyme disease (infectious agent: Borrelia burgdorferi) are as follows:

(1) The local health officer shall investigate to determine location of exposure to ticks and identify tick-infested areas.

(2) Standard precautions for hospitalized patients are required.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(5) Protection/immunization of contacts is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-80; filed Sep 11, 2000, 1:36 p.m.: 24 IR 356)

410 IAC 1-2.3-81 Lymphogranuloma venereum; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 81. The specific control measures for lymphogranuloma venereum (infectious agent: Chlamydia trachomatis) are as follows:

(1) Contact tracing shall be conducted by a trained public health disease control specialist.

(2) Standard precautions for hospitalized patients are required. Refrain from sexual contact until lesions are healed.

(3) Careful disposal of articles contaminated with discharges from lesions and articles soiled by discharges is required.

(4) Quarantine is not required.

(5) Protection/immunization of contacts is not available. Sexual contacts of patients with C. trachomatis infections should be evaluated and treated for C. trachomatis if the last sexual contact was within thirty (30) days of a symptomatic index patient's onset of symptoms, or within sixty (60) days of an asymptomatic index patient's diagnosis. Cases should also be examined serologically for syphilis initially.

(Indiana State Department of Health; 410 IAC 1-2.3-81; filed Sep 11, 2000, 1:36 p.m.: 24 IR 356)

410 IAC 1-2.3-82 Malaria; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 82. The specific control measures for malaria (infectious agents: Plasmodium vivax, P. malariae, P. falciparum, and P. ovale) are as follows:

(1) An investigation by the local health officer to determine history of previous infection or possible exposure. Travel history shall be evaluated to determine if the case is from foreign travel or local exposure. Exposure may occur from exposure to infected mosquitoes, transfusions with infected blood, or through needle sharing.

(2) Standard precautions for hospitalized patients are required. Both hospitalized and nonhospitalized patients shall remain in mosquito-proof areas from dusk to dawn.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required.

(5) Protection/immunization of contacts is not applicable.

(Indiana State Department of Health; 410 IAC 1-2.3-82; filed Sep 11, 2000, 1:36 p.m.: 24 IR 357)

410 IAC 1-2.3-83 Measles (rubeola); specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 83. The specific control measures for measles (rubeola) are as follows:

(1) An investigation and case management shall be performed immediately by department trained immunization field representatives in cooperation with the local health officer. The investigation shall consist of the following:

(A) Ascertainment of immunization history.

(B) Case ascertainment.

(C) Identification and listing of contacts. Contacts are defined as any individual who was in the same room while the case was present, or for two (2) hours afterwards at any time during the infectious period. The infectious period is defined as four (4) days before rash onset until four (4) days after the appearance of the rash. All children and adults attending the same school, child care, or babysitting groups as the case are defined as contacts.

(D) For outbreak control in public or private schools, on the same day that a report of a suspected case of measles is received, school personnel shall do the following:

(i) Conduct an inquiry into absenteeism to determine the existence of any other cases of the illness.

(ii) Immediately report the suspect case or cases to the local health department or the department.

(iii) Send a notice home with each student or attendee who has not presented proof of immunity explaining that the student shall be excluded from a given date, until acceptable proof of immunity is received by the school, or in the case of medical or religious exemptions, until fourteen (14) days after the onset of the last reported measles case. Previously unvaccinated children who are not vaccinated within seventy-two (72) hours of exposure shall also be excluded for fourteen (14) days after completing vaccination. Acceptable proof shall consist of:

(AA) a written record from the student's physician, parent, or guardian, which indicates the dates of vaccination (on or after the first birthday) and the type of vaccine administered;

(BB) a statement from a physician indicating the date when a student had measles; or

(CC) a laboratory report showing a protective measles antibody titer.

(iv) Make available to officials of the local health department or the department, or both, involved in investigating and controlling the outbreak, immunization records of all students in the school or attendees in child care.

(2) Airborne precautions shall be followed for hospitalized patients from onset of the catarrhal stage of the prodromal period through the fourth day of the rash to reduce the exposure of other persons at high risk. Other infected persons shall be excluded from school and day care centers, from public gatherings, and from contact with susceptible persons outside the household for at least four (4) days after appearance of the rash.

(3) Concurrent disinfection is not required.

(4) Quarantine is not required. Children in institutions, wards, or dormitories for young children may be quarantined. If measles occurs in an institution where infants reside, these infants shall be segregated from infected persons and susceptible contacts.

(5) Protection/immunization of contacts shall be as follows:

(A) Live measles vaccine given to inadequately vaccinated persons within seventy-two (72) hours of exposure may provide protection against disease.

(B) Immune globulin (IG) may be given within six (6) days to the susceptible household or other contacts, especially those for whom risk of complications is very high (such as contacts under one (1) year of age), or for whom the measles vaccine is contraindicated.

(C) Live measles vaccine should be given three (3) months later to IG recipients for whom vaccine is not contraindicated.

(Indiana State Department of Health; 410 IAC 1-2.3-83; filed Sep 11, 2000, 1:36 p.m.: 24 IR 357)

410 IAC 1-2.3-84 Meningitis, aseptic; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 84. The specific control measures for aseptic meningitis (infectious agent: various viral agents) is an investigation by the local health officer that shall be conducted when reports exceed the expected number for population in time period. The investigation shall be focused on determining cause of the disease and its distribution. *(Indiana State Department of Health; 410 IAC 1-2.3-84; filed Sep 11, 2000, 1:36 p.m.: 24 IR 358)*

410 IAC 1-2.3-85 Meningococcal infections, invasive; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 85. The specific control measures for meningococcal disease, invasive (infectious agent: Neisseria meningitidis) are as follows:

(1) An investigation shall be performed immediately by the local health officer for the purpose of identifying all close contacts. Contacts are defined as household contacts, day care contacts, and anyone directly exposed to the patient's oral secretions. Investigation shall also be performed to identify school attendance and work history of the case, or history of habitual association with an agency, organization, or institution.

(2) Droplet precautions are required for hospitalized patients until twenty-four (24) hours of effective antimicrobial therapy has been completed.

(3) Concurrent disinfection are required for discharges from nose and throat, and all articles soiled by them. Terminal cleaning is required.

(4) Quarantine is not required.

(5) Protection/immunization of contacts should be treated as follows:

Rifampin	
Children ≤ 1 month of age	5 mg/kg orally every 12 hours for 2 days
Children > 1 month of age and adults	10 mg/kg (maximum 600 mg) orally every 12 hours for 2 days or 20 mg/kg (maximum 600 mg) orally every 24 hours for 4 days
Ceftriaxone	
≤ 12 years of age	125 mg intramuscular (IM) single dose
> 12 years of age	250 mg intramuscular (IM) single dose
Ciprofloxacin	
≥ 18 years of age	500 mg orally single dose

(Indiana State Department of Health; 410 IAC 1-2.3-85; filed Sep 11, 2000, 1:36 p.m.: 24 IR 358)

410 IAC 1-2.3-86 Mumps; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 86. The specific control measures for mumps are as follows:

(1) An investigation shall be conducted by trained department immunization field representatives in cooperation with the local health officer. The investigation shall include obtaining serology for mumps IgM in suspect cases, and identifying susceptible contacts who should be immunized.

(2) For hospitalized patients, droplet precautions are indicated for nine (9) days from the onset of swelling.

(3) Concurrent disinfection shall be followed to disinfect articles contaminated with nose and throat secretions.

(4) Infected persons shall be excluded from school and day care centers, public gatherings, and contact with susceptible persons outside the household for nine (9) days after the onset of swelling. Exclude exposed susceptibles from school or the workplace from the twelfth to the twenty-fifth days after exposure to prevent spread to other susceptibles.

(5) Vaccination of susceptibles after exposure to mumps may not prevent disease; however, vaccination may be given to protect against subsequent exposures.

(Indiana State Department of Health; 410 IAC 1-2.3-86; filed Sep 11, 2000, 1:36 p.m.: 24 IR 358)

410 IAC 1-2.3-87 Pediatric blood lead; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 87. The specific control measures for pediatric venous blood lead are as follows:

(1) Local health officers shall ensure the monitoring of children, equal to or less than six (6) years of age, who have been reported to have a venous blood lead level of greater than ten (10) µg per deciliter. Monitoring shall include referrals for case management if not already accomplished and environmental assessment. Additional guidance may be found in Center for Disease Control and Prevention publication Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials, November 1997.

(2) Ensure that additional testing is accomplished in accordance with the following schedule:

(A) Initial blood level ten (10)–nineteen (19) µg per deciliter, rescreen within three (3) months.

(B) Initial blood level twenty (20)–forty-four (44) µg per deciliter, rescreen within one (1) month.

(C) Initial blood level forty-five (45)–fifty-nine (59) µg per deciliter, rescreen within forty-eight (48) hours.

(D) Initial blood level sixty (60)–sixty-nine (69) µg per deciliter, rescreen within twenty-four (24) hours.

(E) Initial blood level equal to or greater than seventy (70) µg per deciliter, rescreen immediately as an emergency lab test.

(Indiana State Department of Health; 410 IAC 1-2.3-87; filed Sep 11, 2000, 1:36 p.m.: 24 IR 358)

410 IAC 1-2.3-88 Pertussis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 88. The specific control measures for pertussis (infectious agent: Bordetella pertussis) are as follows:

(1) Immediate investigation shall be performed by trained department immunization field representatives in cooperation with the local health officer. An investigation shall be performed for the purpose of case ascertainment and identification of close contacts. Close contacts are defined as household and day care contacts and persons who have had direct contact with respiratory secretions of the case, including, but not limited to, the following:

(A) Explosive cough or sneeze in the face.

(B) Sharing food or utensils.

(C) Kissing.

(D) Mouth to mouth resuscitation.

(E) Performing a full medical exam, including examination of the nose and throat.

A search for unrecognized or unreported, early, and atypical cases is indicated where a nonimmune infant or young child is, or might be, at risk.

(2) Droplet precautions shall be utilized for hospitalized patients for five (5) days after the start of effective therapy. For others, inadequately immunized household contacts less than seven (7) years of age shall be excluded from schools, day care centers, and public gatherings for fourteen (14) days after the last exposure, or until they have received five (5) days of a minimum fourteen (14) day course of erythromycin or trimethoprim-sulfamethoxazole. Infected persons shall be excluded from:

(A) schools and day care centers;

(B) public gatherings; and

(C) contact with susceptible persons outside the household;

until they have received at least five (5) days of a minimum fourteen (14) day course of erythromycin or trimethoprim-sulfamethoxazole. Infected persons shall not have contact with unimmunized infants. Infected persons not receiving the prophylaxis as established in this subdivision shall be excluded from schools, day care centers, and public gatherings for twenty-one (21) days.

(3) Concurrent disinfection is required for nose and throat discharges, and any articles soiled by nose and throut *[sic.]* discharges.

(4) For quarantine, see subdivision (1) for inadequately immunized contacts.

(5) Close contacts less than seven (7) years of age who have not received four (4) diphtheria, tetanus, or pertussis (DTP or DTaP) doses, or have not received a DTP dose within three (3) years should be given a DTaP dose as soon after exposure as possible. A fourteen (14) day course of erythromycin (forty (40) to fifty (50) milligram *[sic., milligrams]* per kilogram per day (mg/kg/day), orally in four (4) divided doses, maximum two (2) grams per day (gm/day)) for all household and other close contacts regardless of age and vaccination status should be given. While efficacies have not been established, clarithromycin,

other macrolides, or trimethoprim-sulfamethoxazole are alternatives for those who cannot tolerate erythromycin. Those with symptoms should be cultured before antibiotic therapy. Immunization after discovery of a case or an outbreak does not provide protection to newly immunized persons during that outbreak; therefore, contacts must be protected immediately by other measures.

(Indiana State Department of Health; 410 IAC 1-2.3-88; filed Sep 11, 2000, 1:36 p.m.: 24 IR 359)

410 IAC 1-2.3-89 Plague; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 89. The specific control measures for plague (infectious agent: Yersinia pestis) are as follows:

(1) The local health officer shall perform an immediate investigation to identify all contacts. Contacts are defined as those individuals who have been in household or face to face contact with patients with pneumonic plague. Establish if the case had traveled to endemic areas in the past seven (7) days. Determine if patients were exposed to rodents, or cats, or dogs, or visited areas of rodent habitat during travel.

(2) Standard precautions are required for hospitalized patients with bubonic plague. Droplet precautions for hospitalized patients with pneumonic plague are required until seventy-two (72) hours after the start of effective therapy.

(3) Concurrent disinfection is required for sputum and purulent discharges, and articles soiled with them.

(4) Those who have had face-to-face contact or are in a household with patients shall be placed on chemoprophylaxis and observed for seven (7) days. Those who refuse chemoprophylaxis must be isolated for seven (7) days.

(5) Close contacts (including medical personnel) shall be evaluated for chemoprophylaxis. Contacts of pneumonic plague shall be provided chemoprophylaxis. Children less than eight (8) years of age should be given trimethoprim-sulfamethoxazole. For children older than eight (8) years of age and adults, doxycycline or tetracycline is recommended.

(6) Streptomycin and gentamycin are drugs of choice in most cases. Tetracyclines and chloramphenicol are alternatives.

(Indiana State Department of Health; 410 IAC 1-2.3-89; filed Sep 11, 2000, 1:36 p.m.: 24 IR 359)

410 IAC 1-2.3-90 Poliomyelitis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 90. The specific control measures for poliomyelitis are as follows:

(1) Immediate investigation shall be performed by a trained department immunization field representative in cooperation with the local health officer. The investigation shall include the following:

(A) Laboratory confirmation.
(B) Immunization status of the case.
(C) Time since the last vaccination.
(D) Type of vaccine given.
(E) History of underlying immunosuppressive condition.
(F) History of contact with high risk individuals (such as persons who object to vaccination, recent immigrants, travelers, and persons who are a probable or confirmed case of polio).

Travel history of the case shall be determined. If wild poliovirus is implicated and at least two (2) cases are associated by time and place, an immunization program designed to contain the spread shall be initiated using trivalent oral polio vaccine. A thorough search shall be conducted for sick persons, especially children, to assure early detection, facilitate control, and permit appropriate treatment of unrecognized and unreported cases.

(2) For hospitalized patients, standard precautions are required. Other infected persons shall be excluded from schools and day care centers, public gatherings, and contact with susceptible persons outside the home for a period of not less than fourteen (14) days after the onset of illness.

(3) Concurrent disinfection shall be followed for throat discharges, feces, and articles soiled by throuat *[sic., throat]* discharges or feces, or both. Feces may be disposed of directly into sanitary sewage system. Terminal cleaning shall also be followed.

(4) Familial and other close contacts may be vaccinated, but this measure, when implemented after recognition of the case,

is of unknown value.

(Indiana State Department of Health; 410 IAC 1-2.3-90; filed Sep 11, 2000, 1:36 p.m.: 24 IR 360)

410 IAC 1-2.3-91 Psittacosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 91. The specific control measures for psittacosis (infectious agent: Chlamydia psittaci) are as follows:

(1) An investigation by the local health officer shall be instituted to identify the source of infection and implementation of control measures. The investigation shall identify exposure to:

(A) psittacine birds (owned by individuals or pet shops);

(B) occupational exposure to poultry flocks; or

(C) processing plants;

for the previous four (4) weeks. Identified locations for potential exposure shall be forwarded to the Indiana state board of animal health for investigation.

(2) Standard precautions are required. Coughing patients shall cough into tissue to prevent aerosolization of infectious agent.

(Indiana State Department of Health; 410 IAC 1-2.3-91; filed Sep 11, 2000, 1:36 p.m.: 24 IR 360)

410 IAC 1-2.3-92 Q fever; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2-1

Sec. 92. The specific control measure for Q fever (infectious agent: Coxiella burnetii) are as follows:

(1) An investigation shall be conducted by the local health officer for case ascertainment and identification of an infection source.

(2) Standard precautions for hospitalized patients shall be taken.

(3) Quarantine is not required.

(4) Investigation for the infection source shall be directed at exposure to sheep, cattle, goats, laboratories that handle the agents, and consumption of unpasteurized milk.

(Indiana State Department of Health; 410 IAC 1-2.3-92; filed Sep 11, 2000, 1:36 p.m.: 24 IR 360)

410 IAC 1-2.3-93 Rabies, human and animal; specific control measures

Authority: IC 16-41-2-1
Affected: IC 15-2.1-6-11; IC 16-41-2; IC 16-41-9

Sec. 93. The specific control measures for rabies (see animal bites also) are as follows:

(1) An investigation shall be accomplished by the department veterinary epidemiologist in collaboration with the local health officer. The investigation shall identify the route of exposure, the animal responsible for exposure, and other individuals who may have been exposed to that animal or to the salivary secretions of the patient. Individuals who have been exposed to salivary secretions of the patient shall be evaluated for postexposure prophylaxis (postexposure prophylaxis guidance is provided in section 52 of this rule).

(2) Standard precautions shall be followed for hospitalized patients. Health care workers shall prevent mucous membrane and open wound contact with patient's saliva.

(3) Concurrent disinfection is required. Saliva and articles contaminated with saliva shall be disinfected.

(4) Contacts who have experienced saliva exposure to open wounds or mucous membranes should receive postexposure prophylaxis.

(Indiana State Department of Health; 410 IAC 1-2.3-93; filed Sep 11, 2000, 1:36 p.m.: 24 IR 360)

410 IAC 1-2.3-94 Rocky mountain spotted fever; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 94. The specific control measures for Rocky mountain spotted fever (infectious agent: Rickettsia rickettsii) are as follows:
(1) The local health officer shall investigate to determine location of exposure to infected ticks. Recent travel, as well as exposure to tick infected areas, shall be identified.
(2) Standard precautions are required for hospitalized patients.
(3) Carefully remove all ticks from the patient to avoid contact with infectious agent.
(4) Quarantine not necessary.
(5) Immunizations for contacts are not available.

(Indiana State Department of Health; 410 IAC 1-2.3-94; filed Sep 11, 2000, 1:36 p.m.: 24 IR 361)

410 IAC 1-2.3-95 Rubella (German measles); specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 95. The specific control measures for rubella (German measles) are as follows:
(1) An investigation and case management shall be performed immediately by a trained department immunization field representative with the cooperation of the local health officer. The investigation shall include case ascertainment, previous immunization history, and identification of exposed pregnant female and other susceptible contacts. For outbreak control in public or private schools or child care facilities, on the same day that a report of a suspected case of rubella is received, school personnel shall do the following:
(A) Conduct an inquiry into absenteeism to determine the existence of any other cases of the illness.
(B) Immediately report the suspect case or cases to the local health department or the department.
(C) Send a notice home with each student or attendee who has not presented proof of immunity, explaining that the student shall be excluded from a given day, until acceptable proof of immunity is received by the school, or in the case of medical or religious exemptions, until twenty-three (23) days after the onset of the last reported rubella case. Acceptable proof shall consist of the following:
(i) A written record from the student's physician or parent or guardian that indicates the dates of vaccination (on or after the first birthday) and the type of vaccine administered.
(ii) A laboratory report showing a protective rubella antibody titer.
(D) Make available to officials of the local health department or the department, or both, involved in investigating and controlling the outbreak, immunization records of all students in the school, or attendees in child care.
(2) Droplet precautions shall be followed for seven (7) days after onset of a rash. Contact precautions shall be followed for suspected or known congenital rubella until one (1) year of age unless urine and nasopharyngeal cultures are negative for the virus after three (3) months. In hospitals and institutions, patients suspected of having rubella shall be managed in a private room. Infected persons shall be excluded from:
(A) schools and day care centers;
(B) places of work;
(C) public gatherings; and
(D) contact with susceptibles outside the household;
for seven (7) days after onset of a rash.
(3) Immunization, while not contraindicated (except during pregnancy), will not necessarily prevent infection or illness. Passive immunization with immune globulin may be given to a susceptible pregnant woman exposed to the disease, but should only be administered after thorough consultation with her attending physician, and any such measure should be provided by her attending physician. Pregnant female contacts, especially those in the first trimester, should be referred immediately to their attending physician for serological testing to determine susceptibility or early infection (IgM) antibody and for thorough medical consultation.

(Indiana State Department of Health; 410 IAC 1-2.3-95; filed Sep 11, 2000, 1:36 p.m.: 24 IR 361)

410 IAC 1-2.3-96 Salmonellosis, other than typhoid fever; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 96. The specific control measures for salmonellosis, other than typhoid fever, (infectious agent: Salmonella species) are as follows:

(1) An investigation by the local health officer shall be accomplished immediately to determine if the affected individual is a food handler, day care attendant or attendee, or health care worker. Further investigation shall be performed to determine a three (3) day food consumption history with emphasis on exposure to inadequately cooked poultry and poultry products, uncooked or lightly cooked eggs or egg products, raw milk, and dairy products. Interview meal companions to identify additional cases and if a commercial food product or restaurant is suspected, conduct active surveillance for additional cases. Medical evaluation, including adequate laboratory examination of feces of contacts should be limited to food handlers, child care attendants, health care workers, or other situations where outbreaks may occur.

(2) Contact precautions shall be followed for diapered or incontinent patients less than six (6) years of age for the duration of the illness, and standard precautions shall be followed for other hospitalized patients. For other individuals, the following guidelines shall be followed:

(A) Symptomatic persons shall be excluded from employment involving food handling, direct care of children, or hospitalized or institutionalized patients.

(B) Asymptomatic day care workers and health care workers may return to work, providing they have met the requirement of clauses (C) and (D) prior to that person's return to work. Once clauses (C) and (D) are met, asymptomatic food handlers may return to work, but will be restricted from working with:

(i) exposed food;

(ii) clean equipment, utensils, and linens; and

(iii) unwrapped single-service and single-use articles;

until they are determined to be free of salmonella as described in clause (E).

(C) The local health officer discusses with the asymptomatic worker his or her symptoms and determines that he or she is indeed asymptomatic, and that the worker is further counseled about measures, such as hand washing, that shall be followed to prevent transmission of disease.

(D) The local health officer contacts the employer to reemphasize the need to:

(i) comply with local and state rules requiring proper hand washing facilities for all employees; and

(ii) correct any observed lapses in hygiene measures of any employees.

(E) The worker has had two (2) successive negative fecal samples or rectal swabs (collected greater than twenty-four (24) hours apart) and no sooner than forty-eight (48) hours after cessation of any antibiotic therapy.

(F) Symptomatic individuals shall be excluded from schools and day care centers. Once determined to be asymptomatic, excluded individuals may be readmitted to schools and day care centers.

(G) If an outbreak of the infection occurs in a day care center, all attendees may be required to submit stool specimens for examination. In addition, the local health officer may order asymptomatic attendees and staff who are infected with Salmonella organisms to be isolated from other attendees and staff in the same center, and admission of all new attendees suspended while the outbreak continues.

(3) Concurrent disinfection is required for feces and fecal contaminated articles. Feces may be disposed directly into a sanitary sewage system. Terminal cleaning is required.

(Indiana State Department of Health; 410 IAC 1-2.3-96; filed Sep 11, 2000, 1:36 p.m.: 24 IR 361)

410 IAC 1-2.3-97 Shigellosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 97. The specific control measures for shigellosis (infectious agent: Shigella species) are as follows:

(1) An investigation shall be performed immediately by the local health officer to determine whether the case is a food handler, day care worker, health care worker, day care attendee, or attendee at other institutions. Further investigation shall be performed to determine a seven (7) day food consumption and water source history. The investigation shall identify household members and contacts who are food handlers, health care or day care workers, or those who care for elderly people in institutional settings. Any such contacts shall have stools cultured, whether asymptomatic or not, to identify other infected individuals.

(2) Contact precautions are required for diapered or incontinent patients less than six (6) years of age for the duration of the

illness, and standard precautions for other hospitalized patients. For others, the following steps shall be taken:

(A) Patients with known Shigella infections shall be excluded from employment involving food handling, direct care of children, or hospitalized or institutionalized patients until two (2) successive fecal specimens collected more than twenty-four (24) hours apart, and not less that forty-eight (48) hours after completion of antimicrobial therapy, have been determined to be culture negative for Shigella organisms. Infected children shall be excluded from day care centers until asymptomatic and have completed five (5) days of specific antimicrobial therapy or if antibiotics are not administered until two (2) successive fecal specimens collected not less than twenty-four (24) hours apart have been determined to be negative for Shigella organisms.

(B) Symptomatic school children shall be excluded from schools, but may be allowed to return after:

(i) symptoms cease;

(ii) appropriate antimicrobial therapy has been initiated for at least forty-eight (48) hours; and

(iii) education regarding good hygiene has been provided to the case.

If an outbreak occurs in a school, the administrator may exclude symptomatic students and staff until two (2) successive fecal specimens collected not less than twenty-four (24) hours apart, and at least forty-eight (48) hours after cessation of specific therapy have been determined to be negative for Shigella organisms. If an outbreak occurs in a day care center, all attendees and staff may be required to submit stool specimens for examination. Symptomatic children shall be excluded until asymptomatic, and completion of five (5) days of specific antimicrobial therapy. The day care administrator may consider isolation of infected but asymptomatic attendees from other attendees instead of exclusion until stool negative or five (5) days of specific antimicrobial therapy. This alternative can only be considered if the physical structure and staff organization of the center can accommodate isolation of various attendee groups from one another.

(3) Concurrent disinfection is required for feces and fecal contaminated articles. Feces may be disposed of directly in sanitary sewage system.

(4) There is no immunization available.

(Indiana State Department of Health; 410 IAC 1-2.3-97; filed Sep 11, 2000, 1:36 p.m.: 24 IR 362)

410 IAC 1-2.3-98 Staphylococcus aureus, vancomycin resistant level ≥ 8 μg/mL; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 98. The specific control measures for Staphylococcus aureus, vancomycin resistant level ≥ 8 μg/mL, are as follows:

(1) An investigation by the department in collaboration with the local health officer shall be accomplished within seventy-two (72) hours to verify resistant or intermediate resistant culture isolate to vancomycin. The investigation includes laboratory verification of resistance. Abrupt increases in the prevalence of the disease in the community shall be investigated for a common source.

(2) For hospitalized patients, contact precautions are required.

(3) Concurrent disinfection is required for all discharges from the skin, wound, or burn and articles contaminated with discharges. Fecal material may be disposed of in a sanitary sewer.

(Indiana State Department of Health; 410 IAC 1-2.3-98; filed Sep 11, 2000, 1:36 p.m.: 24 IR 363)

410 IAC 1-2.3-99 Invasive Streptococcus pneumoniae; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 99. The specific control measures for invasive Streptococcus pneumoniae are as follows:

(1) An investigation of contacts and the source of infection shall be as follows:

(A) An investigation by a department-trained immunization field representative in collaboration with the local health officer for cases less than or equal to five (5) years of age within seventy-two (72) hours. The investigation shall include complete pneumococcal vaccine immunization history, history of antibiotic use, history of chronic underlying disease, asplenia or immunosuppression, and drug resistance pattern of isolate.

(B) An investigation by a local health officer for all other cases shall be performed within seventy-two (72) hours. The

investigation shall include complete pneumococcal vaccine immunization history, history of chronic underlying disease, asplenia or immunosupresssion, and drug resistance pattern of isolate.

(2) For hospitalized patients, standard precautions are required.

(3) Disinfect purulent discharges and articles soiled by them.

(4) Protection/immunization of contacts is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-99; filed Sep 11, 2000, 1:36 p.m.: 24 IR 363)

410 IAC 1-2.3-100 Streptococcal disease, invasive, Group A and streptococcal toxic shock syndrome; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 100. The specific control measures for invasive streptococcal infections and toxic shock syndrome (infectious agent: Streptococcus pyogenes) are as follows:

(1) An investigation within seventy-two (72) hours by the local health officer to ascertain that the case meets the case definition for invasive Group A streptococcal or streptococcal toxic shock syndrome. Identify if the case had a recent case of varicella or underlying chronic disease. Be alert for outbreaks defined as two (2) or more cases occurring close together in place and time.

(2) For hospitalized young children with pharyngitis, pneumonia, or scarlet fever, droplet precautions shall be followed until at least twenty-four (24) hours of antimicrobial therapy have been administered. For patients with skin, wound, or burn infections, contact precautions shall be followed for at least twenty-four (24) hours after antimicrobial therapy has been administered.

(3) Discharges and articles soiled with discharges shall be disinfected.

(4) Immunization is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-100; filed Sep 11, 2000, 1:36 p.m.: 24 IR 363)

410 IAC 1-2.3-101 Invasive Group B streptococcal infections (infectious agent: Streptococcus agalactiae); specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 101. The specific control measures for invasive Group B streptococcus are as follows:

(1) An investigation within seventy-two (72) hours by the local health officer to ascertain that the case meets the case definition (infection of a normal sterile site, that is, blood or CSF) and to identify outbreaks, defined as two (2) or more cases occurring close together in place and time.

(2) For hospitalized patients, standard precautions are required.

(3) Disinfection of discharges and articles contaminated by discharges shall be done.

(Indiana State Department of Health; 410 IAC 1-2.3-101; filed Sep 11, 2000, 1:36 p.m.: 24 IR 364)

410 IAC 1-2.3-102 Syphilis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 102. The specific control measures for syphilis (infectious agent: Treponema pallidum) are as follows:

(1) An investigation shall by accomplished by trained public health disease control specialists in cooperation with the local health officer. The investigation shall be focused on identifying sexual partners who were at risk for transmitting to or contacting the infection from the case. Cases and contacts shall be fully evaluated (including pregnancy status of females) and treated as recommended in the MMWR 1998 Guidelines for Treatment of Sexually Transmitted Diseases, January 23, 1998, Volume 47/RR1.

(2) For hospitalized patients standard precautions are required. For others, the infected persons shall refrain from sexual activities involving exchange of body fluids until their lesions clear and they have been on appropriate antibiotic therapy for

at least twenty-four (24) hours. Treated persons shall also avoid sexual activities involving exchange of body fluids with untreated partners to avoid reinfection.

(3) Disinfection is not required in adequately treated cases, but care shall be taken to avoid contact with discharges from open lesions and articles soiled by discharges.

(4) Quarantine is not required.

(5) Immunization is not available.

(Indiana State Department of Health; 410 IAC 1-2.3-102; filed Sep 11, 2000, 1:36 p.m.: 24 IR 364)

410 IAC 1-2.3-103 Tetanus; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 103. The specific control measures for tetanus (infectious agent: Clostridium tetani) are as follows:

(1) An investigation shall be accomplished within seventy-two (72) hours by a department-trained immunization field representative with the cooperation of the local health officer.

(2) The investigation shall include:

(A) a complete tetanus toxoid immunization history;

(B) circumstance of injury; or

(C) possible source of infection.

(Indiana State Department of Health; 410 IAC 1-2.3-103; filed Sep 11, 2000, 1:36 p.m.: 24 IR 364)

410 IAC 1-2.3-104 Toxic shock syndrome; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 104. The specific control measures for toxic shock syndrome (Staphylococcal) are as follows:

(1) An investigation by the local health officer shall be accomplished within seventy-two (72) hours for case ascertainment, clinical findings, culture results, and suspected source of infection.

(2) Standard precautions shall be followed.

(3) Sanitary disposal of blood and articles soiled with body discharges.

(Indiana State Department of Health; 410 IAC 1-2.3-104; filed Sep 11, 2000, 1:36 p.m.: 24 IR 364)

410 IAC 1-2.3-105 Trichinosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 105. The specific control measures for trichinosis (infectious agent: Trichinella spiralis) are as follows:

(1) An investigation by the local health officer shall be accomplished within seventy-two (72) hours. Collect food consumption history, concentrating on meats, for eight (8) to forty-five (45) days prior to the onset of symptoms. Travel history may provide leads to unusual foods or source of foods with increased risk. Identify and interview family members and others that the case normally shares meals with to identify additional cases.

(2) Standard precautions are required.

(Indiana State Department of Health; 410 IAC 1-2.3-105; filed Sep 11, 2000, 1:36 p.m.: 24 IR 364)

410 IAC 1-2.3-106 Tuberculosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 106. The specific control measures for tuberculosis (infectious agent: Mycobacterium tuberculosis) are as follows:

(1) An investigation and case management are the responsibility of the local health officer and shall begin immediately. The local health officer shall request laboratory, radiological, and other studies as required for case ascertainment and to determine

if the suspect case should be isolated as described in subdivision (5)(B). For confirmed and suspected cases of tuberculosis, a contact investigation shall be performed, identifying both household and close contacts. As used in this subdivision, "close contact" means an individual who has shared breathing air space with a tuberculosis case for prolonged periods of time in circumstance or frequency that would allow airborne transmission. Examples of close contacts are household members, co-workers, and friends. If several of the close contacts are PPD positive, then contact investigation shall be expanded to include persons who have been progressively in less contact with source or suspect.

(2) Pulmonary tuberculosis cases and suspects who are sputum-smear negative, are clinically improving, and are known to be on adequate tuberculosis chemotherapy are defined as noninfectious. All other pulmonary tuberculosis cases and suspects must be isolated until no longer infectious. In the hospital, tuberculosis cases and suspects must be isolated in accordance with the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, as published by Centers for Disease Control and Prevention in Morbidity and Mortality Weekly Report, October 28, 1994, Volume 43, No. RR-13. Prior to discharge of cases or suspects, the hospital shall notify the local health department in the jurisdiction where the tuberculosis suspect or case resides. Prior to discharge of the tuberculosis case or suspect, the local health department shall make plans, in writing, for continuation of medical follow-up, assuring adherence to therapy and isolation. Plans shall be developed in cooperation with the treating physician and the patient, and must be in accordance with this rule. For patients with confirmed or suspected pulmonary tuberculosis who do not need to be hospitalized, in-home isolation is an acceptable alternative. Contact with persons outside the home shall be prohibited unless the infected person wears a surgical mask, properly tied. Children should not be in the home while the case is considered infectious.

(3) Concurrent disinfection is required and shall include hand washing and good housekeeping practices combined with dilution of particles in the air by ventilation.

(4) Because the potential for unrecognized exposure as well as known exposure of medical personnel to tuberculosis, hospital and laboratories shall develop and follow tuberculosis prevention and control programs for their facilities as described in the Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings as published by Centers for Disease Control and Prevention in Morbidity and Mortality Weekly Report, October 28, 1994, Volume 43, No. RR-13.

(5) For every case of pulmonary tuberculosis the local health officer must initiate a complete contact investigation within three (3) working days of the report of the case. The first step in performing the contact investigation for pulmonary cases is to estimate the degree of infectiousness and determine the infectious period. Infectiousness is generally predicted by disease in a pulmonary or respiratory (for example, endobronchial or laryngeal site), a lung cavity seen on a chest X-ray, acid fast bacilli (AFB) seen in a smear of concentrated sputum, and protracted cough. Under most circumstances, tuberculosis without a pulmonary or respiratory site is not infectious. The infectious period is defined as the period beginning with onset of symptoms (especially cough) until any of the following endpoints is attained:

(A) Contact is broken with the infectious case.

(B) Effective isolation measures are instituted for that case.

(C) The case is determined to be noninfectious by all of the following criteria:

(i) The index tuberculosis patient has three (3) negative smears for AFB taken twenty-four (24) hours apart.

(ii) Is known to be taking effective antituberculosis chemotherapy.

(iii) Is clinically improving.

The case shall be interviewed in detail to identify all contacts who shared air space during the infectious period. The list of contacts shall then be prioritized according to length and duration of contact with the case, with household contacts, and other close social or workplace contacts given highest priority. High priority shall also be assigned to exposed infants and any exposed persons who have medical conditions, for example, HIV infection, making them vulnerable to tuberculosis.

(6) All household and close contacts not known to have a previously positive tuberculin skin test or active tuberculosis, shall be tested with five (5) TU purified protein derivative (PPD) intradermally by the Mantoux method administered by an individual trained in the administration and reading of tuberculin skin tests. The skin test should be read seventy-two (72) hours later by a trained individual, and the amount of induration in millimeters shall be recorded. If any of the following conditions are met, then the contact investigation shall be progressively expanded to include contacts with lesser degrees of exposure:

(A) The prevalence of positive tuberculin skin tests (induration $\geq$ 5 mm) is higher in contacts tested than the prevalence in similar populations residing in the jurisdiction.

(B) A new positive tuberculin skin test is found in a young child.

(C) A documented skin test conversion is found among contacts.

(D) A secondary case of active tuberculosis is found among contacts.

When none of the criteria in this subdivision are met, further expansion of the contact investigation is not necessary.

(7) Contacts with positive tuberculin skin test results, those with symptoms, those with immunosuppressive conditions or those younger than six (6) months of age should have a chest X-ray performed to determine if they have tuberculosis disease. Those with symptoms or with an infiltrate on chest X-ray should submit a sputum sample for AFB smear, culture, and sensitivity.

(8) Contacts with suspected or confirmed active tuberculosis shall be evaluated and managed according to this section.

(9) Contacts identified through contact investigation who have a positive PPD (induration ≥ 5 mm) and a normal chest X-ray, should be offered preventive therapy, usually with isoniazid, regardless of age, unless otherwise medically contraindicated. Contacts should also be considered for treatment of latent infection with tuberculosis in any of the following situations:

(A) Evaluation of other contacts with a similar degree of exposure demonstrates a high prevalence of infection.

(B) The contact is a child or an adolescent, or the contact is immunosuppressed.

(10) Infants who are exposed to a person with infectious active tuberculosis should be evaluated with a tuberculin skin test and a chest radiograph. If the skin test result is negative and the chest radiograph is normal, the infant should be skin tested again at three (3) to four (4) months of age and at six (6) months of age. The infant should receive preventive therapy even if skin test negative. Preventive therapy may be discontinued if the infant is skin test negative at six (6) months of age, provided at least ten (10) weeks have passed since the infant was last exposed to infectious tuberculosis.

(11) The local health officer shall assure that contacts are appropriately evaluated for tuberculosis infection and that a complete course of preventive therapy is recommended for contacts with evidence of tuberculosis infection, regardless of age, unless medically contraindicated. The local health officer is responsible for recording the results of contact investigation and follow-up according to this rule and reporting the results to the department.

(12) The local health department of the jurisdiction shall actively follow every tuberculosis case and suspect where the case or suspect resides until they have completed an adequate course of tuberculosis chemotherapy as described in Treatment of Tuberculosis and Tuberculosis In Adults and Children, published in the American Journal of Respiratory and Critical Care Medicine, Volume 149, pages 1359 through 1374, 1994, or until the patient is determined not to have tuberculosis. The duties of the local health department shall include the following:

(A) Requesting laboratory studies, such as AFB smear and cultures as needed for case ascertainment and for determining whether isolation is necessary.

(B) Requesting drug susceptibility testing of all initial tuberculosis isolates as needed.

(C) Assuring appropriate anti-tuberculosis medications are initiated at the appropriate dose in accordance with this subsection.

(D) Assuring that the pulmonary tuberculosis patient is isolated until confirmed to be noninfectious according to the following criteria:

(i) Three (3) consecutive sputum smears are negative for AFB taken at a minimum twenty-four (24) hours apart.

(ii) Clinical improvement is documented.

(iii) The patient is known to be on adequate anti-tuberculosis medication.

(E) Assessing that medication is taken as prescribed. Directly observed therapy is the standard of care for achieving adherence.

(F) Documenting conversion of sputum and culture to negative for AFB.

(G) Contact investigation.

(Indiana State Department of Health; 410 IAC 1-2.3-106; filed Sep 11, 2000, 1:36 p.m.: 24 IR 364)

410 IAC 1-2.3-107 Tularemia; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 107. The specific control measures for tularemia (infectious agent: Francisella tularensis) are as follows:

(1) An investigation shall be conducted by the local health officer for case ascertainment and identification of infection source.

(2) Standard precautions for hospitalized patients are required.

(3) Quarantine is not required.

(4) Protection of contacts is not required.

(Indiana State Department of Health; 410 IAC 1-2.3-107; filed Sep 11, 2000, 1:36 p.m.: 24 IR 366)

410 IAC 1-2.3-108 Typhoid fever; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 108. The specific control measures for typhoid fever (infectious agent: Salmonella typhi) are as follows:

(1) An investigation by the local health officer shall be conducted immediately to determine if the affected individual is a food handler, day care worker, or health care worker. Further investigation shall be performed to determine food consumption history for three (3) weeks prior to the onset of symptoms. Every case should be investigated for an actual or probable source. The investigation shall focus on identifying:

(A) unreported cases or carriers;

(B) contaminated food, water, milk, shellfish, or other food sources; and

(C) recent travel history.

All members of travel groups in which a case has occurred shall be interviewed for probable source of infection and additional cases. When outbreaks are associated with restaurants or other food service operations, all food handlers shall be screened for Salmonella typhi. Household members and close contacts of the case shall be excluded from food handling, child care, and health care employment until they have two (2) negative stool and urine cultures taken twenty-four (24) hours apart.

(2) Contact precautions for diapered or incontinent patients less than six (6) years of age for the duration of the illness, and standard precautions for other hospitalized patients. For others, the following guidelines shall apply:

(A) Infected persons, whether clinically ill or not, shall be excluded from employment involving food handling, or direct care of children or hospitalized or institutionalized patients. Infected children shall be excluded from day care centers and schools until three (3) consecutive fecal and urine specimens taken at intervals of not less than twenty-four (24) hours, and not earlier than one (1) month after onset, and not earlier than forty-eight (48) hours after the last administration of antibiotics are negative for Salmonella typhi. If any one (1) of this series is positive, an infected person whose employment involves food handling shall continue to be excluded until three (3) consecutive fecal and urine specimens are negative for Salmonella typhi taken at intervals of not less than twenty-four (24) hours, and not earlier than forty-eight (48) hours after last administration of antibiotics.

(B) Persons whose employment does not involve food handling, but whose employment required their exclusion from work under this section, and who are still infected after the initial follow-up testing, may be returned to work provided that all of the following have been met:

(i) They have been fully compliant with all instructions and screening requirements under this section.

(ii) The local health officer or his or her designee discusses with the asymptomatic worker his or her symptoms and determines that he or she is indeed asymptomatic, and that the worker is further counseled about measures, such as hand washing, that shall be followed to prevent transmission of disease.

(iii) The local health officer or his or her designee contacts the employer to reemphasize the need to comply with local and state rules requiring proper hand washing facilities for all employees, and to correct any observed lapses in hygienic measures of any employees.

(iv) Household and other intimate contacts of the patient shall be excluded from employment involving food handling, or direct care of children or hospitalized or institutionalized patients until two (2) fecal and urine cultures, taken at least twenty-four (24) hours apart, are determined to be negative for Salmonella typhi.

(3) Concurrent disinfection is required. Fecal material, urine, and articles soiled with either require disinfection. Fecal matter and urine may be disposed of directly in a sanitary sewer system. Terminal cleaning is required.

(4) Immunization is available for those who may be exposed to carriers. Immunization is of little value to family, household, or other contacts exposed to active cases.

(Indiana State Department of Health; 410 IAC 1-2.3-108; filed Sep 11, 2000, 1:36 p.m.: 24 IR 366)

410 IAC 1-2.3-109 Typhus, endemic (flea borne)

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 109. The specific control measures for endemic typhus are as follows:

(1) An environmental investigation for the presence of rodents or squirrels, or both, around the premises or the home of the patient shall be done. Provide guidance on the use of insecticides to kill rodent fleas as well as rodent exclusion from the premises or home.

(2) Standard precautions are required for hospitalized individuals.

(Indiana State Department of Health; 410 IAC 1-2.3-109; filed Sep 11, 2000, 1:36 p.m.: 24 IR 367)

410 IAC 1-2.3-110 Varicella (chicken pox) resulting in hospitalization or death; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 110. The specific control measures for chicken pox are as follows:

(1) An investigation of primary varicella disease resulting in hospitalization or death shall be performed by a department-trained immunization field representative to ascertain immunization history, history of underlying chronic or immunosupressive disease, and resultant complications.

(2) For hospitalized patients, institute airborne and contact precautions.

(3) Concurrent disinfection of articles soiled by nose or throat discharges.

(4) Susceptible children with known recent exposure to chicken pox who must remain in a hospital setting for medical reasons may be quarantined for a period from ten (10) to twenty-one (21) days after exposure (up to twenty-eight (28) days if Varicella-Zoster Immune Globulin (VZIG) had been given). Infected persons shall be excluded from schools and day care centers, public gatherings, and contact with susceptible persons outside the household until vesicles become dry.

(5) VZIG may be given within ninety-six (96) hours of exposure to prevent or modify disease in certain close contacts of cases. VZIG is available from regional offices of the American Red Cross, or through a central ordering number (800) 272-7972 for certain high-risk individuals significantly exposed to chicken pox. VZIG should be utilized in newborns of mothers who develop chicken pox within five (5) days before or within forty-eight (48) hours after delivery. Other susceptible high-risk individuals who should be considered for VZIG include the following:

(A) Immunocompromised susceptible children and adults.

(B) Hospitalized premature infants (twenty-eight (28) weeks gestation or more) whose mothers lack a prior history of chicken pox.

(C) Premature infants of less than twenty-eight (28) weeks gestation, or weighing one thousand (1,000) grams or less (regardless of maternal history).

(D) Susceptible pregnant women.

(Indiana State Department of Health; 410 IAC 1-2.3-110; filed Sep 11, 2000, 1:36 p.m.: 24 IR 367)

410 IAC 1-2.3-111 Yellow fever; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; IC 16-41-9

Sec. 111. The specific control measures for yellow fever are as follows:

(1) An investigation shall be performed by a department-trained immunization field representative in cooperation with the local health officer. The investigation shall include laboratory confirmation, immunization status, and history of foreign travel in three (3) to six (6) days prior to onset. Identify traveling companions who may also have been exposed.

(2) Standard precautions are required for hospitalized individuals.

(Indiana State Department of Health; 410 IAC 1-2.3-111; filed Sep 11, 2000, 1:36 p.m.: 24 IR 368)

410 IAC 1-2.3-112 Yersiniosis; specific control measures

Authority: IC 16-41-2-1
Affected: IC 16-41-2; 16-41-9

Sec. 112. The specific control measure for Yersiniosis (infectious agents: Yersinia enterocolitica or Yersiniosis pseudotuberculosis) are as follows:

(1) An investigation by the local health officer shall be conducted within seventy-two (72) hours to determine if the affected individual is a food handler, day care attendant, or health care worker. The investigation shall include food consumption history, exposure to contaminated water, and exposure to animals three (3) to seven (7) days prior to onset. Interview meal companions for additional cases and if a commercial food product or restaurant is suspected, conduct active surveillance for additional cases.

(2) Contact precautions are required for diapered or incontinent children less than six (6) years of age. Standard precautions are required for other hospitalized patients.

(3) Symptomatic persons shall be excluded from the following:

(A) Employment involving food handling.

(B) Direct care of children.

(C) Hospitalized or institutionalized patients.

(4) Asymptomatic excluded workers may return to work provided there is no indication of poor personal hygiene and the worker understands the importance of good hand washing procedures.

(Indiana State Department of Health; 410 IAC 1-2.3-112; filed Sep 11, 2000, 1:36 p.m.: 24 IR 368)

410 IAC 1-2.3-113 Incorporation by reference

Authority: IC 16-41-2-1
Affected: IC 16-41-2

Sec. 113. (a) The following documents are hereby incorporated by reference:

(1) Centers for Disease Control and Prevention publication: Case Definitions for Infectious Conditions Under Public Health Surveillance, MMWR, Recommendations and Reports, Volume 46, No. RR-10, May 2, 1997.

(2) Centers for Disease Control and Prevention publication: 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults, MMWR, Recommendations and Reports, Volume 41, No. RR-17, December 18, 1992.

(3) Guideline for Isolation Precautions in Hospitals, Infection Control and Hospital Epidemiology, Volume 17, No. 1, January 1996. Copies may be obtained from Infection Control and Epidemiology, 6500 Grove Road, Thorofare, NJ 08086.

(4) Centers for Disease Control and Prevention: 1994 Revised Classification System for Human Immunodeficiency Virus Infection in Children Less Than 13 Years of Age MMWR, Volume 43, No. RR-12, September 30, 1994.

(5) Control of Communicable Diseases Manual, 17th Edition, 2000, a publication of the American Public Health Association, Washington, D.C. Copies may be obtained from American Public Health Association, 800 I Street NW, Washington, D.C. 20001-3170.

(6) Centers for Disease Control and Prevention publication: Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials, November 1997.

(7) Centers for Disease Control and Prevention: CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome, Volume 48, No. RR-13, December 10, 1999.

(8) Centers for Disease Control and Prevention: MMWR 1998 Guidelines for Treatment of Sexually Transmitted Diseases, January 23, 1998, Volume 47/RR1.

(9) Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, as published by Centers for Disease Control and Prevention in Morbidity and Mortality Weekly Report, October 28, 1994, Volume 43, No. RR-13.

(10) Treatment of Tuberculosis and Tuberculosis In Adults and Children, published in the American Journal of Respiratory and Critical Care Medicine, Volume 149, pages 1359 through 1374 (1994). Copies may be obtained from the American Thoracic Society, 1740 Broadway, New York, New York 10019-4374.

(b) All incorporated material is available for public review at the department.

(c) Copies of MMWR publications may be obtained from Centers for Disease Control and Prevention, MMWR Series, Mail Stop C-08, 1600 Clifton Road, N.E., Atlanta, Georgia 30333. *(Indiana State Department of Health; 410 IAC 1-2.3-113; filed Sep 11, 2000, 1:36 p.m.: 24 IR 368)*

Rule 3. Infectious Waste

410 IAC 1-3-1 "Bedding" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 1. "Bedding" means bedding that has been used for laboratory animals. *(Indiana State Department of Health; 410 IAC 1-3-1; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 436; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-2 "Carcasses, body parts, blood and body fluids, and bedding of laboratory animals" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 2. "Carcasses, body parts, blood and body fluids, and bedding of laboratory animals" means carcasses, body parts, blood and body fluids in liquid or semiliquid form, and bedding of animals that have been intentionally or are suspected of having been exposed to pathogens in:

(1) research;
(2) production of biologicals;
(3) the in vivo testing of pharmaceuticals; or
(4) other procedures.

(Indiana State Department of Health; 410 IAC 1-3-2; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 436; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-3 "Container" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 3. "Container" means any portable device or material in which infectious waste is:

(1) stored;
(2) transported;
(3) treated;
(4) disposed of; or
(5) otherwise handled.

(Indiana State Department of Health; 410 IAC 1-3-3; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 436; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-4 "Contaminated sharp" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 4. "Contaminated sharp" means an object that is capable of cutting or penetrating the skin and has been in contact with blood or body fluids. The term includes any of the following:

(1) Hypodermic or suture needle.
(2) Syringe.
(3) Scalpel blade.
(4) Pipette.
(5) Lancet.
(6) Broken glass.

(Indiana State Department of Health; 410 IAC 1-3-4; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-5 "Communicable disease" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-2-1

Sec. 5. "Communicable disease" means a communicable disease as defined by rule under IC 16-41-2-1. *(Indiana State Department of Health; 410 IAC 1-3-5; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-5.5 "Department" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 5.5. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 1-3-5.5; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-6 "Emergency medical services provider" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-31-3

Sec. 6. "Emergency medical services provider" means a person certified under IC 16-31-3. *(Indiana State Department of Health; 410 IAC 1-3-6; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-7 "Facility" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-21-2; IC 16-28-1; IC 16-41-12; IC 16-41-16

Sec. 7. "Facility" means any of the following places where infectious waste activity occurs:
(1) Hospital.
(2) Ambulatory surgical center as defined in IC 16-21-2.
(3) Medical/diagnostic laboratory.
(4) Blood center as defined in IC 16-41-12.
(5) Pharmaceutical company.
(6) Academic research laboratory company.
(7) Industrial research laboratory.
(8) Health facility as defined in IC 16-28-1.
(9) Office and mobile units of a health care provider.
(10) Diet or health care clinic.
(11) Office of a veterinarian.
(12) Veterinary hospital.
(13) Emergency medical services provider.
(14) Mortuary.

(Indiana State Department of Health; 410 IAC 1-3-7; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-8 "Health care provider" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-18-2-163; IC 16-41-16

Sec. 8. "Health care provider" means a person employed as, or by, or receiving training from, a provider as defined in IC 16-18-2-163, or by a laboratory, blood center, state institution, or any other facility where the person is likely to have direct contact

with blood or body fluids. *(Indiana State Department of Health; 410 IAC 1-3-8; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-9 "Infectious waste activity" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 9. "Infectious waste activity" means the:
(1) generation;
(2) collection;
(3) storage;
(4) transportation;
(5) treatment; or
(6) disposal of infectious waste;
as defined in this rule. *(Indiana State Department of Health; 410 IAC 1-3-9; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-10 "Infectious waste" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 10. (a) "Infectious waste", except as provided in subsection (b), means waste that epidemiologic evidence indicates is capable of transmitting a dangerous communicable disease. The term includes, but is not limited to, the following:
(1) Contaminated sharps or contaminated objects that could potentially become contaminated sharps.
(2) Infectious biological cultures, infectious associated biologicals, and infectious agent stock.
(3) Pathological waste.
(4) Blood and blood products in liquid and semiliquid form.
(5) Carcasses, body parts, blood and body fluids in liquid and semiliquid form, and bedding of laboratory animals.
(6) Other waste that has been intermingled with infectious waste.
(b) The term, as it applies to a home health agency or to services delivered in the home of a hospice patient, includes only contaminated sharps. *(Indiana State Department of Health; 410 IAC 1-3-10; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-11 "Mortuary" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16; IC 25-15-2-15

Sec. 11. "Mortuary" means a funeral home as defined in IC 25-15-2-15. *(Indiana State Department of Health; 410 IAC 1-3-11; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-12 "Pathological waste" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 12. "Pathological waste" means:
(1) tissues;
(2) organs;
(3) body parts; and
(4) blood or body fluids in liquid or semiliquid form of humans;
that are removed during surgery, biopsy, or autopsy. *(Indiana State Department of Health; 410 IAC 1-3-12; filed Jan 17, 1989, 3:30*

p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-13 "Person" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 13. "Person" means any:
(1) individual;
(2) facility;
(3) partnership;
(4) copartnership;
(5) firm;
(6) company;
(7) association;
(8) joint-stock company;
(9) corporation;
(10) governmental entity; or
(11) agent.

(Indiana State Department of Health; 410 IAC 1-3-13; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-14 "Secured area" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 14. "Secured area" means an area that is designed and maintained to prevent the entry of unauthorized persons. *(Indiana State Department of Health; 410 IAC 1-3-14; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-15 "Semiliquid blood and blood products" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 15. "Semiliquid blood and blood products" means blood and blood products that have intermediate fluid properties and are capable of flowing in a manner similar to a liquid. *(Indiana State Department of Health; 410 IAC 1-3-15; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-16 "State board" defined (Repealed)

Sec. 16. *(Repealed by Indiana State Department of Health; filed Sep 18, 1998, 11:38 a.m.: 22 IR 440)*

410 IAC 1-3-17 "Storage" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 17. "Storage" means the containment of infectious waste in such a manner as not to constitute:
(1) collection;
(2) treatment;
(3) transport; or
(4) disposal.

(Indiana State Department of Health; 410 IAC 1-3-17; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.:

22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-18 "Veterinarian" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 15-5-1.1; IC 16-41-16

Sec. 18. "Veterinarian" means a person authorized to practice veterinary medicine under IC 15-5-1.1. *(Indiana State Department of Health; 410 IAC 1-3-18; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-19 "Waste" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 19. "Waste" means any solid, liquid, or semiliquid material that:

(1) is discarded or being accumulated prior to being discarded; or

(2) has served its natural, biological, medical, or intended purpose and is generally discarded and not reused.

(Indiana State Department of Health; 410 IAC 1-3-19; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-20 "Waste handlers" defined

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 20. "Waste handlers" means any person who handles infectious waste. *(Indiana State Department of Health; 410 IAC 1-3-20; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-21 Applicability of standards

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-11

Sec. 21. (a) This rule applies, without regard to quantity, to defined facilities and persons involved in infectious waste activity.

(b) This rule represents minimum standards, and persons may utilize more stringent standards.

(c) All written policies required under this rule shall, at a minimum, comply with the requirements of IC 16-41-11. *(Indiana State Department of Health; 410 IAC 1-3-21; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-22 Appropriate containment and labeling; effective treatment, transport, or disposal

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 22. For purposes of IC 16-41-16 and this rule, the generator of infectious waste is responsible for the appropriate containment, appropriate labeling, effective treatment, transport, and disposal of infectious waste as required by this rule. A person may provide services to the generator of infectious waste, including the appropriate containment, appropriate labeling, effective treatment, transport, or disposal of infectious waste. Both the generator of infectious waste and the person providing services to the generator of infectious waste are responsible for complying with the requirements set forth in this rule. *(Indiana State Department of Health; 410 IAC 1-3-22; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-23 Written policies, procedures

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16-9

Sec. 23. All persons and facilities subject to this rule shall:

(1) have a written policy and procedures that, at a minimum, contain:

(A) the requirements contained in this rule; and

(B) the sanctions, including discipline and dismissal of persons, if warranted, for failure to follow the requirements set forth in this rule;

(2) provide necessary instruction and materials, including protective garments, to implement this rule prior to giving a person an assignment where contact with infectious waste is likely;

(3) maintain a record of such instruction, including an attendance record of a person's participation in the instruction; and

(4) make all records available to the department for inspection under IC 16-41-16-9.

(Indiana State Department of Health; 410 IAC 1-3-23; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-24 Containment

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 24. (a) All persons and facilities subject to this rule shall ensure that infectious waste is at all times contained in a manner that will reasonably protect waste handlers and the public from contracting dangerous communicable disease that may result from exposure to the infectious waste.

(b) All persons and facilities subject to this rule shall place contaminated sharps or contaminated objects that could potentially become contaminated sharps, infectious biological cultures, infectious associated biologicals, and infectious agent stock in containers that are:

(1) leak proof, rigid, puncture-resistant;

(2) tightly sealed to prevent expulsion;

(3) labeled with the biohazard symbol; and

(4) effectively treated in accordance with this rule prior to being stored in an unsecured area and sent for final disposal.

(c) All persons and facilities subject to this rule shall place pathological waste; laboratory animal carcasses, laboratory animal body parts, laboratory animal blood and body fluids, and laboratory animal bedding; human blood; human blood products in liquid or semiliquid form; and human body fluids that are visibly contaminated with blood in containers that are:

(1) impervious to moisture;

(2) sufficient strength and thickness to prevent expulsion;

(3) secured to prevent leakage or expulsion;

(4) labeled with the biohazard symbol; and

(5) effectively treated in accordance with this rule prior to being placed in an unsecured area and sent for final disposal.

(Indiana State Department of Health; 410 IAC 1-3-24; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1385; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-25 Storage

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 25. If infectious waste is stored prior to final disposal, all persons subject to this rule shall:

(1) store infectious waste in a secure area that:

(A) is locked or otherwise secured to eliminate access by or exposure to the general public;

(B) affords protection from adverse environmental conditions and vermin; and

(C) has a prominently displayed biohazard symbol;

(2) store infectious waste in a manner that preserves the integrity of the container, and is not conducive to rapid microbial growth and putrefaction; and

(3) disinfect reusable containers for infectious waste each time that they are emptied, unless the surfaces of the reusable containers have been protected from contamination by disposable liners, bags, or other devices that are removed with the infectious waste.

(Indiana State Department of Health; 410 IAC 1-3-25; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1385; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-26 Treatment

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 26. (a) All persons and facilities subject to this rule shall either effectively treat infectious waste in accordance with this rule or transport infectious waste off-site for effective treatment in accordance with this rule.

(b) A treatment is effective if it reduces the pathogenic qualities of infectious waste for safe handling, is designed for the specific infectious waste involved, and is carried out in a manner consistent with this rule. Effective treatment may include:

(1) incineration;
(2) steam sterilization;
(3) chemical disinfection;
(4) thermal inactivation;
(5) irradiation; or
(6) discharge in a sanitary sewer or septic system that is properly installed and operating in accordance with state and local laws.

(c) Except as provided in section 28 of this rule, all persons and facilities subject to this rule may store, transport, and dispose of infectious waste that has been effectively treated in accordance with this rule in the usual manner for waste that is noninfectious.

(Indiana State Department of Health; 410 IAC 1-3-26; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1385; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-27 Protection in transport

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 27. All persons and facilities subject to this rule shall:

(1) transport infectious waste in a manner that reasonably protects waste handlers and the public from contracting dangerous communicable disease; and
(2) effectively treat infectious waste in accordance with this rule before it is compacted.

(Indiana State Department of Health; 410 IAC 1-3-27; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1385; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-28 Transporting off-site

Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16

Sec. 28. (a) All persons and facilities subject to this rule who are transporting infectious waste off-site, whether effectively treated or not, shall:

(1) mark containers of infectious waste with a label that states the name, address, and telephone number of the generating facility and treatment facility, if applicable; and
(2) provide a form that contains:
    (A) the name, address, and telephone number of the generating facility and treatment facility, if applicable;
    (B) a brief description of the waste and the method of effective treatment; and
    (C) the signature of a responsible person.

(b) The information required in subsection (a) may be enclosed between the secondary packaging and the outer packaging, when such packaging is used. The outer packaging must contain a biohazard symbol. *(Indiana State Department of Health; 410 IAC*

1-3-28; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1386; filed Sep 18, 1998, 11:38 a.m.: 22 IR 440; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-29 Penalties for violation
Authority: IC 16-19-3-4; IC 16-41-16-8
Affected: IC 16-41-16-10

Sec. 29. Penalties for violation of this rule are set forth in IC 16-41-16-10. *(Indiana State Department of Health; 410 IAC 1-3-29; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1386; filed Sep 18, 1998, 11:38 a.m.: 22 IR 440; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 4. Universal Precautions

410 IAC 1-4-0.5 Applicability of definitions
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 0.5. The definitions in this rule apply throughout this rule. Additionally, the definitions of any other terms contained in the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) are incorporated by reference. *(Indiana State Department of Health; 410 IAC 1-4-0.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-1 "Blood" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 1. "Blood" means human blood, human blood components, and products made from human blood. *(Indiana State Department of Health; 410 IAC 1-4-1; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-1.1 "Bloodborne pathogens" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 1.1. "Bloodborne pathogens" means pathogenic micro-organisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, HBV and HIV. *(Indiana State Department of Health; 410 IAC 1-4-1.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 753; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-1.2 "Contaminated" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 1.2. "Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface. *(Indiana State Department of Health; 410 IAC 1-4-1.2; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-1.3 "Contaminated laundry" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 1.3. "Contaminated laundry" means laundry which has been soiled with blood or other potentially infectious materials

or laundry which may contain sharps. *(Indiana State Department of Health; 410 IAC 1-4-1.3; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-1.4 "Covered individual" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11-4

Sec. 1.4. "Covered individual" means any individual covered by IC 16-41-11-4 whose professional, employment, training, or volunteer activities or duties include any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials. *(Indiana State Department of Health; 410 IAC 1-4-1.4; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-1.5 "Decontamination" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 1.5. "Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item which does not require sterilization to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. *(Indiana State Department of Health; 410 IAC 1-4-1.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-2 "Department" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 2. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 1-4-2; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-2.1 "Employee" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11; IC 22-8-1.1-1

Sec. 2.1. "Employee" has the meaning set forth in IC 22-8-1.1-1. *(Indiana State Department of Health; 410 IAC 1-4-2.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-3 "Employer" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11; IC 22-8-1.1-1

Sec. 3. "Employer" has the meaning set forth in IC 22-8-1.1-1. *(Indiana State Department of Health; 410 IAC 1-4-3; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-3.1 "ERP" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 3.1. "ERP" means expert review panel, as defined in section 8.1 of this rule. *(Indiana State Department of Health; 410 IAC 1-4-3.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4 "Facility" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4. "Facility" means a building or location where an individual can be reasonably anticipated in the course of performing his or her professional, employment, training, or volunteer activities or duties to have skin, eye, mucous membrane, or parenteral contact with potentially infectious materials. *(Indiana State Department of Health; 410 IAC 1-4-4; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 754; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.1 "HBeAg" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.1. "HBeAg" means the presence of hepatitis B e antigen in human blood as an indicator of high infectivity for hepatitis B virus. *(Indiana State Department of Health; 410 IAC 1-4-4.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.2 "HBsAg" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.2. "HBsAg" means the presence of hepatitis B surface antigens in human blood as an indicator of infectivity for hepatitis B virus. *(Indiana State Department of Health; 410 IAC 1-4-4.2; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.3 "HBV" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.3. "HBV" means hepatitis B virus. *(Indiana State Department of Health; 410 IAC 1-4-4.3; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.4 "Health care worker" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.4. "Health care worker" means any covered individual providing health care for or to a patient during the patient's care or treatment and whose professional, employment, volunteer, or student training duties or activities can be reasonably anticipated to result in skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials. *(Indiana State Department of Health; 410 IAC 1-4-4.4; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.5 "HIV" defined
Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.5. "HIV" means human immunodeficiency virus. *(Indiana State Department of Health; 410 IAC 1-4-4.5; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.6 "Other potentially infectious materials" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.6. "Other potentially infectious materials" means the following:

(1) Human body fluids as follows:

(A) Semen.
(B) Vaginal secretions.
(C) Cerebrospinal fluid.
(D) Synovial fluid.
(E) Pleural fluid.
(F) Pericardial fluid.
(G) Peritoneal fluid.
(H) Amniotic fluid.
(I) Saliva in dental procedures.
(J) Any body fluid that is visibly contaminated with blood.
(K) All body fluids where it is difficult or impossible to differentiate between body fluids.

(2) Any unfixed tissue or organ, other than intact skin, from a human, living or dead.

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

(Indiana State Department of Health; 410 IAC 1-4-4.6; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-4-4.7 "Parenteral" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.7. "Parenteral" means piercing the mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, or abrasions. *(Indiana State Department of Health; 410 IAC 1-4-4.7; filed Nov 22, 1993, 5:00 p.m.: 17 IR 755; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-4.8 "Sterilize" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 4.8. "Sterilize" means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. *(Indiana State Department of Health; 410 IAC 1-4-4.8; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-5 "Universal precautions" defined

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 5. "Universal precautions" means an approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. *(Indiana State Department of Health; 410 IAC 1-4-5; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-6 Facility operator responsibilities

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 6. (a) An individual or entity that is a facility operator shall comply with the following:

(1) Inform all health care workers and covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility, that it is strongly recommended by the department that all persons who have reason to believe they are at risk of HIV infection should know their HIV status.

(2) Inform all health care workers that it is strongly recommended by the department that all those:

(A) who perform procedures during which there is a recognized risk of percutaneous injury to the health care worker, and, if such injury occurs, the health care worker's blood may contact the patient's body cavity, subcutaneous tissue, or mucous membranes; and

(B) who do not have serologic evidence of immunity to HBV from vaccination or from previous infection should know their HBsAg status and, if that is positive, should also know their HBeAg status.

(3) Ensure that the training described in the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) is provided to all covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility.

(4) Ensure that a record is maintained, as required under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) of an individual's participation in the training that is provided. The record shall be made available to the department for inspection upon request.

(5) Ensure that each covered individual whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility, is provided appropriate equipment and expendables needed to implement the precautions required under section 8 of this rule and under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).

(6) Require all health care workers whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of the facility to provide evidence of compliance with the continuing universal precautions education requirements contained in section 7.1 of this rule.

(b) The operator of a facility, if providing services to patients or the public in which there is a risk of skin, eye, mucous membrane, or parenteral contact to human blood or other potentially infectious materials, shall display, or make available to the public, a description of compliance with the requirements contained in subsection (a)(6).

(c) The operator of a facility, if providing services to patients or the public in which there is a risk of skin, eye, mucous membrane, or parenteral contact to human blood or other potentially infectious materials, shall display, or make available to the public, written materials prepared or approved by the department explaining universal precautions and patients' rights under this rule. These materials shall include information on how to report violations of universal precautions and shall include information regarding the department's duties to investigate. *(Indiana State Department of Health; 410 IAC 1-4-6; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 756; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-7 Facility operator policies

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 7. A facility operator shall develop a written policy in compliance with this rule and the requirements of the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030), that:

(1) requires the use of universal precautions by a covered individual when performing those professional, employment, training, or volunteer activities or duties that include any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials;

(2) provides sanctions, including discipline and dismissal, if warranted, for failure to use universal precautions; and

(3) proscribes the facility operator, or any covered individual acting at or on behalf of the facility, from retaliating against any person, including any professional, employee, trainee, volunteer, or patient, for filing a complaint with the department in good faith under this rule.

(Indiana State Department of Health; 410 IAC 1-4-7; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-4-7.1 Covered individuals' minimum training and certification requirements

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 7.1. All covered individuals shall comply with the following:

(1) Covered individuals, including health care workers, whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of a facility, must complete the training programs which the facility is required to have employees attend under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030). Approved programs under this rule shall be as follows:

(A) A bloodborne pathogen training session provided by a facility or employer under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).

(B) Unless the department makes a specific determination to the contrary, any continuing professional education program on current universal precautions techniques that has been accepted or accredited by the applicable professional credentialing or health licensing entity.

(2) Covered individuals who are health care workers shall, either individually or through their employer, upon receipt of a written request by the department, employer, or a patient to whom direct services have been provided, provide evidence of compliance with the requirements of this section.

(Indiana State Department of Health; 410 IAC 1-4-7.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-4-8 Precautions generally

Authority: IC 16-41-11-9
Affected: IC 16-19; IC 16-41-11

Sec. 8. (a) All covered individuals and health care workers under this rule shall comply with the requirements imposed under the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030).

(b) The operator and all covered individuals whose professional, employment, training, or volunteer activities or duties are performed at or on behalf of a facility providing services to patients or other members of the public in which there is a reasonably anticipated risk of skin, eye, mucous membrane, or parenteral contact with human blood or other potentially infectious materials shall also comply with the following requirements:

(1) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(2) Heating procedures capable of sterilization must be used when heat stable, nondisposable equipment is sterilized. Heat labile, reusable equipment requiring sterilization must be sterilized by chemical means. Records must be maintained to document the following:

(A) Duration of sterilization technique.

(B) Mechanisms for determination of effective sterility.

(C) Routine monthly equipment maintenance inspections.

These documents must be made available to the department upon request.

(3) Environmental surfaces and equipment not requiring sterilization which have been contaminated by blood or other potentially infectious materials shall be cleaned then decontaminated. Disinfectant solutions shall:

(A) be a hospital grade, tuberculocidal Environmental Protection Agency (EPA) registered disinfectant; or

(B) be sodium hypochlorite, five-tenths percent (0.5%) concentration, by volume (common household bleach in ten percent (10%) concentration in water); the solution shall be dated and shall not be used if it is more than twenty-four (24) hours old.

(4) If a patient's diagnosis, laboratory analysis, or medical condition requires additional infection control measures or isolation, those specific measures apply in addition to the requirements of this rule and other requirements found at IC 16-19.

(Indiana State Department of Health; 410 IAC 1-4-8; filed Oct 6, 1989, 4:20 p.m.: 13 IR 280; filed Nov 22, 1993, 5:00 p.m.: 17 IR 757; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-4-8.1 Expert review panel

Authority: IC 16-41-11-9
Affected: IC 16-41-11

Sec. 8.1. (a) An HIV infected or HBV infected (and HBeAg positive) health care worker whose practices include digital palpation of a needle tip in a body cavity or the simultaneous presence of the health care worker's finger and needle or other sharp instrument in a poorly visualized or highly confined human anatomic site should either seek the advice of an ERP approved by the department or voluntarily cease these practices.

(b) As used in this rule, "expert review panel" means a group of experts authorized under this rule to provide confidential consultation and advice to HIV and HBV (and HBeAg) infected health care workers as indicated to promote the highest achievable level of safe, professional care. To be deemed authorized, an ERP must be sponsored by an organization which has been approved by the department under subsection (c).

(c) Before any public or private medical, surgical, dental, nursing, or other health care organization may sponsor an authorized ERP under this section, the potential sponsor must be approved by the department as having provided credible assurances that:

(1) the sponsor is capable of establishing specific ERP protocols and procedures that will accomplish the purposes of an ERP under this section; and

(2) it will comply with general protocols to be established and disseminated on request by the department.

(d) The ERP will consist of:

(1) an expert review entity consisting of:

(A) the HIV or HBV infected health care worker's treating physician, either directly or through medical and historical treatment records;

(B) an infectious disease specialist knowledgeable in the epidemiology of HIV and HBV infection;

(C) a health care provider of the same profession as the infected health care provider with expertise in the procedures practiced; and

(D) an infection control expert or epidemiologist; or

(2) any other expert review entity expressly authorized by the department.

(e) An ERP sponsored by an organization approved by the department under subsection (c) will be deemed an authorized ERP.

(f) An ERP shall advise the health care worker whether and how to modify techniques or to cease performing certain procedures. In rendering this advice, the ERP shall consider the past history of the health care worker's technique, and the extent to which, in the context of other indicated procedures with a measurable and unavoidable significant risk to patients, an indicated invasive procedure in the hands of that health care worker does or does not expose patients to the significant risk of HIV or HBV transmission from the health care worker.

(g) The role of the ERP is strictly confidential and advisory to the health care worker.

(h) All proceedings and communications of the ERP shall be confidential. All communications to an ERP shall be privileged communications. Neither the personnel nor any participant in a panel proceeding shall reveal the identity of any health care worker consulting such panel nor any content of communication to the records of or the outcomes of an ERP outside the panel to any person or other entity, other than the health care worker consulting such panel.

(i) No person who participates in an ERP proceeding shall be permitted or required to disclose any information acquired in connection with, or in the course of, the proceeding, any opinion, recommendation, or evaluation of the panel or of any panel member.

(j) The only duty of an ERP is to provide good faith consultation and advice to the HIV or HBV infected health care worker seeking such advice. A health care worker is not, by this rule, relieved of any responsibility, either to himself or herself or to others, for all actions taken or not taken in his or her professional capacity after consulting with an ERP. Neither an ERP nor any member of an ERP is approved by this rule to substitute or assume responsibility for the subsequent actions of the health care worker. No civil or other legal action of any nature shall arise against any member or personnel of an ERP for any good faith act or statement made in the confines of the panel or proceeding thereof.

(k) Neither an ERP nor any member of an ERP shall, by virtue of their consultation and advice, assume any liability of any kind to the health care worker, his or her patients, or any other person. The personnel and members of an ERP shall be immune from any civil action arising from any determination or recommendation made in good faith in the scope of their duties. *(Indiana State Department of Health; 410 IAC 1-4-8.1; filed Nov 22, 1993, 5:00 p.m.: 17 IR 759; errata, 17 IR 1009; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-4-9 Complaints

Authority: IC 16-41-11-9
Affected: IC 4-15-2-34; IC 4-15-2-35; IC 16-41-11; IC 25

Sec. 9. A person who believes that this rule has been violated may file a complaint with the department. A complaint must be in writing unless, in the opinion of the department, the violation complained of constitutes an emergency. The department shall reduce an emergency oral complaint to writing. The department shall maintain the confidentiality of the person who files the complaint. The department shall also comply with the following:

(1) The department shall promptly investigate, or cause to be investigated with available resources, all complaints received alleging violations of this rule.

(2) The department shall not disclose the name or identifying characteristics of the person who files a complaint under this rule:

(A) unless the person consents in writing to the disclosure; or

(B) the investigation results in an administrative or judicial proceeding and disclosure is ordered by the administrative law judge or the court.

Confidential communication of the complaint information to the Indiana department of labor for compliance purposes shall not constitute disclosure for the purposes of this rule.

(3) The department shall give a person who files a complaint under this section the opportunity to withdraw the complaint at any time prior to the issuance of an order under subdivision (2)(B).

(4) A person filing a complaint must make a reasonable attempt to ascertain the correctness of any information to be furnished. Failure to make a reasonable attempt may subject that person to other sanctions available at law.

(5) A determination of a substantiated and unresolved violation of this rule by a health care provider licensed under IC 25 shall be referred by the department to the appropriate licensing board through notification of the attorney general's consumer protection division.

(6) In the investigation of a complaint regarding a violation of this rule, the department shall coordinate the investigation, as appropriate, with the state or federal enforcement agency having jurisdiction over the industry or occupation. All complaints alleging violations of the Indiana occupational safety and health administration's bloodborne pathogens standards (as found in 29 CFR 1910.1030) shall be forwarded to the Indiana department of labor.

(Indiana State Department of Health; 410 IAC 1-4-9; filed Oct 6, 1989, 4:20 p.m.: 13 IR 282; filed Nov 22, 1993, 5:00 p.m.: 17 IR 760; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 5. Sanitary Operation of Tattoo Parlors

410 IAC 1-5-1 Applicability

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 1-5-1; filed May 12, 1998, 10:00 a.m.: 21 IR 3815)*

410 IAC 1-5-2 "Blood" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 2. "Blood" means human blood. *(Indiana State Department of Health; 410 IAC 1-5-2; filed May 12, 1998, 10:00 a.m.: 21 IR 3815)*

410 IAC 1-5-3 "Bloodborne pathogens" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 3. "Bloodborne pathogens" means pathogenic micro-organisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, the following:

(1) HBV.

(2) HCV.

(3) HIV.

(Indiana State Department of Health; 410 IAC 1-5-3; filed May 12, 1998, 10:00 a.m.: 21 IR 3815)

410 IAC 1-5-3.5 "Body piercer" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 3.5. "Body piercer" means any person who performs body piercing on an individual. *(Indiana State Department of Health; 410 IAC 1-5-3.5; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710)*

410 IAC 1-5-3.6 "Body piercing" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 3.6. "Body piercing" means the perforation of any human body part other than ear lobe for the purpose of inserting jewelry or other decoration or for some other nonmedical purpose. *(Indiana State Department of Health; 410 IAC 1-5-3.6; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710)*

410 IAC 1-5-4 "Cleaned" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 4. "Cleaned" means removal of all visible dust, soil, or any other foreign material. *(Indiana State Department of Health: 410 IAC 1-5-4; filed May 12, 1998, 10:00 a.m.: 21 IR 3815)*

410 IAC 1-5-5 "Contaminated" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 5. "Contaminated" means the presence or reasonably anticipated presence of blood or OPIM on an item or surface. *(Indiana State Department of Health; 410 IAC 1-5-5; filed May 12, 1998, 10:00 a.m.: 21 IR 3815)*

410 IAC 1-5-6 "Decontaminated" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 6. "Decontaminated" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item which does not require sterilization to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. *(Indiana State Department of Health; 410 IAC 1-5-6; filed May 12, 1998, 10:00 a.m.: 21 IR 3815)*

410 IAC 1-5-7 "Department" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 7. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 1-5-7; filed May 12, 1998, 10:00 a.m.: 21 IR 3815)*

410 IAC 1-5-7.5 "Facility" defined
Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 7.5. "Facility" means a tattoo parlor or a body piercing facility, or both, which is any room or space where tattooing or body piercing, or both, is provided or where the business of tattooing or body piercing, or both, is conducted. *(Indiana State Department of Health; 410 IAC 1-5-7.5; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710)*

410 IAC 1-5-8 "HBV" defined
Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 8. "HBV" means the hepatitis B virus. *(Indiana State Department of Health; 410 IAC 1-5-8; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)*

410 IAC 1-5-9 "HCV" defined
Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 9. "HCV" means the hepatitis C virus. *(Indiana State Department of Health; 410 IAC 1-5-9; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)*

410 IAC 1-5-9.5 "High level disinfection" defined
Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 9.5. "High level disinfection" means a process that destroys all micro-organisms, with the exception of high numbers of bacterial spores. *(Indiana State Department of Health; 410 IAC 1-5-9.5; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710)*

410 IAC 1-5-10 "HIV" defined
Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 10. "HIV" means the human immunodeficiency virus. *(Indiana State Department of Health; 410 IAC 1-5-10; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)*

410 IAC 1-5-11 "Infectious waste" defined
Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 11. "Infectious waste" means waste that epidemiologic evidence indicates is capable of transmitting a dangerous communicable disease. Infectious waste includes, but is not limited to, the following:

(1) Contaminated sharps or contaminated objects that could potentially become contaminated sharps.
(2) Infectious biological cultures, infectious associated biologicals, and infectious agent stock.
(3) Pathological waste.
(4) Blood and blood products in liquid and semiliquid form.
(5) Carcasses, body parts, blood and body fluids in liquid and semiliquid form, and bedding of laboratory animals.
(6) Other waste that has been intermingled with infectious waste.

(Indiana State Department of Health; 410 IAC 1-5-11; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)

410 IAC 1-5-11.2 "Intermediate level disinfection" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 11.2. "Intermediate level disinfection" means a process that inactivates:
(1) Mycobacterium tuberculosis;
(2) vegetative bacteria;
(3) most viruses; and
(4) most fungi;
but does not necessarily kill bacterial spores. *(Indiana State Department of Health; 410 IAC 1-5-11.2; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2710)*

410 IAC 1-5-11.5 "Operator" defined

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 11.5. "Operator" means any person who controls, operates, manages, or owns any facility. *(Indiana State Department of Health; 410 IAC 1-5-11.5; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2711)*

410 IAC 1-5-12 "Other potentially infectious materials" or "OPIM" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 12. "Other potentially infectious materials" or "OPIM" means the following:
(1) Human body fluids as follows:
(A) Semen.
(B) Vaginal secretions.
(C) Cerebrospinal fluid.
(D) Synovial fluid.
(E) Pleural fluid.
(F) Pericardial fluid.
(G) Peritoneal fluid.
(H) Amniotic fluid.
(I) Saliva in dental procedures.
(J) Any body fluid that is visibly contaminated with blood.
(K) All body fluids where it is difficult or impossible to differentiate between body fluids.
(2) Any unfixed tissue or organ, other than intact skin, from a human, living or dead.
(3) HIV-containing cell or tissue cultures, and HIV or HBV-containing culture medium or other solutions, and blood, organs, or other tissues from experimental animals infected with HIV or HBV.
(Indiana State Department of Health; 410 IAC 1-5-12; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)

410 IAC 1-5-13 "Parenteral" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 13. "Parenteral" means piercing the mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, or abrasions. *(Indiana State Department of Health; 410 IAC 1-5-13; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)*

410 IAC 1-5-14 "Personal protective equipment" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 14. "Personal protective equipment" means specialized clothing or equipment worn for protection against contact with blood or OPIM. *(Indiana State Department of Health; 410 IAC 1-5-14; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)*

410 IAC 1-5-15 "Secure area" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 15. "Secure area" means an area that is designated and maintained to prevent the entry of unauthorized persons. *(Indiana State Department of Health; 410 IAC 1-5-15; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)*

410 IAC 1-5-16 "Semiliquid blood, blood products" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 16. "Semiliquid blood, blood products" means blood, blood products that have intermediate fluid properties and are capable of flowing in a manner similar to liquid. *(Indiana State Department of Health; 410 IAC 1-5-16; filed May 12, 1998, 10:00 a.m.: 21 IR 3816)*

410 IAC 1-5-17 "Sterilize" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 17. "Sterilize" means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores. *(Indiana State Department of Health; 410 IAC 1-5-17; filed May 12, 1998, 10:00 a.m.: 21 IR 3817)*

410 IAC 1-5-18 "Store" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 18. "Store" means the containment of infectious waste in such a manner as not to constitute collection, treatment, transport, or disposal. *(Indiana State Department of Health; 410 IAC 1-5-18; filed May 12, 1998, 10:00 a.m.: 21 IR 3817)*

410 IAC 1-5-19 "Tattoo" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 19. "Tattoo" means:

(1) any indelible design, letter, scroll, figure, symbol, or other mark placed with the aid of needles or other instruments; or

(2) any design, letter, scroll, figure, or symbol done by scarring;

upon or under the skin. *(Indiana State Department of Health; 410 IAC 1-5-19; filed May 12, 1998, 10:00 a.m.: 21 IR 3817)*

410 IAC 1-5-20 "Tattoo artist" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 20. "Tattoo artist" means any person who provides a tattoo to an individual. *(Indiana State Department of Health; 410 IAC 1-5-20; filed May 12, 1998, 10:00 a.m.: 21 IR 3817)*

410 IAC 1-5-21 "Tattoo operator" defined (Repealed)

Sec. 21. *(Repealed by Indiana State Department of Health; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2714)*

410 IAC 1-5-22 "Tattoo parlor" defined (Repealed)

Sec. 22. *(Repealed by Indiana State Department of Health; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2714)*

410 IAC 1-5-23 "Universal precautions" defined

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 23. "Universal precautions" means an approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens. *(Indiana State Department of Health; 410 IAC 1-5-23; filed May 12, 1998, 10:00 a.m.: 21 IR 3817)*

410 IAC 1-5-24 Operator training responsibilities

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 24. An individual or entity that is an operator shall comply with the following training responsibilities:

(1) Ensure that the training described in the Indiana occupational safety and health administration's bloodborne pathogens standard (as found in 29 CFR 1910.1030) is provided to all tattoo artists and body piercers, anyone employed by the facility or anyone acting on behalf of the facility, who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood or OPIM.

(2) Ensure that training on the handling of infectious waste is provided to all tattoo artists and body piercers, or anyone employed by the facility or anyone acting on behalf of the facility who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood or OPIM.

(3) Ensure that a record of training described in subdivision (1) is maintained, as required under the Indiana occupational safety and health administration's bloodborne pathogens standard (as found in 29 CFR 1910.1030) of an individual's participation in the training that is provided. The record shall be made available to the department for inspection upon request.

(4) Ensure that a record of training described in subdivision (2) is maintained.

(Indiana State Department of Health; 410 IAC 1-5-24; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2711)

410 IAC 1-5-25 Operator responsibilities

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 25. (a) The operator shall ensure that tattoo artists, body piercers, or anyone employed by the facility or anyone acting on behalf of the facility who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood have and use personal protective equipment and expendables needed to implement the precautions required by this rule and the Indiana occupational safety and health administration's bloodborne pathogens standard (as found in 29 CFR 1910.1030).

(b) The operator shall require tattoo artists and body piercers, anyone employed by the facility, or anyone acting on behalf of the facility who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood to provide evidence of compliance with the universal precautions education requirements contained in section 27 of this rule.

(c) The operator shall display a description of compliance with the requirements contained in subsection (d).

(d) The operator shall display written materials prepared or approved by the department explaining universal precautions and patrons' rights under this rule. These materials shall include information on how to report violations of universal precautions and shall include information regarding the department's duties to investigate. *(Indiana State Department of Health; 410 IAC 1-5-25; filed May 12, 1998, 10:00 a.m.: 21 IR 3817; errata filed Aug 31, 1998, 1:08 p.m.: 22 IR 127; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2711)*

410 IAC 1-5-26 Operator policies

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 26. The operator shall develop a written policy in compliance with this rule and the requirements of the Indiana occupational safety and health administration's bloodborne pathogen standard (as found in 29 CFR 1910.1030) that:

(1) requires the use of universal precautions when performing tattooing or body piercing and any activity or duty that includes any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIM;

(2) requires disinfection or sterilization of contaminated reusable items;

(3) includes the safe handling of infectious waste; and

(4) provides sanctions, including discipline and dismissal, if warranted, for failure to use universal precautions or handle infectious waste safely, or both.

(Indiana State Department of Health; 410 IAC 1-5-26; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2711)

410 IAC 1-5-27 Tattoo artist and body piercer minimum training and certification requirements

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 27. (a) All tattoo artists, body piercers, anyone employed by the facility, and anyone acting on behalf of the facility, who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood or OPIM shall complete the training program that is required under the requirements of the Indiana occupational safety and health administration's bloodborne pathogen standard (as found in 29 CFR 1910.1030). The programs under this section shall be as follows:

(1) A bloodborne pathogen training session provided by the operator meeting the requirements under the Indiana occupational safety and health administration's bloodborne pathogens standard (as found in 29 CFR 1910.1030).

(2) Any bloodborne pathogen continuing education program provided by a health care agency.

(b) All tattoo artists, body piercers, anyone employed by the facility, and anyone acting on behalf of the facility, who has a reasonably anticipated risk for skin, eye, mucous membrane, or parenteral contact with blood or OPIM must be trained in the facility's policies on the handling of infectious waste. *(Indiana State Department of Health; 410 IAC 1-5-27; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712)*

410 IAC 1-5-28 Patron records

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 28. Records of each patron shall be maintained by the operator for two (2) years. The record shall include the following, but not be limited to:

(1) Patron's name.

(2) Address.

(3) Age.

(4) Date tattooed or body pierced.

(5) Design of the tattoo.

(6) Location of the tattoo or body piercing on the patron's body.

(7) The name of the tattoo artist or body piercer who performed the work.

(8) Jewelry or other decoration used.

(Indiana State Department of Health; 410 IAC 1-5-28; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712)

410 IAC 1-5-29 Illness

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 29. Tattoo artists or body piercers who are experiencing symptoms of acute disease that include, but are not limited to:
(1) diarrhea;
(2) vomiting;
(3) fever;
(4) rash;
(5) productive cough;
(6) jaundice; or
(7) draining (or open) skin infections, boils, impetigo, or scabies;
shall refrain from providing tattoos or body piercing. *(Indiana State Department of Health; 410 IAC 1-5-29; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712)*

410 IAC 1-5-30 Handwashing
Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 30. (a) Handwashing facilities shall be readily accessible where tattooing or body piercing, or both, is provided.
(b) Hands shall be washed with soap and running water immediately before putting on gloves and after removal of gloves or other personal protective equipment.
(c) Only single-use towels shall be used. *(Indiana State Department of Health; 410 IAC 1-5-30; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712)*

410 IAC 1-5-31 Personal protective equipment
Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 31. Appropriate personal protective equipment shall be worn as follows:
(1) A clean protective clothing layer shall be worn whenever there is a reasonably anticipated risk of contamination of clothing by blood or OPIM.
(2) Masks in combination with eye protection devices, such as goggles or glasses with solid side shield, or chin length face shield, shall be worn whenever splashes, spray, splatter, or droplets of blood or OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated.
(3) Disposable gloves, such as surgical or examination type, shall be worn during the tattooing or body piercing process. Gloves shall be changed and properly disposed of each time there is an interruption in the application of the tattoo or body piercing, when the gloves become torn or punctured, or whenever the ability to function as a barrier is compromised. Disposable gloves shall not be reused.
(4) Gloves shall be worn when decontaminating environmental surfaces and equipment.
(Indiana State Department of Health; 410 IAC 1-5-31; filed May 12, 1998, 10:00 a.m.: 21 IR 3818; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2712)

410 IAC 1-5-32 Tattooing equipment
Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 32. (a) Only single-use razors shall be used to shave the area to be tattooed.
(b) All stencils shall be properly disposed of after a single use.
(c) If the design is drawn directly onto the skin, it shall be applied with a single-use article only. *(Indiana State Department of Health; 410 IAC 1-5-32; filed May 12, 1998, 10:00 a.m.: 21 IR 3819)*

410 IAC 1-5-33 Needles
Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 33. (a) Needles shall be individually packaged and sterilized prior to use.

(b) Needles shall be single-use only.

(c) Needles shall be discarded in sharps containers immediately after use.

(d) Contaminated needles shall not be bent or broken or otherwise manipulated by hand. *(Indiana State Department of Health; 410 IAC 1-5-33; filed May 12, 1998, 10:00 a.m.: 21 IR 3819)*

410 IAC 1-5-34 Reusable equipment

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 34. (a) Heating procedures capable of sterilization must be used when heat stable, nondisposable equipment is sterilized.

(b) Equipment that is to be sterilized shall be put in single-use packaging.

(c) Records must be maintained to document the following:

(1) Duration of sterilization technique.

(2) Determination of effective sterility, such as use of a biological indicator, is performed monthly.

(3) Equipment is maintained as recommended by the owner's manual, and proof is available that the owner's manual recommendations are reviewed monthly.

(d) Reusable contaminated equipment shall not be stored or processed in a manner that requires any person to reach by hand into the containers where these sharp items have been placed.

(e) Reusable contaminated equipment shall be:

(1) placed in puncture-resistant containers;

(2) labeled with the biohazard symbol;

(3) leakproof on both sides and bottom; and

(4) stored in a manner that does not require reaching by hand into the container where the equipment is stored until cleaning prior to sterilization.

(f) Reusable contaminated equipment shall be effectively cleaned prior to sterilization or disinfection.

(g) Any reusable contaminated equipment that comes into direct contact, or is likely to come into direct contact, with an instrument that penetrates the skin other than a piercing gun shall be effectively cleaned and sterilized prior to use.

(h) All sterilized equipment shall not be removed from wrappers or sterilizer packaging until immediately prior to use.

(i) Any reusable equipment that comes into contact with mucus *[sic., mucous]* membranes shall be effectively cleaned and sterilized prior to use.

(j) Piercing guns shall be cleaned and undergo, at a minimum, high level disinfection after each use and whenever visibly contaminated.

(k) All reusable equipment that has contact with intact skin shall undergo, at a minimum, intermediate level disinfection.

(l) All other equipment used during the tattooing or body piercing procedure shall be single use, including corks.

(m) All body piercers and tattoo artists shall comply with all other equipment manufacturer's recommendations. *(Indiana State Department of Health; 410 IAC 1-5-34; filed May 12, 1998, 10:00 a.m.: 21 IR 3819; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2713)*

410 IAC 1-5-35 Dyes or pigments or other objects placed under the skin

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 35. (a) All dyes or pigments used in tattooing shall be from professional suppliers specifically providing dyes or pigments for the tattooing of human skin.

(b) In preparing dyes or pigments to be used by tattoo artists, only nontoxic, sterile materials shall be used. Single-use or individual portions of dyes or pigments in clean, single-use containers shall be used for each patron.

(c) After tattooing, the remaining unused dye or pigment in single-use or individual containers shall be discarded along with the container.

(d) Any object placed under the skin shall be sterile. *(Indiana State Department of Health; 410 IAC 1-5-35; filed May 12, 1998, 10:00 a.m.: 21 IR 3819; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2713)*

410 IAC 1-5-36 Work environment

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 36. (a) No tattooing or body piercing shall be conducted in any room used as living quarters or in any room that opens directly into living or sleeping quarters.

(b) Live animals shall be excluded from areas where tattooing or body piercing is being conducted. This exclusion does not apply to the following:

(1) Patrol dogs accompanying security or police officers.

(2) Guide dogs accompanying the following:

(A) Blind persons.

(B) Partially blind persons.

(C) Physically disabled persons.

(D) Guide dog trainers.

(E) Persons with impaired hearing.

(c) Eating, drinking, smoking, applying cosmetics, or handling contact lenses shall not be allowed in work areas where there is a likelihood of exposure to blood or OPIM.

(d) Food and drink shall not be kept in areas where there is a reasonably anticipated risk of exposure to blood or OPIM.

(e) All equipment and environmental surfaces shall be cleaned and disinfected after contact with blood or OPIM.

(f) Environmental surfaces and equipment not requiring sterilization that have been contaminated by blood shall be cleaned and disinfected.

(g) All work surfaces shall be:

(1) nonabsorbent;

(2) easily cleanable;

(3) smooth; and

(4) free of:

(A) breaks;

(B) open seams;

(C) cracks;

(D) chips;

(E) pits; and

(F) similar imperfections.

(h) Disinfectant solutions shall be:

(1) a hospital grade, tuberculocidal Environmental Protection Agency (EPA) registered disinfectant; or

(2) sodium hypochlorite, five-tenths percent (0.5%) concentration, by volume (common household bleach in ten percent (10%) concentration in water); the solution shall be dated and shall not be used if it is more than twenty-four (24) hours old.

(Indiana State Department of Health; 410 IAC 1-5-36; filed May 12, 1998, 10:00 a.m.: 21 IR 3821; errata filed Aug 31, 1998, 1:08 p.m.: 22 IR 127; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2713)

410 IAC 1-5-37 Infectious waste containment

Authority: IC 16-19-3-4.1
Affected: IC 16-19-3-4.1

Sec. 37. (a) Contaminated disposable needles or instruments shall be:

(1) stored in:

(A) leak-resistant; and

(B) puncture-resistant;

containers;

(2) tightly sealed to prevent expulsion;

(3) labeled with the biohazard symbol; and

(4) effectively treated in accordance with this rule prior to being stored in an unsecured area and sent for final disposal.

(b) Infectious wastes that are not contaminated sharps or objects that could potentially become contaminated sharps shall be placed in containers that meet the following requirements:

(1) Impervious to moisture.

(2) Sufficient strength and thickness to prevent expulsion.

(3) Secured to prevent leakage expulsion.

(4) Labeled with the biohazard symbol.

(5) Effectively treated in accordance with this rule prior to being placed in an unsecured area and sent for final disposal.

(c) If infectious waste is stored prior to final disposal, all persons subject to this rule shall store infectious waste in a secure area that:

(1) is locked or otherwise secured to eliminate access by or exposure to the general public;

(2) affords protection from adverse environmental conditions and vermin; and

(3) has a prominently displayed biohazard symbol.

(d) Infectious waste shall be stored in a manner that preserves the integrity of the container and is not conducive to rapid microbial growth and putrefaction.

(e) Disinfect reusable containers for infectious waste each time that they are emptied unless the surfaces of the reusable containers have been protected from contamination by disposable liners, bags, or other devices that are removed with the infectious waste. *(Indiana State Department of Health; 410 IAC 1-5-37; filed May 12, 1998, 10:00 a.m.: 21 IR 3820; errata filed Aug 31, 1998, 1:08 p.m.: 22 IR 127)*

410 IAC 1-5-38 Treatment and transport of infectious waste

Authority: IC 16-19-3-4.1; IC 16-19-3-4.2
Affected: IC 16-19-3

Sec. 38. (a) All operators shall ensure that infectious waste is either treated on-site in accordance with this rule or transported off-site for treatment in accordance with this rule.

(b) A treatment is effective if it reduces the pathogenic qualities of infectious waste for safe handling, is designed for the specific waste involved, and is carried out in a manner consistent with this rule. Effective treatment may include:

(1) incineration in an incinerator designed to accommodate infectious waste;

(2) steam sterilization;

(3) chemical disinfection under circumstances where safe handling of the waste is assured;

(4) thermal inactivation;

(5) irradiation; or

(6) discharge in a sanitary sewer or septic system that is properly installed and operating in accordance with state and local laws.

(c) All persons subject to this rule shall:

(1) transport infectious waste in a manner that reasonably protects waste haulers and the public from contracting a dangerous communicable disease; and

(2) effectively treat infectious waste in accordance with this rule before it is compacted.

(d) The operator shall ensure that infectious waste, effectively treated or not is transported off-site in compliance with 410 IAC 1-3. *(Indiana State Department of Health; 410 IAC 1-5-38; filed May 12, 1998, 10:00 a.m.: 21 IR 3821; errata filed Aug 31, 1998, 1:08 p.m.: 22 IR 127; filed Jun 30, 2000, 4:10 p.m.: 23 IR 2714)*

Rule 6. Offering of Human Immunodeficiency Virus Information and Counseling and Human Immunodeficiency Virus Testing

410 IAC 1-6-1 Applicability

Authority: IC 16-19-3-5
Affected: IC 16-41-6-2.5

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 1-6-1; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1970)*

410 IAC 1-6-2 "Department" defined

Authority: IC 16-19-3-5
Affected: IC 16-41-6-2.5

Sec. 2. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 1-6-2; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1970)*

410 IAC 1-6-3 "Prenatal care provider" defined

Authority: IC 16-19-3-5
Affected: IC 16-41-6-2.5; IC 25-22.5; IC 25-23

Sec. 3. "Prenatal care provider" means:
(1) a physician licensed under IC 25-22.5;
(2) a registered nurse licensed under IC 25-23;
(3) a licensed practical nurse licensed under IC 25-23; or
(4) an advanced practice nurse licensed under IC 25-23;
who provides prenatal care within the scope of the provider's license. *(Indiana State Department of Health; 410 IAC 1-6-3; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971)*

410 IAC 1-6-4 Human immunodeficiency virus information and counseling to a pregnant patient

Authority: IC 16-19-3-5
Affected: IC 16-41-6-2.5

Sec. 4. (a) The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall offer human immunodeficiency virus (HIV) information and counseling to the pregnant patient. The information and counseling must include the following:
(1) A description of the methods of human immunodeficiency virus (HIV) transmission.
(2) A discussion of risk reduction behavior modifications, including methods to reduce the risk of perinatal transmission.
(3) Referral information to other human immunodeficiency virus (HIV) prevention and psychosocial services, if appropriate, including anonymous and confidential test sites approved by the state department.
(b) A group practice, clinic, or hospital shall designate, in writing, a health care professional to implement this rule. *(Indiana State Department of Health; 410 IAC 1-6-4; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971)*

410 IAC 1-6-5 Reasons for not offering a human immunodeficiency virus test

Authority: IC 16-19-3-5
Affected: IC 16-41-6-2.5

Sec. 5. The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall offer an *[sic., a]* human immunodeficiency virus (HIV) test to the patient unless:
(1) a positive human immunodeficiency virus (HIV) test result is already documented in the patient's medical record; or
(2) the patient has acquired immune deficiency syndrome (AIDS) as diagnosed by a physician.
(Indiana State Department of Health; 410 IAC 1-6-5; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971)

410 IAC 1-6-6 Human immunodeficiency virus test

Authority: IC 16-19-3-5
Affected: IC 16-41-6-2.5

Sec. 6. (a) In offering an *[sic., a]* human immunodeficiency virus (HIV) test under section 5 of this rule, the prenatal care provider shall discuss the following with the pregnant patient:
(1) The purpose of the human immunodeficiency virus (HIV) test.
(2) The risk and benefits of the human immunodeficiency virus (HIV) test.

(3) The voluntary nature of the human immunodeficiency virus (HIV) test.

(b) If the pregnant patient voluntarily consents to human immunodeficiency virus (HIV) testing, the prenatal care provider shall arrange for human immunodeficiency virus (HIV) testing directly or by referral, including referral to anonymous and confidential test sites approved by the department. *(Indiana State Department of Health; 410 IAC 1-6-6; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971)*

410 IAC 1-6-7 Documentation

Authority: IC 16-19-3-5
Affected: IC 16-41-6-2.5

Sec. 7. (a) The prenatal care provider primarily responsible for providing prenatal care to a pregnant patient shall document in the patient's medical record that the prenatal care provider offered the following to the patient:

(1) Human immunodeficiency virus (HIV) information and counseling.

(2) An *[sic., A]* human immunodeficiency virus (HIV) test.

(b) Documentation in the patient's medical record must include notation that the following was offered to the patient:

(1) A description of the methods of human immunodeficiency virus (HIV) transmission.

(2) A discussion of risk reduction behavior modifications, including methods to reduce the risk of perinatal transmission.

(3) Referral information to other human immunodeficiency virus (HIV) prevention and psychosocial services, if appropriate, including anonymous and confidential test sites approved by the department.

(4) Discussion of the purpose of the human immunodeficiency virus (HIV) test.

(5) Discussion of the risk and benefits of the human immunodeficiency virus (HIV) test.

(6) Discussion of the voluntary nature of the human immunodeficiency virus (HIV) test.

(7) Documentation that the patient understood the information offered.

(c) Signature by the patient on a form provided by the department, or one which is substantially similar, acknowledging that she has been provided and has read, or, if unable to read and understand, has had the contents of the document read and explained to her by her prenatal care provider to her satisfaction, complies with the requirements of this section. *(Indiana State Department of Health; 410 IAC 1-6-7; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1971)*

410 IAC 1-6-8 Compliance

Authority: IC 16-19-3-5
Affected: IC 16-41-6-2.5; IC 16-41-9-12

Sec. 8. Compliance with this rule may be enforced under IC 16-41-9-12. *(Indiana State Department of Health; 410 IAC 1-6-8; filed Feb 9, 1999, 5:13 p.m.: 22 IR 1972)*

ARTICLE 2. TUBERCULOSIS CONTROL

Rule 1. General Regulations

410 IAC 2-1-1 Definitions

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-41

Sec. 1. Definitions. Unless the provisions of the context otherwise require, the definitions herein contained shall govern the construction of these regulations *[410 IAC 2-1]*.

(1) Tuberculosis Infection–Any person who gives evidence of tuberculosis infection by means of a positive tuberculin reaction or clinical findings or x-ray or bacteriological examination without regard to development or activity of disease.

(2) Infectious State–A case of pulmonary tuberculosis in which the chest x-ray interpretation, the laboratory findings, the physical findings or any combination of these informative sources indicate active disease, and in all cases of extrapulmonary form in which tubercle bacilli are found in the discharge from the disease process.

(3) Suspect Case–Any person having a pulmonary or other lesion that may, but is not yet proven to be, tuberculosis; also, any

person with symptoms suggestive of tuberculosis, with or without x-ray shadows.

(4) Contact–An individual who has been in intimate association with an infectious case of tuberculosis in the home or equivalent.

(5) Associate–Any person in close association with a tuberculin reactor, as differentiated from a person in close association with a diagnosed case of tuberculosis.

(6) Diagnostic X-ray–This is interpreted as a 14" × 17" film.

(Indiana State Department of Health; Reg HT 1R; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 205; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 2-1-2 Reporting requirements

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-41

Sec. 2. Type of Cases to be Reported. In addition to the identifying information the following shall be reported:

(1) Pulmonary Disease–The extent of the pulmonary lesions and the clinical status as interpreted and defined in the 1969 edition of "Diagnostic Standards and Classifications of Tuberculosis", published by the National Tuberculosis Association, New York, New York, copies of which are available in the Supreme Court Library, office of the Attorney General and the office of the Commissioner of the State Board of Health.

(2) Extrapulmonary–The site and clinical status of disease.

(3) Positive Tuberculin Reactor–The measurement of the Mantoux tuberculin test, using Intermediate PPD(t), in millimeters, diagnostic chest x-ray findings and final diagnosis as either primary active, primary inactive or adult tuberculosis. If other than the Mantoux skin test is used, all positive reactors to such tests are to be confirmed by the Mantoux skin test.

(Indiana State Department of Health; Reg HT 2R; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 206; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 2-1-3 Moving patient; permission

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-41

Sec. 3. Moving Patient. Permission of the local health officer having jurisdiction is to be obtained for removal of infectious patients from one dwelling to another within his jurisdiction. *(Indiana State Department of Health; Reg HT 3R; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 206; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 2-1-4 Moving patient between jurisdictions; report

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-41

Sec. 4. Moving of Patient Into or Out of a Health Jurisdiction. Whenever any local health officer learns that any person with infectious or noninfectious tuberculosis has been or is being transported into or out of his health jurisdiction, the health officer shall immediately notify the Indiana State Board of Health of such movement. Both the new and old address shall be stated. *(Indiana State Department of Health; Reg HT 4R; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 206; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 2-1-5 X-rays of school employees

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-41

Sec. 5. X-rays. Any diagnostic film submitted for review for school employees' examination requirements shall have the date the film was taken, the name or number identification of the patient, in a readable position on the film. The contrast and density of the film shall be such that the detail of the lung parenchyma is satisfactory to the examining physician. *(Indiana State Department of Health; Reg HT 5R; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 206; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR*

4234)

410 IAC 2-1-6 Hospital passes

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-41

Sec. 6. Patient Passes. Passes from the tuberculosis sanatoria or hospitals shall be restricted to individuals with a negative sputum; except in extenuating circumstances. Infectious cases may transfer from the hospital to their home only on written approval of the local health officer. *(Indiana State Department of Health; Reg HT 7R; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 207; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. Tuberculosis Out-Patient Clinic Subsidy Payments

410 IAC 2-2-1 Definitions

Authority: IC 16-46-9-5
Affected: IC 16-46-9

Sec. 1. Definitions–Unless the provisions of the context otherwise require, the definitions herein contained shall govern the construction of these regulations *[410 IAC 2-2]*.

(1) "Local clinic", "out-patient care center", and "out-patient treatment center" are considered synonymous terms and may be used interchangeably.

(2) Contract private physician–Means any private physician with whom the State Board of Health has currently entered into a contract to provide services pursuant to Sec. 1, IC 1971, 16-3-4-1/4 *[IC 16-3 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as originally enacted in the acts of 1969, Chapter 424.

(3) Clinic visit–For the purpose of IC 1971, 16-3-4-1/4 *[IC 16-3 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as originally enacted in the acts of 1969, Chapter 424, as amended by Public Law 209, Acts 1971, means those instances during which patient is examined and treated by a physician at a location as designated in (1) above.

(a) Visits for the purpose of completion of previous tests or treatments shall be deemed to not constitute a separate visit.

(Indiana State Department of Health; Reg HT 9; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 207; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 2-2-2 Facility standards

Authority: IC 16-46-9-5
Affected: IC 16-46-9

Sec. 2. Facility Standards. (1) Each facility as specified in HT 9 (1) *[410 IAC 2-2-1(1)]* above shall be required to:

(a) Be approved by the State Board of Health.

(b) Have equipment, or have contractual arrangements, to permit the taking of diagnostic chest x-ray film.

(c) Have the services of a physician with training in diseases of the chest.

(d) Have needed equipment and materials to perform a Mantoux skin test.

(e) Have State Board of Health approved capability for laboratory services to permit examination of sputum for tubercle bacilli, sensitivity tests to the antituberculosis antibiotics, and has facilities to differentiate the unclassified acid fast organisms.

(f) Have required professional assistance to permit recording of the following essential data for each patient: history, physical examination, x-ray findings, Mantoux skin tests, laboratory findings, diagnosis and recommendations, treatment and progress reports, nurse visits and observations, social information and rehabilitation appraisal and recommendations.

(g) Geographical location of the facility shall be in accordance with the general program of the Indiana State Board of Health in the control and eradication of tuberculosis and must be area wide in concept and service.

(Indiana State Department of Health; Reg HT 10; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 207; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 2-2-3 Physician referral required

Authority: IC 16-46-9-5
Affected: IC 16-46-9

Sec. 3. Only those patients who are referred by a physician may be accepted by any out-patient care center coming within the purview of IC 1971, 16-3-4-1/4 *[IC 16-3 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as originally enacted in the acts of 1969, Chapter 424 as amended by Public Law 209, Acts 1971, Indiana General Assembly. *(Indiana State Department of Health; Reg HT 11; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 208; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 2-2-4 State subsidy payment

Authority: IC 16-46-9-5
Affected: IC 16-46-9

Sec. 4. (1) Determination of source of payment–The county of residence of the referred patient shall have the sole responsibility for the determination and certification of the fact that the referred county resident is financially unable to pay such clinic costs.

(a) Proper county officials will submit, on forms furnished by the State Board of Health, assurance to the clinic that the county will pay the entire cost of examination and treatment for those patients financially unable to pay.

(b) The out-patient treatment center will bill the county of residence for services provided those patients whom the county has certified as being financially unable to pay such costs. The entire charge will, however, be reduced and so shown on the billing in the amount of $5.00 per each "examination and treatment visit", which reduction represents a state subsidy in the interest of the control of tuberculosis.

(c) The state subsidy will not be paid until an official morbidity report is filed with the local health officer and the State Board of Health.

(Indiana State Department of Health; Reg HT 12; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 208; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 2-2-5 Filing subsidy claim

Authority: IC 16-46-9-5
Affected: IC 16-46-9

Sec. 5. (1) Claim filing–On the first day of January, April, July, and October, the director of the out-patient treatment center providing the services within the provisions of IC 1971, 16-3-4-1/4 *[IC 16-3 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as originally enacted in the acts of 1969, Chapter 424 as amended by Public Law 209, Acts 1971, Indiana General Assembly, and these regulations, shall, on forms provided by the State Board of Health, list by name, those patients for whom such "examination and treatment" state subsidy payment is requested.

(a) Each "examination and treatment" clinic visit will be eligible for state subsidy, provided the county of residence has paid the clinic charge, less the $5.00 state subsidy for each resident unable to pay the same. Distribution of monies to the several counties pursuant to Sec. 3, IC 1971, 16-3-4-1/4 *[IC 16-3 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as originally enacted in the acts of 1969, Chapter 424 as amended by Public Law 209, Acts 1971, Indiana General Assembly, shall be through the payment of $5.00 state subsidy to the various clinics.

(Indiana State Department of Health; Reg HT 13; filed Mar 14, 1972, 3:45 pm: Rules and Regs. 1973, p. 208; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

ARTICLE 3. MATERNAL AND CHILD HEALTH

Rule 1. Vision Acuity Testing

NOTE: This rule was promulgated jointly with the state board of education and also appears at 511 IAC 4-2-1.

410 IAC 3-1-1 Testing

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 1. (a) All school corporations shall conduct an annual screening test of the visual acuity of all children enrolled in or transferred to grades 3 and 8 and all other school children suspected of having a visual defect.

(b) Equipment for testing visual acuity shall consist of the following:

(1) The minimum equipment to be used shall be a Snellen Chart illuminated by two (2) sixty (60) watt bulbs.

(2) The Snellen E Chart shall be used for grade 3.

(3) The Snellen Alphabetical Chart shall be used for grade 8.

(4) The use of testing equipment equivalent to or more elaborate than the Snellen test is at the discretion of the local school system and shall be based on the recommendations of the school's professional health advisory sources.

(Indiana State Department of Health; Reg MCH 1,A; filed Mar 21, 1960: Rules and Regs. 1961, p. 217; filed May 11, 1988, 4:30 pm: 11 IR 3539; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-1-2 Testing procedures; standards

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 2. Procedures for vision testing are as follows:

(1) Equipment shall be used as follows:

(A) The Snellen Chart (E or Alphabetical) shall be used at a distance of twenty (20) feet.

(B) The lamps used to illuminate the chart shall be placed one (1) foot from the chart.

(2) The following standards apply:

(A) Children in grade 3 who are unable to read with each eye the 20/30 line of the Snellen Chart shall be recommended for further examination based upon the recommendations of the professional advisors of a school's eye screening program.

(B) Children in grade 8 who are unable to read with each eye the 20/20 line of the Snellen Chart shall be recommended for further examination.

(C) Parents of children with corrective lenses or other ocular devices shall be informed of the eye screening program but these children need not be referred for further examination.

(Indiana State Department of Health; Reg MCH 1,B; filed Mar 21, 1960: Rules and Regs. 1961, p. 217; filed May 11, 1988, 4:30 pm: 11 IR 3539; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-1-3 Qualification of testers

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 3. The school administrator shall assign the best qualified person in the school system or school health service to supervise eye screening tests. *(Indiana State Department of Health; Reg MCH 1,C; filed Mar 21, 1960: Rules and Regs. 1961, p. 218; filed May 11, 1988, 4:30 pm: 11 IR 3539; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-1-4 Reports

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 4. Reporting of School Testing Program

(1) Each school corporation shall submit an annual report of its vision testing program to the Indiana state board of health.

(2) The report shall include the following:

(A) the number of children in each grade tested;

(B) the number of children in each grade requiring further examination;

(C) the number of children receiving further professional attention;
(D) the type of screening test used;
(E) the person or department supervising the testing program.

(3) The school's testing program shall be subject to review and approval by the state board of education and the state board of health.

(Indiana State Department of Health; Reg MCH 1,D; filed Mar 21, 1960: Rules and Regs. 1961, p. 218; filed May 11, 1988, 4:30 pm: 11 IR 3539; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 1.1. Visual Acuity Testing; Modified Clinical Technique

NOTE: This rule was promulgated jointly with the state board of education and also appears at 511 IAC 4-2-1.1.

410 IAC 3-1.1-1 Annual vision test

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 1. Every school corporation shall conduct an annual visual test, using the modified clinical technique, of children when they enroll in either kindergarten or grade 1 unless an eye care professional requests, in writing, that the child not be tested. The modified clinical technique consists of testing for vision acuity, refractive error, ocular health, and binocular coordination. The school corporation shall use the suggested equipment unless the professional health personnel of the school recommend other equivalent or superior equipment. *(Indiana State Department of Health; 410 IAC 3-1.1-1; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-1.1-2 Visual acuity

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 2. To test for visual acuity, the school corporation shall use the Snellen Alphabetical, Stycar (HOTV) Chart or equivalent test. The chart shall be calibrated at ten (10) to twenty (20) feet for distance vision and fourteen (14) inches for near vision. For testing distance vision, the chart shall be illuminated by two (2) sixty (60) watt bulbs and for near vision, by one (1) sixty (60) watt bulb. The chart shall be located at a distance of ten (10) to twenty (20) feet from the student and calibrated accordingly. Lamps shall be placed one (1) foot from the chart. The school shall recommend for further examination those students who:

(1) are unable to read the 20/40 line with either eye;
(2) with one (1) eye can read a line that is two (2) or more lines higher or lower on the chart than the line that can be read with the other eye; or
(3) are unable to read the 20/30 line at 14 inches using both eyes.

(Indiana State Department of Health; 410 IAC 3-1.1-2; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-1.1-3 Refractive error

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 3. To test for refractive error, a retinoscope with loose lenses or a lens bar shall be used. The child shall focus on an object at twenty (20) feet for distance vision of 3/4 meter (29.53 inches) for near vision. A school corporation shall recommend for further examination a student who has:

(1) refraction of + 2.00D or greater;
(2) refraction of - 1.00D or greater;
(3) astigmatism of 1.00D or greater;
(4) anisometropia of 1.00D or greater.

(Indiana State Department of Health; 410 IAC 3-1.1-3; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-1.1-4 External health of eye

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 4. To determine the external health of the eyes, the ocular adnexa, conjunctiva and cornea of the eyes shall be observed in a room with normal illumination and the illumination from a pen light. *(Indiana State Department of Health; 410 IAC 3-1.1-4; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-1.1-5 Internal health of eye

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 5. To determine the internal health of the eyes, the anterior chamber, iris, posterior chamber, lens, vitreous, optic nerve head, and retina shall be observed with a direct ophthalmoscope with rheostat, variable aperture and variable plus and minus lenses. *(Indiana State Department of Health; 410 IAC 3-1.1-5; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-1.1-6 Binocularity

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 6. Binocularity shall be tested respectively at twenty (20) feet (distance) and fourteen (14) inches (near). To test the binocularity of the eyes, any of the following equipment may be used:

(1) A paddle occuluder *[sic.]* to alternately cover the eyes while the opposite eye fixates on a target.

(2) Plastic or glass prisms loose or in a bar or rotary pedestal to measure manifest or latent deviation.

(3) Stereopsis targets with appropriate testing spectacles. Disparity shall be recorded in seconds of arc.

(Indiana State Department of Health; 410 IAC 3-1.1-6; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-1.1-7 Further examination

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 7. The school corporation shall recommend for further examination those students who demonstrate:

(1) a manifest deviation of any size;

(2) a latent deviation of 10 prism diopters of exodeviation;

(3) a latent deviation of 8 prism diopters of esodeviation; or

(4) a lack of stereo acuity.

(Indiana State Department of Health; 410 IAC 3-1.1-7; filed May 11, 1988, 4:30 pm: 11 IR 3541; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-1.1-8 Eye health care professional; qualifications

Authority: IC 20-8.1-7-16
Affected: IC 20-8.1-7-16

Sec. 8. Qualification of testers:

(1) The school administrator shall be responsible for assigning the best qualified person(s) in the school system or school health service for conducting, supervising, and assisting in eye screening.

(2) The school administration shall be responsible for obtaining the services of a licensed eye health care professional to conduct testing using the modified clinical technique (internal and external diseases of the eye, testing of refraction and binocularity using paddle occlusion test with prism measurement) for students upon first entrance into the school.

(Indiana State Department of Health; 410 IAC 3-1.1-8; filed May 11, 1988, 4:30 pm: 11 IR 3541; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 2. Lead Poisoning Testing; Sickle Cell Anemia Testing

NOTE: This rule was promulgated jointly with the state board of education and also appears at 511 IAC 4-2-2.

410 IAC 3-2-1 Lead poisoning testing

Authority: IC 20-8.1-7-1; IC 20-8.1-7-15
Affected: IC 20-8.1-7-15

Sec. 1. Lead Poisoning Test. Lead poisoning test methods shall include one or more of the following acceptable quantitative test procedures for screening or confirmatory purposes to determine the content of lead in blood, urine or other clinial specimen from human sources.

(a) The acceptable quantitative test procedures for the detection of blood lead shall include the following methods: dithizone, colorimetric, atomic absorption spectrophotometric, emission spectroscopic, anodic stripping voltametric, fluorimetric test for free erythrocyte porphyrins (indirect test for blood lead), or any other procedure shown to be accurate and reliable.

(b) Also acceptable is the quantitative test on urine to measure elevated urinary ALA (delta-aminolevulnic acid) as an indirect test for lead poisoning or any other accurate and reliable test on urine, specimens of hair or other clinical specimen from human sources.

(Indiana State Department of Health; Rule MCH 2,Sec 1; filed Apr 10, 1974, 2:00 pm: Rules and Regs. 1975, p. 342; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-2-2 Sickle cell anemia testing

Authority: IC 20-8.1-7-1; IC 20-8.1-7-14
Affected: IC 20-8.1-7-14

Sec. 2. Sickle Cell Anemia.

(a) The sickle cell anemia testing equipment shall be of a type generally recognized as suitable to provide accurate test results by one or more of the test procedures indicated in (c). The equipment may be of manual or automated design, subjected to whatever periodic preventive maintenance and quality control measures are necessary to assure satisfactory operation and accurate test results.

(b) The qualifications of the sickle cell anemia testing personnel shall indicate sufficient training and experience in the techniques of the tests employed to assure competency in operation of the testing equipment and accuracy in the test results obtained.

(c) The sickle cell anemia testing procedures shall consist of one or more test methods generally recognized as dependable and accurate for the detection of sickle cell anemia. The test procedures may be of manual or automated type. The screening tests and/or confirmatory tests recognized as useful include the sodium metabisulfite method, the solubility or dithionite-type tests, hemoglobin electrophoresis procedures, and other tests which detect sickle cell anemia.

(Indiana State Department of Health; Rule MCH 2,Sec 2; filed Apr 10, 1974, 2:00 pm: Rules and Regs. 1975, p. 342; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 3. Examination of Infants for Disorders

410 IAC 3-3-1 Definitions

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 1. As used in 410 IAC 3-3:

"Birthing center" means any non-hospital facility in which live births routinely take place.

"Board" means the Indiana state board of health.

"Galactosemia" means an inherited error in the metabolism of galactose.

"Hemoglobinopathy" means an abnormal hemoglobin which results from an inherited defect, some of which may produce a sickling phenomenon in erythrocytes.

"Homocystinuria" means an inherited error in the metabolism of methionine.

"Hospital" means a licensed hospital with obstetric services.

"Hypothyroidism" means a deficient amount or activity of thyroid hormone.

"Maple syrup urine disease" means an inherited error in the metabolism of leucine, isoleucine and valine.

"MCH" means division of maternal and child health, genetic diseases section, at the Indiana state board of health.

"Phenylketonuria" means an inherited error in the metabolism of phenylalanine.

"Satisfactory blood specimen" means a blood specimen on which an accurate laboratory analysis can be performed for the disorder for which it is submitted.

"Unsatisfactory blood specimen" means any of the following:

(1) A filter paper kit on which an insufficient quantity of blood is obtained.

(2) A filter paper kit on which an accurate analysis or interpretation cannot be performed due to improper collection, handling, submission, or a technical or laboratory problem.

(3) Cord blood.

(4) Blood from any transfused neonate.

(5) A filter paper kit which does not provide all of the information regarding the patient as required. The blood specimen within such a filter paper kit may be satisfactory according to the criteria above.

(Indiana State Department of Health; 410 IAC 3-3-1; filed Nov 7, 1986, 3:30 pm: 10 IR 415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-3-2 Provision of testing information; religious objection

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 2. (a) The board shall provide public educational materials, including descriptions of the disorders and of the screening program, to hospitals, birthing centers, physicians, midwives, and other health care providers for distribution to patients. Physicians and midwives engaged in providing prenatal and/or perinatal care shall provide pregnant women, prior to the estimated date of delivery, with this information. Hospitals and birthing centers shall provide each pregnant woman admitted for delivery with a copy of this information prior to collection of the blood specimen. If a woman is unable to read such material, it shall be translated or read to her in a language she understands.

(b) Any parent or guardian who objects to the testing for reasons pertaining to religious beliefs only shall so indicate by signing a statement of informed refusal. Such objection shall become part of the medical record and the infant shall be exempted from the testing. *(Indiana State Department of Health; 410 IAC 3-3-2; filed Nov 7, 1986, 3:30 pm: 10 IR 416; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-3-3 Screening for phenylketonuria, hypothyroidism, galactosemia, homocystinuria, maple syrup urine disease, hemoglobinopathies, congenital adrenal hyperplasia, and biotinidase deficiency; collection procedures

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 3. (a) All newborn infants born in the state of Indiana shall be screened for:

(1) phenylketonuria;

(2) hypothyroidism;

(3) galactosemia;

(4) homocystinuria;

(5) maple syrup urine disease;

(6) hemoglobinopathies;

(7) congenital adrenal hyperplasia; and

(8) biotinidase deficiency;

except as provided for in section 2(b) of this rule.

(b) The responsible physician, midwife, or hospital shall collect a specimen of the infant's blood on a filter paper kit approved by the board. The specimen shall consist of capillary blood obtained by heel puncture and applied directly to the special filter paper. All circles shall be saturated with blood from one (1) side of the filter paper only. All information requested on the form attached to the special filter paper shall be provided. The specimen shall be air dried and then inserted into the protective envelope with complete data. If multiple specimens are forwarded in one (1) envelope, care must be taken to avoid cross-contamination. Completed specimens shall be forwarded to a designated laboratory within twenty-four (24) hours after collection.

(c) The infant's blood for these tests shall be collected not earlier than forty-eight (48) hours after birth and not before the infant has been on a protein diet for at least twenty-four (24) hours, except as stated in subsection (d), and no later than one hundred twenty (120) hours after birth, except as stated in subsection (f).

(d) When a live birth occurs in a hospital, the responsible physician shall have a specimen of the infant's blood taken prior to the infant's discharge from the hospital. If the infant is discharged from the hospital before forty-eight (48) hours after birth, or before being on a protein diet for twenty-four (24) hours, a blood specimen shall be collected regardless, but collection shall be repeated after forty-eight (48) hours and no later than one hundred twenty (120) hours after birth. The hospital administrator or a designated representative shall provide a written notice to the parents, guardian, or other legally responsible person, at or before discharge, of the requirements for such newborn to be tested again prior to one hundred twenty (120) hours after birth.

(e) When a live birth occurs in a facility other than a licensed hospital, it shall be the responsibility of the physician or midwife in attendance at the birth to assure that the newborn is referred to an appropriate facility, such as a physician office, hospital, or local health department, and to make the arrangements to obtain and submit a satisfactory blood specimen in accordance with this section. In the absence of an attending physician or midwife, the registrar of births shall refer the infant immediately to the parent's physician or to the local health department for submission of a specimen in accordance with this section and notify the MCH immediately.

(f) For preterm infants, the specimen shall be taken on the day of discharge or on the sixth day if nursery stay is prolonged beyond six (6) days. Prematurity and transfusion status shall be noted on the request form in the space provided. If the infant is to receive total exchange transfusion, then the specimen for the newborn screening test is to be obtained from the first draw, which represents the infant's own blood. *(Indiana State Department of Health; 410 IAC 3-3-3; filed Nov 7, 1986, 3:30 p.m.: 10 IR 416; filed Sep 17, 1999, 10:42 a.m.: 23 IR 324; errata filed Nov 19, 1999, 9:31 a.m.: 23 IR 814; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-3-4 Designated laboratories; requirements to perform screening tests for disorders

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 4. An approved laboratory must meet the following requirements in order to perform screening tests for disorders on dried blood samples from newborns: (a) Complies with Public Law 90-174, the Federal Clinical Laboratory Improvement Act of 1967, or is accredited by the College of American Pathologists, or is accredited by the Joint Commission on Accreditation of Hospitals.

(b) Performs or makes reasonable assurances that it will perform each one of the above screening tests on a minimum of 25,000 newborns annually.

(c) Uses laboratory procedures and values for normal and abnormal test results which have been submitted to and approved by the board.

(d) Initiates the approved tests within twenty-four (24) hours of receipt of the specimen and the tests shall be completed within seventy-two (72) hours.

(e) Reports findings in a timely manner and maintains records in accordance with the requirements of the board.

(f) Provides at least monthly reports of its screening activities to the board.

(g) Maintains a written quality assurance program covering all aspects of its newborn screening activity which is approved yearly by the board.

(h) Cooperates with other relevant agencies concerned with newborn health care.

(i) Participates in a laboratory quality assurance program, including proficiency testing, approved by the board. *(Indiana State Department of Health; 410 IAC 3-3-4; filed Nov 7, 1986, 3:30 pm: 10 IR 417; filed Feb 25, 1988, 4:30 pm: 11 IR 2579; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-3-5 Laboratory reports

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 5. The laboratory shall report as follows: (a) Negative test results shall be reported within seven (7) days of the date of analysis by mail to MCH and to the hospital submitting the specimens. A copy for the responsible physician shall be included for distribution by the hospital. The report of the test results shall become part of the patient's clinical record.

(b) Confirmed positive tests shall be reported immediately by telephone to the hospital, responsible physician and to MCH. Such notification shall be recorded in the laboratory's records specifying date and time of notification, person notified, and information provided. This shall be followed by a written report within three (3) days. The report of the test result shall become part of the patient's clinical record. If there is no known responsible physician, the local health officer in the county of the mother's residence shall be notified.

(c) Unsatisfactory specimens shall be reported immediately by telephone to the hospital and responsible physician or other health care provider submitting the specimen with an explanation about the reason for rejection. In the event that the responsible physician or health care provider who submitted the specimen is no longer the primary health care provider, he or she shall be responsible for notifying the current primary health care provider.

(d) In the event a specimen is rejected for any reason as unsatisfactory, the physician responsible for the infant's care at the time of the report shall be responsible for the submission of an acceptable specimen within forty-eight (48) hours. If the laboratory does not receive the repeat specimen within five (5) days, it shall notify MCH immediately by telephone.

(e) The designated laboratories performing the tests shall maintain records of the results of all screening and follow up testing of infants for these conditions in accordance with Indiana requirements for records management.

(f) The laboratory shall also provide at least a monthly report to the board which shall contain:

(1) The number of infants tested.

(2) The number of repeat tests.

(3) The number of unacceptable specimens by hospital, birthing center, physician, or other health care provider submitting the specimen.

(4) Presumptive positive results by test.

(5) Confirmed positive results by test, including patient names and identifying information.

(Indiana State Department of Health; 410 IAC 3-3-5; filed Nov 7, 1986, 3:30 pm: 10 IR 417; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-3-6 Maintenance of screening logs; follow-up of missing results; monthly reports

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 6. (a) Each hospital and birthing center, and midwife or physician submitting screening tests on infants born outside a hospital or birthing center, shall maintain a newborn screening log which shall contain the following:

(1) Name of infant.

(2) Attending physician.

(3) Medical record number.

(4) Form number of sample sent.

(5) Date sample collected.

(6) Date sample sent.

(7) Date results received.

(8) What the results were.

(9) Name of person notified of positive results and date and time of notification.

All such information and records shall be confidential but shall be open to examination by the board personnel or its designated agents for any purpose directly connected with the administration of the newborn screening program.

(b) The log shall be reviewed daily to determine that the results of required tests have been recorded within fourteen (14) days of discharge, or that a parent's or legal guardian's signed refusal has been filed in the newborn's medical record.

(c) Whenever a hospital, birthing center, or midwife determines that a discharged newborn has not received the mandated tests,

the hospital, birthing center or midwife shall immediately contact the responsible physician by telephone to inform him or her that a specimen must be obtained and immediately send a written notification to the responsible physician and MCH. If the responsible physician cannot be contacted within three (3) days or will not obtain a specimen, the hospital, birthing center or midwife shall notify MCH immediately by telephone and shall send written notification within three (3) days to MCH. MCH shall then immediately notify the local health officer, who shall arrange collection of a specimen.

(d) Whenever a hospital, birthing center or midwife determines that a specimen has been obtained but there are no results available in the newborn's medical record within fourteen (14) days of discharge, the hospital, birthing center or midwife shall obtain the results from the laboratory by telephone and request that another written copy be sent. The hospital, birthing center or midwife shall also notify MCH that results have not been received. If no results are available from the laboratory, then the hospital, birthing center or midwife shall proceed as in 410 IAC 3-3-7(c).

(e) When the responsible physician is notified by telephone by the hospital, birthing center or midwife that a newborn was discharged before a specimen was taken, or if the physician determines from his or her own records that no test has been performed or that no results are available, the responsible physician shall make every reasonable effort to have a specimen obtained within three (3) days of notification. If the responsible physician cannot obtain the specimen, the physician shall notify MCH immediately by telephone. Such telephone notification shall be noted in the responsible physician's record, specifying the date of notification, the person notified and the information provided.

(f) When the responsible physician is notified by the laboratory by telephone that a specimen is inadequate, the physician so notified shall make every reasonable effort to have an adequate repeat specimen obtained within forty-eight (48) hours of notification. If the responsible physician so notified cannot obtain the repeat specimen, the physician shall notify MCH immediately by telephone. Such telephone notification shall be noted in the responsible physician's records specifying the time and date of notification, the person notified and the information provided.

(g) All repeat specimens shall be forwarded to a designated laboratory within twelve (12) hours after they have been obtained.

(h) MCH shall make every reasonable effort to follow up on all newborns who have been reported as not having received a completed screening in an attempt to ensure that all infants born in the state of Indiana will have received the required screening for disorders.

(i) Hospitals and birthing centers, and midwives and physicians providing home birth services shall provide monthly reports to the board indicating the total number of live births and the number of newborns for whom specimens were submitted for initial screening for phenylketonuria, hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria and hemoglobinopathy, and the total number of positive results by test with patient identifying information. *(Indiana State Department of Health; 410 IAC 3-3-6; filed Nov 7, 1986, 3:30 pm: 10 IR 418; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-3-7 Follow-up of positive results, recommendations

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 7. (a) When the responsible physician is notified by telephone by the laboratory of an initial presumptive positive test result, the responsible physician shall obtain the board approved repeat blood specimen from the newborn and submit it to the designated laboratory within forty-eight (48) hours. If the blood specimen cannot be obtained within forty-eight (48) hours, the responsible physician shall notify MCH by telephone. Such telephone notification shall be noted in the responsible physician's records, specifying the date of notification, the person notified and the information provided. MCH will notify the local health officer and provide the necessary follow-up to ensure that the repeat blood specimen is obtained.

(b) It shall be the responsibility of the responsible physician or, if none, the local health officer to report immediately to the parent or guardian:

(1) all abnormal results from the newborn screening test in order to recommend appropriate diagnostic and possible therapeutic procedures, and

(2) any diagnosis of a disorder in order to recommend appropriate therapeutic procedures and psycho-social support.

(c) When the repeat blood specimen supports a presumptive diagnosis of a disorder, the laboratory shall notify MCH and the responsible physician or local health officer, as appropriate.

(d) The responsible physician retains responsibility for the child's case management as the primary health care provider, and shall make arrangements for the necessary diagnosis, therapy and counseling about the clinical and etiologic nature of the disorder, the chance of recurrence in subsequent children and other family members, existing resources for comprehensive clinical

management, and family emotional and financial support. These can be provided directly by the responsible physician or by referral to appropriate specialists.

(e) The board shall advise the responsible physician of the available referrals and programs for further evaluation, counseling, and management available to the patient and family. These shall include, but are not limited to, care by a clinical biochemical geneticist for children with phenylketonuria, galactosemia, maple syrup urine disease and homocystinuria, care by a pediatric hematologist for children with a clinically significant hemoglobinopathy, and care by a pediatric endocrinologist for children with hypothyroidism. In the case of children identified as carriers of an inherited hemoglobin abnormality (individuals with trait), the board shall recommend further evaluation of parents and appropriate counseling.

(f) All physicians making an initial diagnosis of a treatable disorder for which testing is required under IC 16-8-6 *[IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* shall report such diagnosis and the information necessary for follow-up to the board. Physicians caring for Indiana newborns who have been diagnosed outside the state of Indiana with a disorder for which testing is required under IC 16-8-6 *[IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* shall report in a similar manner.

(g) The board shall maintain a tracking system for follow-up of newborn screening results, and shall maintain a confidential registry of every infant born for whom the diagnosis of phenylketonuria, hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, or hemoglobinopathy has been confirmed. These records shall be utilized only for the purpose of service delivery and program administration and shall be managed in accordance with the procedures described in 410 IAC 1-2-2 *[410 IAC 1-2 was repealed filed Jul 27, 1988, 2:50 pm: 11 IR 4098. See 410 IAC 1-2.1.]*.

(h) The board shall develop and maintain a statewide network of genetic evaluation and counseling services. Regional genetic services centers and outreach services from these centers shall serve as local evaluation and counseling resources for the follow-up program described in this section. *(Indiana State Department of Health; 410 IAC 3-3-7; filed Nov 7, 1986, 3:30 pm: 10 IR 419; filed Feb 25, 1988, 4:30 pm: 11 IR 2579; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-3-7.1 Newborn screening fund; fees; disposition; reporting requirements

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 7.1. (a) The program involving the board and MCH as described in this rule shall be funded by a collection of a newborn screening fee for each newborn screened by a designated laboratory. The designated laboratory shall assess and collect the fees from hospitals, birthing centers, physicians, and midwives. The accumulated collections from the newborn screening fees shall be submitted on a monthly basis by the designated laboratory to the division of finance at the board. Payments shall be postmarked not later than five (5) days after the close of the preceding month. The designated laboratory shall also submit a monthly report on the number of newborns screened. Revenues submitted by the laboratory shall correspond with the number of newborns screened.

(b) The fees shall be deposited in the newborn screening fund. Funds for the program described in this rule shall be disbursed by the board in accordance with normal procedures prescribed by the state budget agency and the state board of accounts.

(c) The newborn screening fee shall be seven dollars ($7) based on the projected cost of the program described in this rule and the estimated number of newborns per year. The fee shall be reviewed annually by the board. *(Indiana State Department of Health; 410 IAC 3-3-7.1; filed Feb 25, 1988, 4:30 p.m.: 11 IR 2580; filed Aug 9, 1991, 11:00 a.m.: 14 IR 2223; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-3-8 Grounds for filing a complaint

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 8. The willful or repeated failure of any physician, midwife, laboratory, hospital, birthing center, or other health care provider to comply with the provisions of 410 IAC 3-3 shall, in addition to any other penalty prescribed by law, constitute grounds for filing a complaint with said individual's or institution's licensing board in addition to other legal remedies. *(Indiana State Department of Health; 410 IAC 3-3-8; filed Nov 7, 1986, 3:30 pm: 10 IR 420; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 3.1. CHILDREN WITH SPECIAL HEALTH CARE NEEDS (REPEALED)

(Repealed by Indiana State Department of Health; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2181)

ARTICLE 3.2. CHILDREN WITH SPECIAL HEALTH CARE NEEDS

Rule 1. Definitions

410 IAC 3.2-1-1 Applicability
Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 3.2-1-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2168; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-2 "Care coordination" defined
Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 2. "Care coordination" means providing assistance necessary to help ensure the effective and efficient organization of and access to services and resources that are appropriate and necessary to meet the needs of a child with special health care needs and the child's family. *(Indiana State Department of Health; 410 IAC 3.2-1-2; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2168; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-3 "Care coordinator" defined
Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 3. "Care coordinator" means a professional staff person assigned to assist a child and family with care coordination services. *(Indiana State Department of Health; 410 IAC 3.2-1-3; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2168; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-4 "Child" defined
Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 4. "Child" means an individual who is less than twenty-one (21) years of age. *(Indiana State Department of Health; 410 IAC 3.2-1-4; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2168; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-5 "Child and family service plan" defined
Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 5. "Child and family service plan" means a written child and family plan that is developed by a family and a care coordinator. The written plan shall reference the medical needs of the child, shall include appropriate strategies recommended by the care coordinator, and shall set forth family goals and objectives. The plan shall be updated periodically in accordance with state department of health policy. *(Indiana State Department of Health; 410 IAC 3.2-1-5; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2168; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-6 "Commissioner" defined
Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 6. "Commissioner" means the commissioner of the Indiana state department of health. *(Indiana State Department of*

Health; 410 IAC 3.2-1-6; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2168; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3.2-1-7 "County department" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 7. "County department" means the county department of public welfare, family and social services agency, or any subsequent successor agency. *(Indiana State Department of Health; 410 IAC 3.2-1-7; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2168; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-8 "Credentials" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 8. "Credentials" means written documentation, including, but not limited to, the CSHCN program application, financial information, medical information, and social information relating to a child and family. *(Indiana State Department of Health; 410 IAC 3.2-1-8; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-9 "CSHCN program" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 9. "CSHCN program" means the program for children with special health care needs, Indiana state department of health. *(Indiana State Department of Health; 410 IAC 3.2-1-9; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-10 "Dental care" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 10. "Dental care" means:
(1) routine dental care;
(2) extractions;
(3) fillings;
(4) x-rays;
(5) space maintainers;
(6) cross-bite treatments;
(7) sealants;
(8) orthodontia; and
(9) gingivectomies;
necessary to treat a child's identified eligible medical condition. *(Indiana State Department of Health; 410 IAC 3.2-1-10; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-11 "Director" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 11. "Director" means the director of the program for children with special health care needs. *(Indiana State Department of Health; 410 IAC 3.2-1-11; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-12 "Durable equipment and supplies" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 12. "Durable equipment and supplies" means assistive appliances, including, but not limited to, the following:
(1) Braces.
(2) Prosthetic limbs.
(3) Hearing aids.
(4) Wheelchairs and related adaptive devices.
(5) Special supplies that are medically necessary to accomplish rehabilitation goals.

Durable equipment and supplies do not include fixed architectural modifications of a dwelling or property related thereto or mechanical lifts needed to provide the child access to a dwelling or automobile. *(Indiana State Department of Health; 410 IAC 3.2-1-12; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-13 "Emergency" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 13. "Emergency" means an unexpected or sudden event or occurrence that requires immediate attention, intervention, and medical care to prevent serious harm or loss of life. *(Indiana State Department of Health; 410 IAC 3.2-1-13; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-14 "Emergency services" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 14. "Emergency services" means that the emergency department treatment or ambulance transportation is for a medical emergency that is directly related to or necessary to stabilize a child for care of an identified eligible medical condition. Lack of such treatment would cause harm or be life threatening if emergency care was not received. Emergency treatment for nonemergent medical care or conditions that do not require urgent care are not eligible for payment through the CSHCN program. *(Indiana State Department of Health; 410 IAC 3.2-1-14; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-15 "Enrollment" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 15. "Enrollment" means that a child's application has been processed, the director has identified and assigned a care coordinator and a health care provider to provide care for the child, and the director may approve eligible services for payment. *(Indiana State Department of Health; 410 IAC 3.2-1-15; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-16 "Family" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 16. "Family" means a group of two (2) or more persons living together as one (1) economic unit. Two (2) separate households or economic units may reside under one (1) roof; however, each household must be economically independent of one another and must have its own source of income that is adequate to support itself without support from the other family. *(Indiana State Department of Health; 410 IAC 3.2-1-16; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2169; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-17 "Health care provider" defined

Authority: IC 16-35-2-7
Affected: IC 16-21-2; IC 16-35-2

Sec. 17. "Health care provider" means a person who is licensed, registered, or certified in Indiana as a health care professional, including, but not limited to, the following:

(1) A physician.
(2) A dentist.
(3) A registered nurse.
(4) An optometrist.
(5) A physical therapist.
(6) An audiologist.
(7) A speech-language pathologist.
(8) A dietitian.
(9) An occupational therapist.
(10) A respiratory therapist.
(11) A hospital licensed under IC 16-10-1 *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-21-2.]*.
(12) A home health agency licensed under IC 16-10-2.5 *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-21-2.]*.

(Indiana State Department of Health; 410 IAC 3.2-1-17; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2170; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3.2-1-18 "Household" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 18. "Household" means all the persons who occupy a housing unit (house or apartment), whether they are related to each other or not, and who are living together as an economic unit. *(Indiana State Department of Health; 410 IAC 3.2-1-18; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2170; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-19 "Inpatient services" defined

Authority: IC 16-35-2-7
Affected: IC 16-21-2; IC 16-35-2

Sec. 19. "Inpatient services" means medically necessary treatment related to a child's identified eligible medical condition that is received during an inpatient stay at a public or private facility licensed in accordance with IC 16-10-1 *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-21-2.]*. Eligible inpatient services include, but are not limited to, the following:

(1) Semiprivate room and specialty care unit room charges.
(2) X-rays.
(3) Laboratory tests.
(4) Use of the operating and recovery rooms.
(5) Drugs and medications.
(6) Oxygen therapy.
(7) Blood products.

Eligible inpatient services do not include personal comfort items, services and supplies not directly related to the care of the child such as guest meals and accommodations, telephone charges, and take home supplies. *(Indiana State Department of Health; 410 IAC 3.2-1-19; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2170; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-20 "Laboratory services" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 20. "Laboratory services" means laboratory procedures that are medically necessary to complete a diagnostic evaluation. Laboratory services shall be performed on an outpatient basis unless inpatient services for this purpose are approved by the director. *(Indiana State Department of Health; 410 IAC 3.2-1-20; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2170; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-21 "Medical specialist" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2; IC 25-22.5

Sec. 21. "Medical specialist" means an individual with an unlimited license to practice medicine under IC 25-22.5 and who is certified by a specialty board that is approved by the American Board of Medical Specialties. *(Indiana State Department of Health; 410 IAC 3.2-1-21; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2170; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-22 "Nonemergent care" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 22. "Nonemergent care" means nonlife threatening situations that require care and follow-up but that require no immediate actions. Nonemergent care is consistent with routine primary care and includes the following:

(1) Immunizations.
(2) Routine follow-up of prior injuries or illness.
(3) Suture removal.
(4) Rashes.
(5) Uncomplicated diarrhea.

(Indiana State Department of Health; 410 IAC 3.2-1-22; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2170; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3.2-1-23 "Person" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 23. "Person" means a corporation, an association, a partnership, or one (1) or more individuals. *(Indiana State Department of Health; 410 IAC 3.2-1-23; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2170; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-24 "Poverty income guidelines" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 24. "Poverty income guidelines" means the poverty income guidelines published annually in the Federal Register, by the Secretary of Health and Human Services, pursuant to 42 U.S.C. 9902(2) and 42 U.S.C. 9847, that provide an update of the poverty income guidelines to account for last year's increase in prices as measured by the Consumer Price Index. *(Indiana State Department of Health; 410 IAC 3.2-1-24; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2170; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-25 "Prescription drugs and medications" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 25. "Prescription drugs and medications" means insulin, insulin syringes, and other generically equivalent drugs and medications requiring a prescription under Indiana or federal law that are medically necessary for treatment or control of a medical condition affecting a child and that are not administered during inpatient care. *(Indiana State Department of Health; 410 IAC 3.2-1-25; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-26 "Primary care physician" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2; IC 25-22.5

Sec. 26. "Primary care physician" means an individual with an unlimited license to practice medicine under IC 25-22.5, providing health care services included in the basic package as defined at 410 IAC 3.2-7-2(b). *(Indiana State Department of Health; 410 IAC 3.2-1-26; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-27 "Primary care visits" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 27. "Primary care visits" means a child's outpatient visit with an approved health care provider that is conducted in accordance with recommendations of the American Academy of Pediatrics and includes the following:

(1) An initial assessment of health problems.
(2) A health history.
(3) Measurements.
(4) Sensory screening.
(5) Developmental and behavioral assessment.
(6) Physical examination.
(7) Medically necessary procedures, including immunizations.
(8) Appropriate discussion.
(9) Referral.

(Indiana State Department of Health; 410 IAC 3.2-1-27; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3.2-1-28 "Processing an application" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 28. "Processing an application" means filling out the application form for the CSHCN program, all activity required for determining whether a child is eligible or ineligible for health care services available through the CSHCN program, and notifying the applicant of the decision. *(Indiana State Department of Health; 410 IAC 3.2-1-28; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-29 "Secondary care visits" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 29. "Secondary care visits" means a child's outpatient visit with an approved provider that includes, but is not limited to, an assessment of health problems and treatment of diagnosed uncomplicated health conditions and eligible medical conditions. *(Indiana State Department of Health; 410 IAC 3.2-1-29; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001,*

2:23 p.m.: 24 IR 4234)

410 IAC 3.2-1-30 "State department of health" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 30. "State department of health" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 3.2-1-30; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-31 "Surgery" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 31. "Surgery" means necessary professional services for surgical procedures, anesthesia services, use of the operating and recovery room, and supplies medically necessary to treat or correct a child's identified eligible medical condition. *(Indiana State Department of Health; 410 IAC 3.2-1-31; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-32 "Temporarily" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 32. "Temporarily" means, for purposes of determining financial eligibility, a child or family is temporarily living within another household or family if the child lives within the family or household for six (6) months or less. *(Indiana State Department of Health; 410 IAC 3.2-1-32; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-33 "Therapy" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 33. "Therapy" means physical therapy, occupational therapy, speech and hearing therapy, nursing and other professional health care services provided by an approved provider and necessary to treat a child's eligible medical condition. *(Indiana State Department of Health; 410 IAC 3.2-1-33; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2171; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-1-34 "X-rays" defined

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 34. "X-rays" means x-ray procedures that are medically necessary to complete a diagnostic evaluation. X-rays shall be performed on an outpatient basis unless the director approved inpatient services for a specific purpose. *(Indiana State Department of Health; 410 IAC 3.2-1-34; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2172; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. Application

410 IAC 3.2-2-1 Eligibility to apply

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. (a) The following persons may apply for a child to receive health care services through the CSHCN program:
(1) A child's parent (regardless of age).

(2) A child's legal guardian.

(3) An emancipated child who is under twenty-one (21) years of age, who is married or single, and who is not dependent on the child's parents for support.

(4) A county department, if a child is a ward of the county.

(5) A licensed child placing agency, if a child has been placed in their legal guardianship.

(b) To apply for services, a parent, legal guardian, or emancipated child shall complete a written application.

(c) The state department of health shall not accept or process applications for children who are living in state operated penal and correctional institutions, state mental hospitals, the Indiana Soldiers' and Sailors' Children's Home, or other facilities where provisions for health care are made for children.

(d) The ability of a person to apply for the CSHCN program is not affected by lack of citizenship unless the child, the child's parents, or the child's legal guardian is in the United States on visas or under circumstances that limit their eligibility to receive public funds. The ability of a person to apply is not affected by the length of time of the person's residency in Indiana. A person must remain a resident in Indiana to continue receiving health care or care coordination services through the CSHCN program. *(Indiana State Department of Health; 410 IAC 3.2-2-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2172; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-2-2 Intake location

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 2. (a) A person may apply for the CSHCN program at a county department located in the county where the child who may receive services through the CSHCN program resides or at any other location approved by the director.

(b) The director shall publish in the Indiana Register the address of approved locations other than the county departments where a child may apply for the CSHCN program. *(Indiana State Department of Health; 410 IAC 3.2-2-2; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2172; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-2-3 County to county transfers

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 3. (a) When a child or the child's family moves from one (1) county to another county, the child or the child's family shall immediately notify the child's CSHCN program care coordinator.

(b) Whenever a county department is aware that a child or a child's family has moved to another county, the county department shall notify the child's CSHCN program care coordinator in writing of the child's new address. *(Indiana State Department of Health; 410 IAC 3.2-2-3; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2172; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-2-4 Application process and enrollment in the Medicaid program

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 4. (a) The state department of health shall not complete the processing of an application and enrollment for the CSHCN program until the applicant shows evidence that the child is enrolled in the Medicaid program or that the child has applied for the Medicaid program.

(b) All children currently enrolled in the CSHCN program shall also meet the conditions specified in subsection (a).

(c) Refusal to comply with the provisions in subsection (a) shall be sufficient cause for the state department of health to deny or cancel enrollment and participation in the CSHCN program.

(d) If a child is denied enrollment in the Medicaid program, the state department of health shall complete the processing of the child's application for the CSHCN program. If the state department of health determines that a child is financially and medically eligible for the CSHCN program, the effective date for payment of services provided by the CSHCN program shall be the date that the applicant submitted a written application form, for processing, for health care services through the CSHCN program.

(e) Children who are enrolled in the Medicaid program may apply for enrollment in the CSHCN program for the following

purposes only:

(1) Care coordination services.

(2) Access to the CSHCN program's regional diagnostic and treatment centers.

(3) Access to other approved providers.

(f) Costs of all eligible services, including travel reimbursement, for children dually enrolled in the Medicaid program and the CSHCN program shall be charged to the Medicaid program. The CSHCN program shall not pay for services that are paid for by the Medicaid program.

(g) Dual enrollment in no way expands the range of services that the CSHCN program provides or pays for.

(h) Dual enrollment does not create a right for children enrolled in the CSHCN program to receive or to be provided by the CSHCN program the range of services available, provided, or paid for by the Medicaid program.

(i) Any person who contracts with the state department of health to provide services shall be limited to the compensation provided for under the terms of the contract. *(Indiana State Department of Health; 410 IAC 3.2-2-4; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2172; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-2-5 State department of health responsibilities in the application process

Authority: IC 16-35-2-7
Affected: IC 4-21.5; IC 16-35-2

Sec. 5. (a) The processing of an application shall only be completed by the state department of health.

(b) The state department of health shall review the information and recommendations submitted by the county department.

(c) The state department of health may request additional information or clarification from the county department, and the county department shall provide such information upon request.

(d) The state department of health shall make the determination of financial and medical eligibility to participate in the CSHCN program after reviewing information submitted by the county department, provide the applicant with written notice of the decision taken on the application, and advise the applicant in writing of the right to reapply or appeal the decision in accordance with the Administrative Orders and Procedures Act (IC 4-21.5 et seq.).

(e) Except as provided in 410 IAC 3.2-4-1, the director shall set an effective date for payment of health care services as the date that a child or child's family submitted a written application form, for processing, for health care services through the CSHCN program. The director may set the effective date for payment of health care services retroactive up to a maximum of seven (7) working days according to the need for health care services. *(Indiana State Department of Health; 410 IAC 3.2-2-5; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2173; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-2-6 County department responsibilities in application process

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 6. (a) The county department shall accept and act on all applications, signed by an applicant, except as provided in section 4 of this rule and 410 IAC 3.2-4-1.

(b) The county department shall be responsible for assisting in the completion of the application form and for all other activity necessary to determine whether the child is financially eligible or ineligible for services under the CSHCN program. The county department shall submit to the state department of health its recommendations concerning the financial eligibility or ineligibility of the child.

(c) To assist in the completion of the application process, the county department shall do the following:

(1) Accept applications for the CSHCN program in accordance with section 1 of this rule.

(2) Explain the information that the applicant needs to supply the county department.

(3) Assist the child and family in completing the CSHCN and Medicaid applications.

(4) Explain the available CSHCN program health care and care coordination services.

(5) Inform families that they are required to inform the county department or state department of health of significant changes in financial circumstances or of a change of address.

(6) Explain the eligibility requirements.

(7) Explain the appeals process.

(8) Verify the child's age by reviewing the child's birth certificate.

(9) Verify the child's residency by reviewing at least one (1) of the following:

(A) Rent or property payment receipts.

(B) Utility records.

(C) City directory.

(D) Voter's registration.

(E) Driver's license.

(F) Federal income tax returns.

(10) Explain any other information provided or requested by the director.

(11) Document the type of services that the applicant is requesting.

(12) Document the child's medical problem according to the applicant.

(13) Document the name of the physician or other provider, including hospitals or emergency departments, that last examined the child and the date and location of the most recent physical examination.

(14) Document health insurance information in accordance with 410 IAC 3.2-5-1.

(d) Except as provided in section 4 of this rule and 410 IAC 3.2-4-1, the county department shall act on all applications and forward all applications to the state department of health within thirty (30) calendar days of the date of application.

(e) The county department shall recommend denial of an application for one (1) or more of the following reasons, including, but not limited to:

(1) Voluntary withdrawal by the applicant.

(2) Location of the child or family is unknown.

(3) Failure of the child or family to cooperate in the processing of the application.

(4) For a child not enrolled as of December 31, 1992, the child or the child's family is financially ineligible for the CSHCN program.

(5) Child or the child's family fails or refuses to apply for the Medicaid program in accordance with section 4 of this rule.

(f) The county department shall forward to the state department of health, within thirty (30) calendar days of the date of application, the recommendation to deny an application. The county department shall include written documentation to substantiate the recommended decision. *(Indiana State Department of Health; 410 IAC 3.2-2-6; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2173; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 3. Reevaluation of Eligibility

410 IAC 3.2-3-1 Reevaluation of eligibility and criteria for closure

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. (a) The state department of health shall reevaluate the financial eligibility and medical eligibility of the children enrolled in the CSHCN program no less frequently than every twelve (12) months.

(b) Upon completion of an annual reevaluation, the state department of health shall stop providing or paying for health care services as of a date certain for one (1) or more of the following reasons, including, but not limited to:

(1) Death of the child.

(2) Child has reached twenty-one (21) years of age.

(3) Child is no longer an Indiana resident.

(4) Location of child or family is unknown.

(5) Child or the child's family refuses further health care services.

(6) Child is institutionalized in a public or private facility that provides health care services.

(7) Child or the child's family fails to cooperate in the process of determining or reevaluating financial or medical eligibility.

(8) For a child not enrolled as of December 31, 1992, the child or the child's family is financially ineligible for the CSHCN program.

(9) For a child not enrolled as of December 31, 1992, the child's physical condition no longer meets the criteria for medical eligibility for the CSHCN program.

(10) Child or the child's family voluntarily withdraws from the CSHCN program.

(11) Failure of the child or family to disclose or utilize health insurance benefits.

(12) Failure of the child or family to disclose any of the following:

(A) Monetary gifts.

(B) Contributions.

(C) Funds raised by popular subscription to assist a child.

(D) Prizes.

(E) Winnings.

(F) Awards.

(G) Inheritances.

(13) The recommendations contained in the child and family service plan have been met.

(c) Any child enrolled in the program as of December 31, 1992, shall be deemed financially and medically eligible and shall not thereafter be removed from the program solely because the child would become medically or financially ineligible under 410 IAC 3.2-6-1(a), 410 IAC 3.2-6-1(b), or 410 IAC 3.2-6-2(b). *(Indiana State Department of Health; 410 IAC 3.2-3-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2174; errata filed Jul 27, 1993, 9:00 a.m.: 16 IR 2859; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 4. Availability of Funds

410 IAC 3.2-4-1 Availability of CSHCN funds

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. (a) The availability and range of all health care services, care coordination services, and travel reimbursement provided to children enrolled in the CSHCN program and their families is contingent upon the availability of funding.

(b) If the commissioner makes a written determination that sufficient funds, in addition to those required to fund services for children already enrolled in the program, are not appropriated or otherwise available to support the costs of health care services for children not already enrolled in the CSHCN program, the state department of health shall document the need for such funds or services by accepting application inquiries in accordance with the provisions specified in this rule.

(c) Applications filed and in the possession of the state department of health prior to the commissioner's written determination, but upon which no determination of eligibility has been made, shall be processed.

(d) If the commissioner subsequently makes a written determination that sufficient funds are appropriated or otherwise available to support the cost of health care services for additional children, the state department of health shall notify, in writing, those persons whose application inquiries are in the possession of the state department of health and who may now be eligible to have their application processed as determined by the availability of funding.

(e) The commissioner shall cause the posting of written notices in conspicuous places in the CSHCN program offices and clinics and in other locations where such notices are likely to be seen by prospective applicants when a determination has been made as described in subsection (b). The written notices shall state the following:

(1) That as of a date certain, the CSHCN program is no longer processing applications because of insufficient funds.

(2) Any other information the state department of health may deem necessary.

(f) The commissioner shall cause the posting of the notice set forth in subsection (e) at least fourteen (14) days prior to terminating the processing of applications for the CSHCN program.

(g) If the commissioner has made a written determination that processing of applications shall not continue, the county department shall, nevertheless, continue to obtain, from prospective applicants, an application inquiry form containing the following information:

(1) Name, address, and telephone number.

(2) Date that the prospective applicant came to the county department to make an application inquiry.

(3) Any other additional information required by the commissioner.

(h) The county department shall inform the prospective applicant that the signing of the application inquiry form and providing of information described in subsection (g) does not mean that the state department of health will process the application inquiry. The prospective applicant shall also be informed the completion and mailing of the application inquiry by the county department to the state department of health does not necessarily ensure eligibility for health care services under the CSHCN program. The county department shall also provide any additional information to the prospective applicant as may be required by the

commissioner.

(i) The county department shall send the information provided in accordance with subsection (g) to the state department of health within fourteen (14) days of the filling out of the application inquiry as described in subsection (g).

(j) The commissioner shall cause the posting of written notices in conspicuous places in the CSHCN program offices and regional diagnostic and treatment centers and in other locations where such notices are likely to be seen by prospective applicants when the CSHCN program reinstates processing applications.

(k) The written notices shall state the following:

(1) The CSHCN program is reopening the processing of applications.

(2) Prospective applicants must contact the county department to complete the application.

(3) The effective date for payment of health care services.

(4) The prospective applicant's failure to contact the county department within thirty (30) days of notification shall result in the application not being processed.

(l) The state department of health shall also notify, in writing, the county department concerning the reopening of the CSHCN program. The written notice shall include the following information:

(1) The estimated number of prospective applicants that may be processed within the limitations of available funding.

(2) An individual listing of the prospective applicants residing within the county whose applications may be eligible for processing.

(m) The state department of health shall mail written notification to the county department and prospective applicants within fourteen (14) days of the date that the commissioner determines that the CSHCN program will resume processing applications.

(n) The county department shall keep copies of the written notification to the prospective applicants and shall make a written record of any other efforts made to notify the prospective applicants. These records shall be made a part of the county department's CSHCN program files and shall be open to the director for review.

(o) The state department of health will reopen the CSHCN program to prospective applicants in the order that the application inquiry information described in subsection (g) is received by the state department of health.

(p) For purposes of this rule, a transfer from one (1) county to another of a child already receiving health care services under the CSHCN program shall not be considered to be a new applicant unless the child or family has not notified their CSHCN care coordinator in accordance with 410 IAC 3.2-5-2. *(Indiana State Department of Health; 410 IAC 3.2-4-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2174; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 5. Information

410 IAC 3.2-5-1 Health insurance information and utilization

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. (a) The county department shall document information on any health insurance that the child's family may have.

(b) Families shall provide health insurance information to the county department. Families shall also release health insurance information to the providers when services are rendered.

(c) Families that are reimbursed directly by an insurance company shall reimburse the provider.

(d) The CSHCN program shall be a payor of last resort. Providers shall bill a family's health care insurance prior to submitting a claim to the CSHCN program for payment of a claim. Providers shall include an insurance rejection or payment statement on the claim when submitting the claim to the CSHCN program for payment. *(Indiana State Department of Health; 410 IAC 3.2-5-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2176; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-5-2 Family responsibility to disclose information

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 2. A person who is applying for CSHCN services or a family of a child enrolled in the CSHCN program shall immediately do the following:

(1) Inform the child's CSHCN care coordinator of changes in their financial circumstances that may affect the family's

financial eligibility.

(2) Inform the child's CSHCN care coordinator of any plans that the family has to move to a new address within the current county of residence, to another county, or to another state.

(3) Inform the child's CSHCN care coordinator of changes in the child's medical condition that may affect the child's medical eligibility.

(4) Inform the child's CSHCN care coordinator of any changes in the child's health insurance benefits.

(Indiana State Department of Health; 410 IAC 3.2-5-2; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2176; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 6. Eligibility

410 IAC 3.2-6-1 Financial eligibility

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. (a) A child not enrolled as of December 31, 1992, is financially eligible for the CSHCN program services set forth in 410 IAC 3.2-7-2 and 410 IAC 3.2-7-3 if the child's family's gross income is equal to or less than one hundred eighty-five percent (185%) of the financial eligibility standard. A child must also be medically eligible according to section 2 of this rule.

(b) If funds are available in addition to those required to provide services to enrolled children eligible under subsection (a), and if the gross income of the family of a child not enrolled as of December 31, 1992, is greater than one hundred eighty-five percent (185%), but less than or equal to two hundred fifty percent (250%) of the financial eligibility standard, such child may be determined to be financially eligible to receive CSHCN program services or insurance. A child must also be medically eligible according to section 2 of this rule.

(c) To determine financial eligibility under the CSHCN program, the county department shall utilize the financial eligibility schedule equal to one hundred eighty-five percent (185%) of the poverty income guideline by family size. The state department of health shall provide the county department with the financial eligibility schedule.

(d) The state department of health shall publish annually in the Indiana Register the poverty income guidelines used to determine the financial eligibility for the CSHCN program.

(e) For purposes of determining financial eligibility, income includes the following:

(1) Public assistance or welfare payments.

(2) Monetary compensation for services, including wages, salary, commissions, or fees.

(3) Net income from farm and nonfarm self-employment.

(4) Social Security.

(5) Dividends or interest on savings, stocks or bonds, income from estates or trusts, or net rental income.

(6) Unemployment compensation.

(7) Government pensions, civilian or military, or veterans' payments.

(8) Private pensions or annuities.

(9) Alimony or child support.

(10) Regular contributions from persons not living in the household.

(11) Net royalties.

(12) Other cash income not previously designated. Other cash income includes, but is not limited to:

(A) cash amounts received or withdrawn from any source, including savings, investments, trust accounts, lottery, or other prize winnings;

(B) settlements or awards resulting from lawsuits;

(C) monetary gifts;

(D) contributions and funds raised by popular subscription; and

(E) other resources that are available to the child's family.

(f) For purposes of determining financial eligibility, the following shall not be considered income:

(1) Payments or allowances received pursuant to the Home Energy Assistance Act of 1980.

(2) The value of assistance to children or their families under the National School Lunch Act, the Child Nutrition Act of 1966, and the Food Stamp Act of 1977.

(3) Reimbursements from the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970.

(4) Any payment to volunteers under Title I (VISTA and others), Title II (RSVP - foster grandparents, and others) of the Domestic Volunteer Service Act of 1973.

(5) Payment to volunteers under Section 8 of the Small Business Act (SCORE and ACT).

(6) Payments received under the Job Training Partnership Act.

(7) Educational grants and student loans.

(8) College or university assistantships.

(9) Subsidized housing.

(10) Food allowance or subsidized housing for military personnel or military housing allowances received by families living off base.

(g) If an individual or family is temporarily living within another household, only the income of child or family applying for the CSHCN program shall be used for determining financial eligibility.

(h) The county department shall verify a family's income by reviewing any one (1) or more of the following:

(1) A card or other written documentation indicating that the applicant is currently enrolled in the Special Supplemental Food Program for Women, Infants, and Children (WIC).

(2) Check stubs from the three (3) most recent consecutive pay periods.

(3) Most recently filed federal income tax form.

(4) Other written documentation approved by the director.

(i) Farm income may be determined by having the applicant show the applicant's most recently filed Internal Revenue Service tax form.

(j) Nonfarm self-employment may be determined by having the applicant show the most recently filed Internal Revenue Service tax form.

(k) Monetary compensation for services, including wages, commissions, or fees may be determined by having the applicant show the most recently filed Internal Revenue Service tax form.

(l) If an applicant states that they receive no income, the county department shall ask the applicant, and document in writing, how the applicant receives economic support for food, shelter, clothing, health care, and other needs. The county department and the state department of health may use this information to assist with care coordination services and referrals.

(m) Income received irregularly shall be averaged over a twelve (12) month period.

(n) If a child marries after the child is enrolled in the CSHCN program, the child's financial eligibility shall be reevaluated.

(o) If a child is adopted after the child is enrolled in the CSHCN program, and there is a court order for support of the child, the child shall continue to be financially eligible for the CSHCN program. *(Indiana State Department of Health; 410 IAC 3.2-6-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2176; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-6-2 Medical eligibility

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 2. (a) To be medically eligible for the CSHCN program, a child shall meet the following requirements:

(1) Be under twenty-one (21) years of age.

(2) Have a physical condition that has lasted or is expected to last at least two (2) years if not treated and the physical condition necessitates more health care services than is usually required for a child of that age.

(3) The physical condition also produces or will produce disability, disfigurement, limitation of function, need for a special diet, or dependence on an assistive device; or nonintervention will, within one (1) year, lead to a chronic disabling physical condition.

(4) Have at least one (1) of the eligible medical conditions defined in subsection (b).

(b) For a child not enrolled in the program as of December 31, 1992, the medical conditions eligible for the CSHCN program are the following:

(1) Apnea defined by one (1) or more of the following criteria:

(A) Infants at high risk for recurring apnea defined by one (1) or more of the following criteria:

(i) Infants with one (1) or more severe apparent life threatening events (ALTE) requiring resuscitation or vigorous stimulation.

(ii) Preterm infants with symptomatic apnea.

(iii) Infants who have had two (2) or more siblings that have been Sudden Infant Death Syndrome (SIDS) victims.

(iv) Infants at high risk of apnea from medical conditions such as central hypoventilation syndrome, myotonic dystrophy, or Arnold Chiari malformation.

(B) Infants at possible increased risk for recurring apnea defined by one (1) or more of the following criteria:

(i) Infants with tracheostomies.

(ii) Infants with craniofacial anomalies such as Pierre Robin.

(iii) Infants with bronchopulmonary dysplasia.

(iv) Infants with myelodysplasia.

(C) Infants shall be reassessed for the need for continued monitoring at least every six (6) months.

(2) Arthritis resulting in disability.

(3) Asthma defined by one (1) or more of the following criteria:

(A) Requiring daily therapy with two (2) or more prescription medications, including, but not limited to, the following:

(i) Inhaled bronchodilators.

(ii) Inhaled cromolyn.

(iii) Inhaled corticosteroid.

(iv) Theophylline.

(v) Oral steroids (daily or every other day).

(vi) Inhaled ipratropium bromide or atropine.

(B) Despite taking appropriate daily medication, more than two (2) hospitalizations for asthma, each lasting at least four (4) days, have occurred within the last twelve (12) months.

(C) Hospitalization for asthma has been required for more than fifteen (15) days in a single twelve (12) month period.

(4) Cerebral palsy or other static encephalopathy resulting in loss of motor function or dysarthria.

(5) Chronic anemia requiring two (2) or more blood transfusions or resulting in two (2) or more crises requiring hospitalization.

(6) Cleft lip or palate, or both.

(7) Congenital or acquired developmental deformities.

(8) Congenital heart disease or arrhythmias requiring electrophysiologic studies, catheterization, or surgery on the heart or major vessels.

(9) Chromosomal disorders resulting in loss of motor function or expressive language function.

(10) Chronic pulmonary disease defined by one (1) or more of the following criteria:

(A) Oxygen dependent as defined by requiring supplemental oxygen to maintain a resting PO_2 greater than seventy (70) millimeters of mercury or an oxygen saturation greater than ninety-two percent (92%).

(B) Requiring oxygen (same criteria as in clause (A)) during feeding or during sleep.

(C) Requiring continuous positive alveolar pressure (CPAP).

(D) Requiring three (3) or more medicines or treatments, including, but not limited to, the following:

(i) Inhaled bronchodilator.

(ii) Inhaled antiinflammatory drugs, such as Intal or corticosteroids.

(iii) Daily theophylline.

(iv) Daily diuretics.

(v) Antihypertensive medication.

(vi) Digoxin.

(vii) High calorie feedings or nutritional supplements.

(viii) Gastrostomy or naso-oro gastric/duodenal/jejunal feedings.

(ix) Tracheostomy.

(x) Home cardiorespiratory monitor.

(xi) Mechanical ventilation, full-time or part-time.

(xii) Other technologic support, such as feeding pump or suction equipment.

(xiii) Home oxygen therapy for longer than two (2) months.

(11) Cystic fibrosis.

(12) Endocrine deficiencies requiring the following replacement therapy longer than five (5) years, including the following:
(A) Hypothyroidism.
(B) Adrenocortical insufficiency.
(C) Insulin dependent diabetes mellitus.
(D) Panhypopituitarism.
Growth hormone therapy for isolated short stature without other medical indications is not an eligible medical condition.
(13) Bilateral hearing loss greater than forty (40) decibels.
(14) Hemophilia requiring factor replacement at least two (2) times a year.
(15) Hydrocephalus requiring or likely to require a shunt during childhood.
(16) Inflammatory bowel disease requiring multiple hospitalizations within the past two (2) years, resection of the bowel, or hyperalimentation for longer than one (1) month.
(17) Inborn errors of metabolism that have a potential for a significantly improved outcome if treated with a special diet or prescription medication.
(18) Neuromuscular dysfunction.
(19) Myelodysplasia or other spinal cord dysfunction.
(20) Oncologic disorders.
(21) Progressive or chronic renal disease with hypertension or renal insufficiency.
(22) Epilepsy requiring daily prescription medication.

(Indiana State Department of Health; 410 IAC 3.2-6-2; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2177; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 7. Delivery Systems

410 IAC 3.2-7-1 Health care service delivery system

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. (a) The director shall select and approve physicians and other persons to provide health care services to children enrolled in the CSHCN program.

(b) To enable the child to receive health care services in a setting that is most appropriate for the type of medical condition affecting the child, the director may assign a child enrolled in the CSHCN program to receive the eligible health care services set forth in sections 2 and 3 of this rule from one (1) or more approved primary care physicians, medical specialists, or other health care providers.

(c) The CSHCN program shall only pay for the health care services set forth in section 2 of this rule if such health care services are provided in the state of Indiana.

(d) Health care services set forth in section 3 of this rule may be provided outside the state of Indiana if the director determines that the specific health care service is not readily available to a child within the state of Indiana. *(Indiana State Department of Health; 410 IAC 3.2-7-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2179; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-7-2 Basic services included in the health care service package

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 2. (a) The availability and provision of health care services included in the basic service component is contingent upon the availability of program funding.

(b) The CSHCN program shall pay no greater than the Medicaid rate for any health care services included in the basic service package as defined as follows:

(1) Primary care visits conducted by approved providers in accordance with recommendations from the American Academy of Pediatrics.
(2) Secondary care visits at approved providers for medically necessary diagnostic and treatment services.
(3) Drugs and medications requiring a prescription under Indiana or federal law that are medically necessary for treatment

or control of any medical conditions affecting the child. Insulin and insulin syringes shall be provided when prescribed by an approved provider.

(4) Immunizations required by Indiana law and administered in accordance with recommendations from the American Academy of Pediatrics and the Centers for Disease Control.

(c) The CSHCN program shall provide or pay only for generically equivalent drugs and medications unless a generically equivalent drug or medication is not available or is medically contraindicated.

(d) If a prescription is filled under the CSHCN program, the pharmacist shall substitute a generically equivalent drug product if the substitution would result in a lower price unless:

(1) the words "Brand Medically Necessary" are written in the practitioner's own writing on the form; or

(2) the practitioner has indicated that the pharmacist may not substitute a generically equivalent drug product by orally stating that a substitution is not permitted.

(e) If the practitioner orally states that a generically equivalent drug product may not be substituted, the practitioner must subsequently forward to the pharmacist a written prescription with the "Brand Medically Necessary" instruction appropriately indicated in the physician's own handwriting.

(f) The brand name of the prescribed drug product may not be included on the prescription container label unless it is the drug product actually dispensed.

(g) The pharmacist shall record on the prescription the name of the manufacturer or distributor, or both, of the actual drug product dispensed under this section.

(h) The CSHCN program shall not pay for over-the-counter drugs, medications, or supplies. Vitamins, nutritional supplements, and formula shall be provided only when medically necessary for treatment of an eligible medical condition, when these items are not provided through other programs, including, but not limited to, the Special Supplemental Food Program for Women, Infants, and Children (WIC) and when authorized by the director. *(Indiana State Department of Health; 410 IAC 3.2-7-2; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2179; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3.2-7-3 Limited health care services included in the health care service package

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 3. (a) The availability and provision of health care services included in the limited service component is contingent upon the availability of program funding.

(b) Available funds may be utilized to purchase insurance or pay for one (1) or more of the following health care services authorized as appropriate to the eligible medical condition or conditions of an enrolled child:

(1) Inpatient services.
(2) Emergency services.
(3) Durable equipment and supplies.
(4) X-rays and laboratory services.
(5) Surgery.
(6) Dental services.
(7) Therapy.

(c) The CSHCN program shall only provide or pay for health care services or insurance set forth in subsection (a) or (b) if the director has approved the health care services as necessary or appropriate for the conditions, as listed under subsection (d), (e), or (f).

(d) Level I eligible medical conditions are defined in 410 IAC 3.2-6-2 and shall include the following:

(1) Apnea.
(2) Arthritis.
(3) Asthma.
(4) Bilateral hearing loss.
(5) Epilepsy.
(6) Hydrocephalus.
(7) Neuromuscular dysfunction.

(e) Level II eligible medical conditions are defined in 410 IAC 3.2-6-2 and shall include the following:

(1) Cerebral palsy.
(2) Chromosomal disorders.
(3) Cleft lip or palate, or both.
(4) Congenital or acquired developmental deformities.
(5) Endocrine deficiencies.
(6) Inborn errors of metabolism.
(7) Hemophilia.
(8) Inflammatory bowel disease.
(f) Level III eligible medical conditions are defined in 410 IAC 3.2-6-2 and shall include the following:
(1) Chronic anemia.
(2) Chronic pulmonary disease.
(3) Congenital heart disease or arrhythmias.
(4) Cystic fibrosis.
(5) Myelodysplasia or spinal cord dysfunction.
(6) Oncologic diseases.
(7) Progressive or chronic renal disease.
(g) The director shall have the authority to determine medical eligibility and the services or insurance to be provided under the program. *(Indiana State Department of Health; 410 IAC 3.2-7-3; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2180; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 8. Coordination Services

410 IAC 3.2-8-1 Care coordination services
Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. The availability and provision of care coordination services is contingent upon the availability of CSHCN program funding. *(Indiana State Department of Health; 410 IAC 3.2-8-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2180; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 9. Travel

410 IAC 3.2-9-1 Travel reimbursement
Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. (a) The availability and provision of travel reimbursement is contingent upon the availability of CSHCN program funding.
(b) The director may reimburse a child or family travel expenses incurred in transporting a child to approved health care providers.
(c) The director shall provide travel reimbursement in accordance with state travel policies and procedures established by the department of administration and approved by the state budget agency.
(d) The director shall not reimburse a child or family for total distances traveled that are less than fifty (50) miles per round trip. *(Indiana State Department of Health; 410 IAC 3.2-9-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2180; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 10. Confidentiality

410 IAC 3.2-10-1 Confidentiality

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. The state department of health shall treat the medical information of children applying for and enrolled in the CSHCN program as confidential and follow all appropriate state and federal laws regarding the confidentiality of medical information. *(Indiana State Department of Health; 410 IAC 3.2-10-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2181; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 11. Advisory Council

410 IAC 3.2-11-1 Advisory council

Authority: IC 16-35-2-7
Affected: IC 16-35-2

Sec. 1. The director shall periodically report to the advisory council on the administration of the CSHCN program, including, but not limited to, providing information on the fiscal status of the CSHCN program. *(Indiana State Department of Health; 410 IAC 3.2-11-1; filed Apr 12, 1993, 5:00 p.m.: 16 IR 2181; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 3.5. INFORMED CONSENT FORM FOR ABORTION (EXPIRED)

(Expired under IC 4-22-2.5, effective January 1, 2002.)

ARTICLE 4. INDUSTRIAL HYGIENE (REPEALED)

(Repealed by Indiana State Department of Health; filed Oct 24, 1996, 4:00 p.m.: 20 IR 752)

ARTICLE 5. RADIOLOGICAL HEALTH

Rule 1. General Provisions

410 IAC 5-1-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. Pursuant to the authority found in IC 13-1-2-9 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* providing for the granting, suspending, revoking, or amending general or specific licenses for radioactive materials and the registration of radiation sources. Nothing in 410 IAC 5 shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.1; filed May 26, 1978, 3:30 pm: 1 IR 127; filed Feb 29, 1984, 10:10 am: 7 IR 829; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-2 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. As used in 410 IAC 5, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

"Accelerator-produced material" means any material made radioactive by exposing it in a particle accelerator.

"Act" means the Radiation Control Act of Indiana, IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, Indiana General Assembly.

"Agreement state" means any state with which the United States Nuclear Regulatory Commission has entered into an effective agreement under Section 274 b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases.

"Airborne radioactivity area" means (1) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations in excess of the amounts specified in Table I, Column 1 of 410 IAC 5-4-27; or (2) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in Table I, Column 1 of 410 IAC 5-4-27.

"Board" means executive board of the Indiana state board of health or its duly authorized representatives.

"Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of 410 IAC 5 except at the beginning of a calendar year.

"Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

"CFR" means Code of Federal Regulations (1982 Edition).

"Controlled area" see "Restricted area."

"Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie = 3.7×10^{7} tps. One microcurie ($^{\mu}$Ci) = 0.000001 curie = 3.7×10^{4} tps. (See 410 IAC 5-1-10.5 for SI equivalent becquerel.)

"Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

"Dose" as used in 410 IAC 5 shall mean absorbed dose or dose equivalent as appropriate.

"Absorbed dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad. (See rad.) (See 410 IAC 5-1-10.5 for SI equivalent gray.)

"Dose equivalent" is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose equivalent is the rem. (See rem.) (See 410 IAC 5-1-10.5 for SI equivalent sievert.)

"Dose commitment" means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake, the period of exposure to retained material will not exceed 50 years.

*"Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. (The special unit of exposure is the roentgen (R).) (See 410 IAC 5-1-10.5 for SI equivalent coulomb per kilogram).

*(When not indicated as above or indicated as "exposure (X)," the term "exposure" has a more general meaning in 410 IAC 5.)

"Exposure rate" means the exposure per unit of time, such as R/min, mR/h etc.

"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants or critical mass experimental facilities where AEC or NRC licenses have been terminated.

"Healing arts" includes any system, treatment, operation, diagnosis, prescription or practice for the ascertainment, cure, relief, palliation, adjustment or correction of any human or animal disease, ailment, deformity, injury or unhealthy or abnormal physical or mental condition.

"High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 100 millirems.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Individual" means any human being.

"Inspection" means an official examination or observation including but not limited to tests, surveys, and monitoring to

determine compliance with rules, regulations, orders, requirements and conditions of the board.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"License" means a license issued by the board in accordance with 410 IAC 5 and IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

"Licensee" means any person who is licensed by the board in accordance with 410 IAC 5 and IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

"Licensing state" means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Section 71.4 of 10 CFR Part 71.

"NARM" means any naturally-occurring or accelerator-produced radioactive material. It does not include byproduct, source or special nuclear material.

"Natural radioactivity" means radioactivity of naturally-occurring nuclides.

"Occupational dose" means exposure of an individual to radiation (1) in a restricted area or (2) in the course of employment in which the individual's duties involve exposure to radiation provided that occupational dose shall not be deemed to include any exposure of an individual to radiation for the purpose of diagnosis or therapy of such individual.

"Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing.

"Personnel monitoring equipment" means devices (e.g. film badges, pocket dosimeters, and thermoluminescent dosimeters) designed to be worn or carried by an individual for the purpose of estimating the dose received by the individual.

"Pharmacist" means an individual licensed by the state of Indiana to compound and dispense drugs, prescriptions, and poisons.

"Physician" means an individual licensed by the state of Indiana to dispense drugs in the practice of medicine.

"Rad" means the special unit of absorbed dose. One rad equals one hundredth of a joule per kilogram of material; for example, if tissue is the material of interest, then 1 rad equals 100 ergs per gram of tissue.

"Radiation" means ionizing radiation; i.e., gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, high speed protons, and other nuclear particles.

"Radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirems, or in any 5 consecutive days a dose in excess of 100 millirems.

"Radiation machine" means any device capable of producing radiation except those which produce radiation only from radioactive material.

"Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection regulations.

"Radioactive material" means any material (solid, liquid or gas) which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Registrant" means any person who is registered with the board and is legally obligated to register with the board as required by 410 IAC 5 and IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

"Registration" means registration with the board in accordance with 410 IAC 5.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

"Rem" means a special unit of dose equivalent. (One millirem (mrem) = 0.001 rem.) For the purpose of 410 IAC 5, any of the following is considered to be equal to one rem:

(1) An exposure of 1 roentgen of x or gamma radiation;

(2) An absorbed dose of 1 rad due to x, gamma or beta radiation;

(3) An absorbed dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye;

(4) An absorbed dose of 0.1 rad due to neutrons or high energy protons.[1/] (See 410 IAC 5-1-10.5 for SI equivalent sievert.)

[1/] If it is more convenient to measure the neutron flux or equivalent than to determine the neutron absorbed dose in rads, one rem of neutron radiation may, for purposes of 410 IAC 5, be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

Neutron Flux Dose Equivalents

Neutron energy (MeV)	Number of neutrons per square centimeter for a dose equivalent to 1 rem (neutrons/cm^2)	Average flux density to deliver 100 millirems in 40 hours (neutrons/cm^2 per second)
Thermal	970×10^6	670
0.0001	720×10^6	500
0.005	820×10^6	570
0.02	400×10^6	280
0.1	120×10^6	80
0.5	43×10^6	30
1.0	26×10^6	18
2.5	29×10^6	20
5.0	26×10^6	18
7.5	24×10^6	17
10.0	24×10^6	17
10 to 30	14×10^6	10

"Research and development" means: (1) theoretical analysis, exploration, or experimentation or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Restricted area" (controlled area) means any area access to which is controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material. "Restricted area" shall not include any areas used for residential quarters although a separate room or rooms in a residential building may be set apart as a restricted area.

"Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58×10^{-4} coulombs/kilogram of air (see "Exposure").

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Source material" means: (1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of byproduct material as defined by definition (2) of source material.

"Source of radiation" means any radioactive material or any device or equipment emitting or capable of producing radiation.

"Special form" means any of the following physical forms of licensed material of any transport group:

(1) The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than five (5) millimeters; does not melt, sublime or ignite in air at a temperature of 1000° F (538° C); will not shatter or crumble if subjected to the percussion test described in Appendix B, 410 IAC 5-1-12; and is not dissolved or converted into dispersible form to the extent of more than 0.005 percent by weight by immersion for 1 week in water at 68° F (20° C) or in air at 86° F (30° C); or

(2) The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one dimension greater than five (5) millimeters, which will retain its contents if subjected to the tests prescribed in Appendix B, 410 IAC 5-1-12; and which is constructed of materials which do not melt, sublime or ignite in air at 1475° F (802° C), and do not dissolve or convert into dispersible form to the extent of more than 0.005 percent by weight by immersion for 1 week in water

at 68° F (20° C) or in air at 86° F (30° C).

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235, U-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{176 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

"Survey" means an evaluation of the production, use, release, disposal, and/or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes but is not limited to tests, physical examination and measurements of levels of radiation or concentration of radioactive material present.

"Test" means the process of verifying compliance with the applicable sections of 410 IAC 5.

"Transport group" means any one of seven groups into which radionuclides in normal form are classified according to their toxicity and their relative potential hazard in transport (see Appendix A, 410 IAC 5-1-11).

(1) Any radionuclide not specifically listed in one of the groups in Appendix A, 410 IAC 5-1-11 shall be assigned to one of the groups in accordance with the following table:

	Radioactive half-life		
Radionuclide	0 to 1000 days	1000 days to 10^6 years	Over 10^6 years
Atomic number 1-81	Group III	Group II	Group III
Atomi number 82 and over	Group I	Group I	Group III

(2) For mixtures of radionuclides the following shall apply:

(i) If the identity and respective activity of each radionuclide are known, the permissible activity of each radionuclide shall be such that the sum for all groups present of the ratio between the total activity for each group to the permissible activity for each group will not be greater than unity.

(ii) If the groups of the radionuclides are known but the amount in each group cannot be reasonably determined, the mixture shall be assigned to the most restrictive group present.

(iii) If the identity of all or some of the radionuclides cannot be reasonably determined, each of those unidentified radionuclides shall be considered as belonging to the most restrictive group which cannot be positively excluded.

(iv) Mixtures consisting of a single radioactive decay chain where the radionuclides are in the naturally-occurring proportions shall be considered as consisting of a single radionuclide. The group and activity shall be that of the first member present in the chain, except that if a radionuclide "X" has a half-life longer than that of the first member and an activity greater than that of any other member, including the first, at any time during transportation, the transport group of the nuclide "X" and the activity of the mixture shall be the maximum activity of that nuclide "X" during transportation.

"U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers, and components and transferred to the U.S. Energy Research and Development Administration and to the administrator thereof pursuant to sections 104(b), (c), and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

"Uncontrolled area" see "Unrestricted area."

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" (uncontrolled area) means any area access to which is not controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive material and any area used for residential quarters.

"Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal and/or persons

licensed to dispose of radioactive waste.

"Worker" means any individual engaged in work under a license or registration issued by the board and controlled by a licensee or registrant but does not include the licensee or registrant. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.2; filed May 26, 1978, 3:30 pm: 1 IR 127; filed Feb 29, 1984, 10:10 am: 7 IR 829; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-3 Exemptions from rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) General Provision. The board may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of 410 IAC 5 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(b) Carriers. Common and contract carriers, freight forwarders, and warehousemen, who are subject to the rules and regulations of the U.S. Department of Transportation or the U.S. Postal Service are exempt from 410 IAC 5 to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Private carriers who are subject to the rules and regulations of the U.S. Department of Transportation are exempted from 410 IAC 5 to the extent that they transport sources of radiation. Common, contract, and private carriers who are not subject to the rules and regulations of the U.S. Department of Transportation or the U.S. Postal Service are subject to applicable sections of 410 IAC 5.

(c) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within the state of Indiana is exempt from 410 IAC 5 to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(3) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

(4) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state of Indiana and the U.S. Nuclear Regulatory Commission jointly determine:

(i) that the exemption of the prime contractor or subcontractor is authorized by law; and

(ii) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.3; filed May 26, 1978, 3:30 pm: 1 IR 130; filed Feb 29, 1984, 10:10 am: 7 IR 834; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-1-4 Recordkeeping

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.4; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-5 Inspections of facilities and records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Each licensee and registrant shall afford the board at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(b) Each licensee and registrant shall make available to the board for inspection, upon reasonable notice, records maintained pursuant to 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.5; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-6 Tests

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. Each licensee and registrant shall perform upon instructions from the board, or shall permit the board to perform such reasonable tests as the board deems appropriate or necessary including, but not limited to, tests of:

(a) sources of radiation;

(b) facilities wherein sources of radiation are used or stored;

(c) radiation detection and monitoring instruments; and

(d) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.6; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-7 Additional requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. The board may by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in 410 IAC 5 as it deems appropriate or necessary to minimize danger to public health and safety or property. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.7; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-8 Violations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. Any person who willfully violates any provision of 410 IAC 5 or order issued thereunder will be subject to controls in IC 13-1-2-20 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and IC 13-1-2-21 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.8; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 835; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-9 Prohibited devices

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Hand-held fluoroscopic screens shall not be used.

(b) Shoe-fitting fluoroscopic devices shall not be used. *(Indiana State Department of Health; Rule HRH-2,PT A,Sec A.9; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 836; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-10 Board address

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. All communications and reports concerning 410 IAC 5, and applications filed thereunder, should be addressed to the board at its office located at the Indiana State Board of Health, 1330 West Michigan Street, Indianapolis, Indiana 46206. *(Indiana*

State Department of Health; Rule HRH-2,PT A,Sec A.10; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 836; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-1-10.5 International system of units

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10.5. The Metric Conversion Act of 1975 (PL 94-168) urged the increasing awareness and use of the International System of Units (SI). Where appropriate, schedules and appendices are provided with notes concerning conversion factors. The inclusion of the SI equivalent is for informational purposes only.

(a) Absorbed dose. The unit of absorbed dose is the gray (Gy), which is equal to 1 joule per kilogram. One rad is equal to 1×10^{-2} gray. Sub-multiples included in this document are the milligray (mGy) and the microgray (μGy).

(b) Dose equivalent. The unit of dose equivalent is the sievert (Sv) which is equal to 1 joule per kilogram. One rem is equal to 1×10^{-2} sievert. Sub-multiples included in this document are the millisievert (mSv) and the microsievert (μSv).

(c) Exposure. The unit of exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram. Submultiples of this unit are the millicoulomb per kilogram (mC/kg) and the microcoulomb per kilogram (μC/kg).

(d) Radioactivity. The unit of measurement of radioactivity is the becquerel (Bq) and is equal to one transformation per second. One curie is equal to 3.7×10^{10} becquerels. Multiples included in this document are kilobecquerel (kBq), megabecquerel (MBq), gigabecquerel (GBq), and petabecquerel (PBq). *(Indiana State Department of Health; 410 IAC 5-1-10.5; filed Feb 29, 1984, 10:10 am: 7 IR 836; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-11 Transport grouping of radionuclides

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11.

APPENDIX A

TRANSPORT GROUPING OF RADIONUCLIDES

Element[1/]	Radionuclide[2/]	Group
Actinium (89)	Ac-277	I
	Ac-228	I
Americium (95)	Am-241	I
	Am-243	I
Antimony (51)	Sb-122	IV
	Sb-124	III
	Sb-125	III
Argon (18)	Ar-37	VI
	Ar-41	II
	Ar-41 (uncompressed)[3/]	V
Arsenic (33)	As-73	IV
	As-74	IV
	As-76	IV
	As-77	IV
Astatine (85)	At-211	III
Barium (56)	Ba-131	IV

	Ba-133	II
	Ba-140	III
Berkelium (97)	Bk-249	I
Beryllium (4)	Be-7	IV
Bismuth (83)	Bi-206	IV
	Bi-207	III
	Bi-210	II
	Bi-212	III
Bromine (35)	Br-82	IV
Cadmium (48)	Cd-109	IV
	Cd-115m	III
	Cd-115	IV
Calcium (20)	Ca-45	IV
	Ca-47	IV
Californium (98)	Cf-249	I
	Cf-250	I
	Cf-252	I
Carbon (6)	C-14	IV
Cerium (58)	Ce-141	IV
	Ce-143	IV
	Ce-144	III
Cesium (55)	Cs-131	IV
	Cs-134m	III
	Cs-134	III
	Cs-135	IV
	Cs-136	IV
	Cs-137	III
Chlorine (17)	Cl-36	III
	Cl-38	IV
Chromium (24)	Cr-51	IV
Cobalt (27)	Co-56	III
	Co-57	IV
	Co-58m	IV
	Co-58	IV
	Co-60	III
Copper (29)	Cu-64	IV
Curium (96)	Cm-242	I
	Cm-243	I
	Cm-244	I
	Cm-245	I

	Cm-246	I
Dysprosium (66)	Dy-154	III
	Dy-165	IV
	Dy-166	IV
Erbium (68)	Er-169	IV
	Er-171	IV
Europium (63)	Eu-150	III
	Eu-152m	IV
	Eu-152	III
	Eu-154	II
	Eu-155	IV
Fluorine (9)	F-18	IV
Gadolinium (64)	Gd-153	IV
	Gd-159	IV
Gallium (31)	Ga-67	III
	Ga-72	IV
Germanium (32)	Ge-71	IV
Gold (79)	Au-193	III
	Au-194	III
	Au-195	III
	Au-196	IV
	Au-198	IV
	Au-199	IV
Hafnium (72)	Hf-181	IV
Holmium (67)	Ho-166	IV
Hydrogen (1)	H-3 (see tritium)	
Indium (49)	In-113m	IV
	In-114m	III
	In-115m	IV
	In-115	IV
Iodine (53)	I-124	III
	I-125	III
	I-126	III
	I-129	III
	I-131	III
	I-132	IV
	I-133	III
	I-134	IV
	I-135	IV
Iridium (77)	Ir-190	IV

	Ir-192	III
	Ir-194	IV
Iron (26)	Fe-55	IV
	Fe-59	IV
Krypton (36)	Kr-85m	III
	Kr-85m (uncompressed).[3/]	V
	Kr-85	III
	Kr-85 (uncompressed).[3/]	VI
	Kr-87	II
	Kr-87 (uncompressed).[3/]	V
Lanthanum (57)	La-140	IV
Lead (82)	Pb-203	IV
	Pb-210	II
	Pb-212	II
Lutetium (71)	Lu-172	III
	Lu-177	IV
Magnesium (12)	Mg-28	III
Manganese (25)	Mn-52	IV
	Mn-54	IV
	Mn-56	IV
Mercury (80)	Hg-197m	IV
	Hg-197	IV
	Hg-203	IV
Mixed fission products (MFP)		II
Molybdenum (42)	Mo-99	IV
Neodymium (60)	Nd-147	IV
	Nd-149	IV
Neptunium (93)	Np-237	I
	Np-239	I
Nickel (28)	Ni-56	III
	Ni-59	IV
	Ni-63	IV
	Ni-65	IV
Niobium (41)	Nb-93m	IV
	Nb-95	IV
	Nb-97	IV
Osmium (76)	Os-185	IV
	Os-191m	IV
	Os-191	IV
	Os-193	IV

Palladium (46)	Pd-103	V
	Pd-109	IV
Phosphorus (15)	P-32	IV
Platinum (78)	Pt-191	IV
	Pt-193	IV
	Pt-193m	IV
	Pt-197m	IV
	Pt-197	IV
Plutonium (94)	Pu-238(F)	I
	Pu-239(F)	I
	Pu-240	I
	Pu-241(F)	I
	Pu-242	I
Polonium (84)	Po-210	I
Potassium (19)	K-42	IV
	K-43	III
Praseodymium (59)	Pr-142	IV
	Pr-143	IV
Promethium (61)	Pm-147	IV
	Pm-149	IV
Protactinium (91)	Pa-230	I
	Pa-231	I
	Pa-233	II
Radium (88)	Ra-223	II
	Ra-224	II
	Ra-226	I
	Ra-228	I
Radon (86)	Rn-220	IV
	Rn-222	II
Rhenium (75)	Re-183	IV
	Re-186	IV
	Re-187	IV
	Re-188	IV
	Re-Natural	IV
Rhodium (45)	Rh-103m	IV
	Rh-105	IV
Rubidium (37)	Rb-86	IV
	Rb-87	IV
	Rb-Natural	IV
Ruthenium (44)	Ru-97	IV

	Ru-103	IV
	Ru-105	IV
	Ru-106	III
Samarium (62)	Sm-145	III
	Sm-147	III
	Sm-151	IV
	Sm-153	IV
Scandium (21)	Sc-46	III
	Sc-47	IV
	Sc-48	IV
Selenium (34)	Se-75	IV
Silicon (14)	Si-31	IV
Silver (47)	Ag-105	IV
	Ag-110m	III
	Ag-111	IV
Sodium (11)	Na-22	III
	Na-24	IV
Strontium (38)	Sr-85m	IV
	Sr-85	IV
	Sr-89	III
	Sr-90	II
	Sr-91	III
	Sr-92	IV
Sulfur (16)	S-35	IV
Tantalum (73)	Ta-182	III
Technetium (43)	Tc-96m	IV
	Tc-96	IV
	Tc-97m	IV
	Tc-97	IV
	Tc-99m	IV
	Tc-99	IV
Tellurium (52)	Te-125m	IV
	Te-127m	IV
	Te-127	IV
	Te-129m	III
	Te-129	IV
	Te-131m	III
	Te-132	IV
Terbium (65)	Tb-160	III
Thallium (81)	Tl-200	IV

	Tl-201	IV
	Tl-202	IV
	Tl-204	III
Thorium (90)	Th-227	II
	Th-228	I
	Th-230	I
	Th-231	I
	Th-232	III
	Th-234	II
	Th-Natural	III
Thulium (69)	Tm-168	III
	Tm-170	III
	Tm-171	IV
Tin (50)	Sn-113	IV
	Sn-117m	III
	Sn-121	III
	Sn-125	IV
Tritium (1)	H-3	IV
	H-3 (as a gas, as luminous paint, or adsorbed on solid material).	VII
Tungsten (74)	W-181	IV
	W-185	IV
	W-187	IV
Uranium (92)	U-230	II
	U-232	I
	U-233 (F)	II
	U-234	II
	U-235(F)	III
	U-236	II
	U-238	III
	U-Natural	III
	U-Enriched (F)	III
	U-Depleted	III
Vandium (23)	V-48	IV
	V-49	III
Xenon (54)	Xe-125	III
	Xe-131m	III
	Xe-131m (uncompressed).[3/]	V
	Xe-133	III

	Xe-133 (uncompressed).[3/]	VI
	Xe-135	II
	Xe-135 (uncompressed).[3/]	V
Ytterbium (70)	Yb-175	IV
Yttrium (39)	Y-88	III
	Y-90	IV
	Y-91m	III
	Y-91	III
	Y-92	IV
	Y-93	IV
Zinc (30)	Zn-65	IV
	Zn-69m	IV
	Zn-69	IV
Zirconium (40)	Zr-93	IV
	Zr-95	III
	Zr-97	IV

[1/] Atomic number shown in parentheses.

[2/] Atomic mass number shown after the element symbol.

[3/] Uncompressed means at a pressure not exceeding one atmosphere.

m Metastable state.

(F) Fissile material.

For any radionuclide not specifically listed or for mixtures of radionuclides, refer to the definition of "transport group" in 410 IAC 5-1-2. *(Indiana State Department of Health; Rule HRH-2,PT A,Appendix A; filed May 26, 1978, 3:30 pm: 1 IR 131; filed Feb 29, 1984, 10:10 am: 7 IR 836; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-1-12 Tests for special form licensed material

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12.

APPENDIX B TESTS FOR SPECIAL FORM LICENSED MATERIAL

(1) Free Drop–A free drop through a distance of 30 feet (9.14 meters) onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage.

(2) Percussion–Impact of the flat circular end of a 1 inch (2.54 centimeters) diameter steel rod weighing 3 pounds (1.36 kilograms), dropped through a distance of 40 inches (1.02 meters). The capsule or material shall be placed on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than 1 inch (2.54 centimeters) thick, supported by a smooth essentially unyielding surface.

(3) Heating–Heating in air to a temperature of 1475° F (801.67° C) and remaining at that temperature for a period of 10 minutes.

(4) Immersion–Immersion for 24 hours in water at room temperature. The water shall be at pH 6-pH 8, with a maximum conductivity of 10 micromhos per centimeter. *(Indiana State Department of Health; Rule HRH-2,PT A,Appendix B; filed May 26, 1978, 3:30 pm: 1 IR 134; filed Feb 29, 1984, 10:10 am: 7 IR 839; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. Registration of Radiation Machine Facilities and Services

410 IAC 5-2-1 Scope of rules; registration of materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. (a) 410 IAC 5-2 provides for the registration of radiation machine facilities.

(b) In addition to the requirements of 410 IAC 5-2, all registrants are subject to the applicable provisions of other sections of 410 IAC 5.

(c) In addition to 410 IAC 5-2-1(a) and 410 IAC 5-2-1(b) each person who receives, possesses, uses, transfers or acquires radioactive material shall register such materials with the board in accordance with the requirements of 410 IAC 5-2. This requirement is effective until the state enters into an effective agreement with the U.S. Nuclear Regulatory Commission for the transfer of regulatory authority under Sec. 274(b) of the Atomic Energy Act of 1954, as amended (73 Stat. 689) at which time 410 IAC 5-3, Licensing of Radioactive Material, becomes effective. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.1; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 839; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-2-2 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) For purposes of 410 IAC 5-2, "facility" means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

(b) Pursuant to 410 IAC 5-2-1(c) "radiation machine" as used throughout 410 IAC 5-2 also refers to radioactive material. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.2; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 840; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-2-3 Exemptions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of 410 IAC 5-2, providing dose equivalent rate averaged over an area of 10 square cm does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of such equipment. The production, testing or factory servicing of such equipment shall not be exempt.

(b) Radiation machines while in transit or storage incident thereto are exempt from the requirements of 410 IAC 5-2.

(c) Domestic television receivers are exempt from the requirements of 410 IAC 5-2. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.3; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 840; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-2-4 Application for registration of facility

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. Each person having a radiation machine facility shall:

(a) Register such facility with the board prior to the operation of a radiation machine facility. The registration shall be completed on forms furnished by the board and shall contain all the information required by the form and accompanying instructions.

(b) Designate on the application form an individual to be responsible for radiation protection.

(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.4; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 840; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-2-5 Issuance of registration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Upon a determination that an applicant meets the requirements of 410 IAC 5, the board shall issue a registration.

(b) The board may incorporate in the registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation machines as it deems appropriate or necessary. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.5; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 840; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-2-6 Notice of changes

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. The registrant shall notify the board in writing before making any change which would render the information contained in the registration no longer accurate. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.6; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-2-7 Advertising prohibitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. No person, in any advertisement, shall refer to the fact that he or his facility is registered with the board pursuant to the provisions of 410 IAC 5-2 and no person shall state or imply that any activity under such registration has been approved by the board. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.7; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-2-8 Dealers and assemblers; duties; notice and reports to board

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this state shall notify the board within 15 days of:

(1) the name and address of persons who have received these machines;

(2) the manufacturer, model, and serial number of each radiation machine transferred; and

(3) the date of transfer of each radiation machine.

(b) In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30(d)) shall be submitted to the board within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

(c) No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.8; filed May 26, 1978, 3:30 pm: 1 IR 135; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-2-9 Bringing radiation machine into state; application

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the board at least two (2) working days before such machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; the exact location(s)

where the radiation machine is to be used; and states in which this machine is registered. If for a specific case the two working-day period would impose an undue hardship on the person, he may, upon application to the board, obtain permission to proceed sooner.

(b) The person referred to in 410 IAC 5-2-9(a) shall:

(1) comply with all applicable requirements of the board including the certification of x-ray machine operators;

(2) supply the board with such other information as the board may reasonably request; and

(3) not operate within the state on a temporary basis in excess of 180 calendar days per year.

(Indiana State Department of Health; Rule HRH-2,PT B,Sec B.9; filed May 26, 1978, 3:30 pm: 1 IR 136; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 3. Licensing of Radioactive Material

410 IAC 5-3-1 Effective dates (Repealed)

Sec. 1. *(Repealed by Indiana State Department of Health; filed Feb 29, 1984, 10:10 am: 7 IR 829)*

410 IAC 5-3-2 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) 410 IAC 5-3 provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to 410 IAC 5-3 or as otherwise provided in 410 IAC 5-3.

(b) Provisions for the licensing of radioactive materials as set forth in 410 IAC 5-3 shall become effective on the date of an effective agreement between the U.S. Nuclear Regulatory Commission and the state for the transfer of regulatory authority under Section 274b of the Atomic Energy Act of 1954, as amended (73 Stat 689); however, NARM materials are covered by all applicable provisions of 410 IAC 5.

(c) In addition to the requirements of 410 IAC 5-3, all licensees are subject to the requirements of 410 IAC 5-1, 410 IAC 5-4 and 410 IAC 5-10. Licensees engaged in industrial radiographic operations are subject to the requirements of 410 IAC 5-5 and licensees using sealed sources in the healing arts are subject to the requirements of 410 IAC 5-7, and licensees engaged in wireline and subsurface tracer studies are subject to the requirements of 410 IAC 5-10.1. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.1; filed May 26, 1978, 3:30 pm: 1 IR 136; filed Feb 29, 1984, 10:10 am: 7 IR 841; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-3 Exemption of source materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses, owns or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution or alloy.

(b) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from 410 IAC 5-3 to the extent that such person receives, possesses, uses or transfers:

(1) Any quantities of thorium contained in:

(i) incandescent gas mantles,

(ii) vacuum tubes,

(iii) welding rods,

(iv) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

(v) germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that each lamp does not contain

more than 2 grams of thorium,

(vi) rare earth metals and compounds, mixtures and products containing not more than 0.25 percent by weight thorium, uranium or any combination of these, or

(vii) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium:

(2) Source material contained in the following products:

(i) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

(ii) glassware, glass enamel and glass enamel frit containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction, or

(iii) piezoelectric ceramic containing not more than 2 percent by weight source material;

(3) Photographic film, negatives and prints containing uranium or thorium;

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

(i) The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40.

(ii) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM", [1/]

(iii) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",[1/] and

(iv) This exemption shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

(6) Uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION–RADIOACTIVE SHIELDING–URANIUM" and which meets the specifications for containers for radioactive material prescribed in Section 173.394 or 173.395 of 49 CFR Part 173 of U.S. Department of Transportation regulations;

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

(i) the shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

(ii) the receipt, possession, use or transfer of thorium contained in contact lenses or in spectacles or in eyepieces in binoculars or other optical instruments;

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(i) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

(ii) the thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

(d) The exemptions in 410 IAC 5-3-3(c)(2), do not authorize the manufacture of any of the products described.

[1/] The requirements specified in 410 IAC 5-3-3(c)(5)(ii) and (iii) need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION–RADIOACTIVE MATERIAL–URANIUM", as previously required by 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.3; filed May 26, 1978, 3:30 pm: 1 IR 136; filed Feb 29, 1984, 10:10 am: 7 IR 842; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-4 Exemption of materials other than source materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. (a) Exempt Concentrations

(1) Except as provided in 410 IAC 5-3-4(a)(2), any person is exempt from this part to the extent that such person receives,

possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Schedule A, 410 IAC 5-3-26.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 410 IAC 5-3-4(a)(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued pursuant to 410 IAC 5-3-13(a) or the general license provided in 410 IAC 5-3-24.

(b) Exempt Quantities

(1) Except as provided in 410 IAC 5-3-4(b)(3) and (4), any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B, 410 IAC 5-3-27.

(2) 410 IAC 5-3-4(b) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

(3) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, 410 IAC 5-3-27, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 410 IAC 5-3-4(b) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 or by the board pursuant to 410 IAC 5-3-13(b) which license states that the radioactive material may be transferred by the licensee to persons exempt under 410 IAC 5-3-4(b) or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or licensing state.[2/]

(c) Exempt Items

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from 410 IAC 5 to the extent that he receives, possesses, uses, transfers, owns or acquires the following products:[2/]

(i) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified radiation dose rate:

(A) 25 millicuries of tritium per timepiece,

(B) 5 millicuries of tritium per hand,

(C) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),

(D) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece,

(E) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand,

(F) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial),

(G) The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(aa) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface,

(bb) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface,

(cc) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(H) One microcurie of radium-226 per timepiece in timepieces acquired prior to the effective date of 410 IAC 5.

(ii) Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber;

(iii) Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part;

(iv) Automobile shift quadrants containing not more than 25 millicuries of tritium;

(v) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas;

(vi) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat;

(vii) Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

(A) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(B) 1 microcurie of cobalt-60;

(C) 5 microcuries of nickel-63;

(D) 30 microcuries of krypton-85;

(E) 5 microcuries of cesium-137;

(F) 30 microcuries of promethium-147;

And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber;[3/]

(viii) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

(A) Each source contains no more than one exempt quantity set forth in Schedule B, 410 IAC 5-3-27, and

(B) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B, 410 IAC 5-3-27, provided that the sum of such fractions shall not exceed unity.

(ix) Spark gap irradiators containing not more than 1 microcurie of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liters) per hour.

(2) Self-Luminous Products Containing Radioactive Material.

(i) Tritium, Krypton-85 or Promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 410 IAC 5-3-4(c)(2) does not apply to tritium, krypton-85 or promethium-147 used in products for frivolous purposes or in toys or adornments.

(ii) Radium-226. Any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers or owns articles containing less than 0.1 microcurie of radium-226 which were acquired prior to the effective date of 410 IAC 5.

(3) Gas and aerosol detectors containing radioactive material.

(i) Except for persons who manufacture, process or produce gas and aerosol detectors containing radioactive material, any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission[2/] pursuant to Section 32.26 of 10 CFR Part 32; or a licensing state pursuant to 410 IAC 5-3-13(c) which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(ii) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under 410 IAC 5-3-4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and provided further that they meet the requirements of 410 IAC 5-3-13(c).

(iii) Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under 410 IAC 5-3-4(c)(3)(i), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of 410 IAC 5-3-13(c).

(4) Resins containing scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from 410 IAC 5 to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing

scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the board or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

[2/] Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

[3/] For purposes of 410 IAC 5-3-4(c)(1)(vii) "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.4; filed May 26, 1978, 3:30 pm: 1 IR 137; filed Feb 29, 1984, 10:10 am: 7 IR 843; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-5 Types of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. Licenses for radioactive materials are of two types: general and specific.

(a) General licenses provided in 410 IAC 5-3 are effective without the filing of applications with the board or the issuance of licensing documents to the particular persons, although the filing of a certificate with the board may be required by the particular general license. The general licensee is subject to all other applicable portions of 410 IAC 5 and any limitations of the general license.

(b) Specific licenses require the submission of an application to the board and the issuance of a licensing document by the board. The licensee is subject to all applicable portions of 410 IAC 5 as well as any limitations specified in the licensing document. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.20; filed May 26, 1978, 3:30 pm: 1 IR 139; filed Feb 29, 1984, 10:10 am: 7 IR 845; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-6 General licenses for source materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

(b) Persons who receive, possess, use or transfer source material pursuant to the general license issued in 410 IAC 5-3-6(a) are exempt from the provisions of 410 IAC 5-4 and 410 IAC 5-10 of 410 IAC 5 to the extent that such receipt, possession, use or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to 410 IAC 5-3-6.

(c) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

(d) Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 410 IAC 5-3-6(d)(2), (3), (4) and (5) depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 410 IAC 5-3-6(d)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 410 IAC 5-3-13(m) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an

agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(3)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) shall file board form "W" "Registration Certificate–Use of Depleted Uranium Under General License," with the board. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on board form "W" the following information and such other information as may be required by that form:

(A) Name and address of the registrant;

(B) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d)(3)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by 410 IAC 5-3-6(d)(1) shall report in writing to the board any changes in information furnished by him in board form W "Registration Certificate–Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1):

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(ii) Shall not abandon such depleted uranium;

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 410 IAC 5-3-22. In the case where the transferee receives the depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form "W", 410 IAC 5-3-32. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or agreement state's rule equivalent to 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form "W" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 410 IAC 5;

(iv) Within 30 days of any transfer, shall report in writing to the board the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(v) Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1)is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the depleted uranium covered by that general license.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.21; filed May 26, 1978, 3:30 pm: 1 IR 140; filed Feb 29, 1984, 10:10 am: 7 IR 846; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-7 General licenses for materials other than source materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. General Licenses*–Radioactive Material Other Than Source Material. (a) Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested, and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-4(a)(2), 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, 410 IAC 5-3-25, 410 IAC 5-4,[4/] and 410 IAC 5-10.

*Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

[4/] Attention is directed particularly to the provisions of 410 IAC 5-4 which relates to the labeling of containers.

(1) Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(2) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.

(b) Reserved

(c) Reserved

(d) Certain Measuring, Gauging or Controlling Devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of 410 IAC 5-3-7(d)(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere.

(2) The general license in 410 IAC 5-3-7(d)(1) applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the board pursuant to 410 IAC 5-3-13(d) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.[5/]

[5/] Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(3) Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in 410 IAC 5-3-7(d)(1):

(i) Shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(ii) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator if any, at no longer than six-month intervals or at such other intervals as are specified on the label; however,

(A) Devices containing only krypton need not be tested for leakage of radioactive material, and

(B) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) Shall assure that other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed:

(A) In accordance with the instructions provided by the labels; or

(B) By a person holding an applicable specific license from the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such activities;

(iv) Shall maintain records showing compliance with the requirements of 410 IAC 5-3-7(d)(3)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by 410 IAC 5-3-7(d)(3)(ii) shall be maintained for 1 year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the on/off mechanism and indicator required by 410 IAC 5-3-7(d)(3)(ii) shall be maintained for 1 year after the next required test of the on/off mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by 410 IAC 5-3-7(d)(3)(iii) shall be maintained for a period of 2 years from the date of the recorded event or until the device is transferred or disposed of;

(v) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on/off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired

by the manufacturer or other person holding an applicable specific license from the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the board a report containing a brief description of the event and the remedial action taken;

(vi) Shall not abandon the device containing radioactive material;

(vii) Except as provided in 410 IAC 5-3-7(d)(3)(viii), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the board a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

(viii) Shall transfer the device to another general licensee only:

(A) Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of 410 IAC 5 and any safety documents identified in the label on the device and within 30 days of the transfer, report to the board the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the board and the transferee; or

(B) Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

(ix) Shall comply with the provisions of 410 IAC 5-4-22 and 410 IAC 5-4-23 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of 410 IAC 5-4 and 410 IAC 5-10.

(4) The general license in 410 IAC 5-3-7(d)(1) does not authorize the manufacture of devices containing radioactive material.

(5) The general license provided in 410 IAC 5-3-7(d)(1) is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

(e) Luminous Safety Devices for Aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(i) Each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147; and

(ii) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the board or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in 410 IAC 5-3-7(e)(1) are exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 except that they shall comply with the provisions of 410 IAC 5-4-22 and 410 IAC 5-4-23.

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

(f) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of 410 IAC 5-3, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

(g) Calibration and Reference Sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5), americium-241 in the form of calibration or reference sources:

(i) Any person who holds a specific license issued by the board which authorizes him to receive, possess, use and transfer radioactive material; and

(ii) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5) to any person who holds a specific license issued by the board which authorizes him to receive, possess, use and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with the provisions of 410 IAC 5-3-7(g)(4) and (5) to any person who holds a specific license issued by the board which authorizes him to receive, possess, use and transfer radioactive material.

(4) The general licenses in 410 IAC 5-3-7(g)(1), (2), and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the board, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in 410 IAC 5-3-7(g)(1), (2) and (3) are subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25 and 410 IAC 5-4, and 410 IAC 5-10. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium-241, 5 microcuries of plutonium or 5 microcuries of radium-226 in such sources;

(ii) Shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statements as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

(A) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION–RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS (AMERICIUM-241). (PLUTONIUM)[6/] DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

[6/] Showing only the name of the appropriate material.

(B) The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION–RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

(iii) Shall not transfer, abandon or dispose of such source except by transfer to a person authorized by a license from the board, the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state to receive the source;

(iv) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(h) Medical Diagnostic Uses[7/8/]

[7/] 410 IAC 5-3-13 requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to affix a certain identifying label to the container or in the leaflet or brochure which accompanies the radiopharmaceutical.

[8/] The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician to receive, possess, transfer or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provision of 410 IAC 5-3-7(h)(2), (3), and (4), the radioactive material is in the form of capsules, disposable syringes or other prepackaged individual doses;

and the radioactive material has been manufactured in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(g), or by the U.S. Nuclear Regulatory Commission, any agreement state or a licensing state pursuant to equivalent rules authorizing distribution to persons generally licensed pursuant to 410 IAC 5-3-7(h) or its equivalent.

(i) Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time;

(ii) Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

(iii) Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(iv) Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

(v) Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(vi) Iodine-131 as sodium iodide for measurement of thyroid uptake; and

(vii) Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(2) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) until he has filed board form "U," 410 IAC 5-3-30, "Certificate–Medical Use of Radioactive Material Under General License" with the board and received from the board a validated copy of the board form "U," 410 IAC 5-3-30, with certification number assigned. The generally licensed physician shall furnish on board form "U," 410 IAC 5-3-30, the following information and such other information as may be required by that form:

(i) name and address of the generally licensed physician;

(ii) a statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in Indiana; and

(iii) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of 410 IAC 5-3-7(h) and that he is competent in the use of such instruments.

(3) A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) shall comply with the following:

(i) he shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(h)(1) more than:

(A) 200 microcuries of iodine-131,

(B) 200 microcuries of iodine-125,

(C) 5 microcuries of cobalt-57,

(D) 5 microcuries of cobalt-58,

(E) 5 microcuries of cobalt-60, and

(F) 200 microcuries of chromium-51;

(ii) he shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;

(iii) he shall use the pharmaceutical only for the uses authorized by 410 IAC 5-3-7(h)(1);

(iv) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and

(v) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(4) The generally licensed physician possessing or using radioactive material under the general license of 410 IAC 5-3-7(h)(1) shall report in duplicate to the board, any changes in the information furnished by him in the "Certificate–Medical Use of Radioactive Material Under General License," board form "U." The report shall be submitted within 30 days after the effective date of such change.

(5) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(h)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the radioactive material covered by the general license.

(i) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.[8/]

[8/] The New Drug provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 410 IAC 5-3-7(i)(2), (3), (4), (5),

and (6), the following radioactive materials in prepackaged units for use in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Carbon-14, in units not exceeding 10 microcuries each;

(ii) Cobalt-57, in units not exceeding 10 microcuries each;

(iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each;

(iv) Iodine-125, in units not exceeding 10 microcuries each;

(v) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie iodine-129 and 0.005 microcurie of americium-241 each;

(vi) Iodine-131, in units not exceeding 10 microcuries each;

(vii) Iron-59, in units not exceeding 20 microcuries each;

(viii) Selenium-75, in units not exceeding 10 microcuries each;

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) until he has filed board form "V," 410 IAC 5-3-31, "Certificate–In Vitro Testing with Radioactive Material Under General License," with the board and received from the board a validated copy of board form "V" with certification number assigned, or until he has been authorized pursuant to 410 IAC 5-3-11(c)(3) to use radioactive material under the general license in 410 IAC 5-3-7(i). The physician, veterinarian, clinical laboratory or hospital shall furnish on board form "V" the following information and such other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 410 IAC 5-3-7(i)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) shall comply with the following:

(i) the general licensee shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(i)(1) at any one location of storage or use, a total amount of iodine-125, iodine-131, iron-59, selenium-75, and/or cobalt-57 in excess of 200 microcuries;

(ii) the general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;

(iii) the general licensee shall use the radioactive material only for the uses authorized by 410 IAC 5-3-7(i)(1);

(iv) the general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier;

(v) the general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 410 IAC 5-3-7(i)(1)(viii) as required by 410 IAC 5-4-16.

(4) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to 410 IAC 5-3-7(i)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 410 IAC 5-3-13(h), or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 410 IAC 5-3-7(i) or its equivalent; and

(ii) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory

authority.

_____
Name of manufacturer

(B) This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

_____
Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 410 IAC 5-3-7(i)(1) shall report in writing to the board, any changes in the information furnished by him in the "Certificate–In Vitro Testing with Radioactive Material Under General License," board form "V," 410 IAC 5-3-31. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(i)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to radioactive material covered by that general license, except, that such persons using the Mock Iodine-125 described in 410 IAC 5-3-7(i)(1)(viii) shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

(j) Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the board or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 410 IAC 5-3-7(j)(1),

(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 410 IAC 5-4-16;

(ii) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) Are exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 except that such persons shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of 410 IAC 5-1-4 through 410 IAC 5-1-9, 410 IAC 5-3-15, 410 IAC 5-3-22, 410 IAC 5-3-23, and 410 IAC 5-3-25.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.22; filed May 26, 1978, 3:30 pm: 1 IR 141; filed Feb 29, 1984, 10:10 am: 7 IR 847; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-8 Intrastate transportation of radioactive material; general license (Repealed)

Sec. 8. *(Repealed by Indiana State Department of Health; filed Feb 29, 1984, 10:10 am: 7 IR 829)*

410 IAC 5-3-9 Applications for specific licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Applications for specific licenses shall be filed (in triplicate) on a form prescribed by the board.

(b) The board may at any time after the filing of the original application, and before the expiration of the license, require

further statements in order to enable the board to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the board provided such references are clear and specific. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.24; filed May 26, 1978, 3:30 pm: 1 IR 148; filed Feb 29, 1984, 10:10 am: 7 IR 855; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-10 Approval of specific licenses; environmental reports; surety for site reclamation; long-term care fund

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. A license application will be approved if the board determines that:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 410 IAC 5 in such a manner as to minimize danger to public health and safety or property;

(b) The applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property;

(c) The issuance of the license will not be inimical to the health and safety of the public; and

(d) The applicant satisfies any applicable special requirements in 410 IAC 5-3-11, 410 IAC 5-3-12, 410 IAC 5-3-13.

(e) Environmental Report, Commencement of Construction. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the board determines will significantly affect the quality of the environment, the board, before commencement of construction of the plant or facility in which the activity will be conducted, shall make a determination, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such determination shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(f) Financial Surety Arrangements for Site Reclamation.

(1) Pursuant to applicable state statutes, and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in 410 IAC 5-3-10(f)(4) shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and 410 IAC 5.

(i) The amount of funds to be ensured by such surety arrangements shall be based on board-approved cost estimates.

(ii) Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

(2) The arrangements required in 410 IAC 5-3-10(f)(1) shall be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

(3) Amendments to licenses in effect on the effective date of 410 IAC 5 may be issued providing that the required surety arrangements are established within 90 days after the effective date of 410 IAC 5-3-10(f).

(4) The following specific licensees are required to make financial surety arrangements:

(i) major processors;

(ii) waste handling licensees;

(iii) former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities;

(iv) source material milling operations; and

(v) all others except persons exempt pursuant to 410 IAC 5-3-10(f)(5).

(5) The following persons are exempt from the requirements of 410 IAC 5-3-10(f)(1):

(i) all state, local, or other government agencies, unless they are subject to 410 IAC 5-3-10(f)(4)(ii) or (iv);

(ii) persons authorized to possess no more than 1,000 times the quantity specified in Schedule B, 410 IAC 5-3-27 or combination of radioactive material listed therein as given in Schedule B, 410 IAC 5-3-27, Note 1;

(iii) persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source; or

(iv) persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

(g) Long-Term Care Requirements. Pursuant to the appropriate state statutes, and as otherwise provided, a long-term care fund shall be established by the following specific licensees prior to the issuance of the license or prior to the termination of the license if the applicant chooses at the time of the licensure to provide a surety in lieu of a long-term care fund:[9/]

(1) Waste handling licensees; and

(2) Source material milling licensees.

[9/] Long-term care funding may also be required for former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.25; filed May 26, 1978, 3:30 pm: 1 IR 148; filed Feb 29, 1984, 10:10 am: 7 IR 855; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-11 Specific licenses for human, medical and industrial uses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. (a) Human Use of Radioactive Material in Institutions. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for human use of radioactive material in institutions will be issued if:

(1) The applicant has appointed a medical isotopes committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of radioactive material within that institution. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced, in assay of radioactive material and protection against radiation;

(2) The applicant possesses adequate facilities for the clinical care of patients;

(3) The physician designated on the application as the individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and

(4) The application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

(b) Licensing of Individual Physicians for Human Use of Radioactive Material.

(1) An application by an individual physician or group of physicians for a specific license for human use of radioactive material will be approved if:

(i) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(ii) The application is for use in the applicant's practice in an office outside a medical institution;

(iii) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(iv) The applicant has extensive experience in the proposed use, the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients.

(2) The board will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:

(i) The use of radioactive material is limited to:

(A) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes,

(B) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered,

(C) The performance of in vitro diagnostic studies, or

(D) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(ii) The physician brings the radioactive material with him and removes the radioactive material when he departs (the institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient); and

(iii) The medical institution does not hold a radioactive material license under 410 IAC 5-3-11(a).

(c) Specific Licenses for Certain Groups of Medical Uses of Radioactive Material.

(1) Subject to the provisions of 410 IAC 5-3-11(c)(2), (3), and (4) an application for a specific license pursuant to 410 IAC 5-3-11(a), (b) or (d) for any medical use or uses of radioactive material specified in one or more of Groups I to VI, inclusive, of Schedule C, 410 IAC 5-3-28, will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:

(i) The applicant satisfies the requirements of 410 IAC 5-3-11(a), (b) and (d);

(ii) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;

(iii) The applicant, or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material, have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

(iv) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups; and

(v) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

(2) Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in 410 IAC 5-3-11(c)(1) and Schedule C, 410 IAC 5-3-28, is subject to the following conditions:

(i) For Groups I, II, IV, and V, no licensee or registrant shall receive, possess or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(j), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

(ii) For Group III, no licensee or registrant shall receive, possess or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

(A) Reagent kits not containing radioactive material that are approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state for use by persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, or equivalent regulations; or

(B) Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(k) a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.73 of 10 CFR Part 32, or a specific license issued by an agreement state or a licensing state pursuant to equivalent regulations.

(iii) For Group VI, no licensee or registrant shall receive, possess, or use radioactive material except as contained in a source or device that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(l), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.

(iv) For Group III, any licensee or registrant who uses generators or reagent kits shall:

(A) Elute the generator, or process radioactive material with the reagent kit, in accordance with instructions approved by the U.S. Nuclear Regulatory Commission, an agreement state or licensing state and furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit;

(B) Before administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;

(C) Prohibit the administration to patients of technetium-99m containing more than 1 microcurie of molybdenum-99 per millicurie of technetium-99m, or more than 5 microcuries of molybdenum-99 per administered dose, at the time of administration; and

(D) Maintain for 3 years for board inspection records of the molybdenum-99 test conducted on each elution from

the generator.

(v) For Groups I, II, and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

(A) Chemical and physical form;

(B) Route of administration; and

(C) Dosage range.

(3) Any licensee who is licensed pursuant to 410 IAC 5-3-11 for one or more of the medical use groups in Schedule C, 410 IAC 5-3-28, also is authorized to use radioactive material under the general license in 410 IAC 5-3-7(i) for the specified in vitro uses without filing board form "V" as required by 410 IAC 5-3-7(i)(2); provided, that the licensee is subject to the other provisions of 410 IAC 5-3-7(i).

(4) Any licensee who is licensed pursuant to 410 IAC 5-3-11(c)(1) for one or more of the medical use groups in Schedule C, 410 IAC 5-3-28, also is authorized, subject to the provisions of 410 IAC 5-3-11(c)(4) and (5), to receive, possess and use for calibration and reference standards:

(i) Any radioactive material listed in Group I, Group II, or Group III of Schedule C, 410 IAC 5-3-28, with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total;

(ii) Any radioactive material listed in Group I, Group II, or Group III of Schedule C, 410 IAC 5-3-28, with half-life greater than 100 days in amounts not to exceed 200 microcuries total;

(iii) Technetium-99m in amounts not to exceed 30 millicuries; and

(iv) Any radioactive material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the board pursuant to 410 IAC 5-3-13(l), a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32, or a specific license issued to the manufacturer by an agreement state or a licensing state pursuant to equivalent regulations.

(5)(i) Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to 410 IAC 5-3-11(c)(4) shall cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than 30 days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within 6 months prior to the transfer, the sealed sources should not be used until tested, provided, however, that no leak tests are required when:

(A) The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or

(B) The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within 6 months prior to the date of use or transfer.

(ii) The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the board;

(iii) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with 410 IAC 5-3 and 410 IAC 5-4. A report shall be filed within 5 days of the test with the board describing the equipment involved, the test results, and the corrective action taken.

(6) Any licensee or registrant who possesses and uses calibration and reference sources pursuant to 410 IAC 5-3-11(c)(4)(iv) shall:

(i) Follow the radiation safety and handling instructions approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form; and

(ii) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the board and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.

(d) Human Use of Sealed Sources. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:

(1) Has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training, and

(2) Is a physician.

(e) Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in 410 IAC 5-3-10, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) The applicant will have an adequate program for training radiographers and radiographer's assistants and submits to the board a schedule or description of such program which specifies the:

(i) Initial training,

(ii) Periodic training,

(iii) On-the-job training,

(iv) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with board rules and licensing requirements, and the operating and emergency procedures of the applicant, and

(v) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(2) The applicant has established and submits to the board satisfactory written operating and emergency procedures described in 410 IAC 5-5-13;

(3) The applicant will have an internal inspection system adequate to assure that these rules, license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants; the inspection system shall include the performance of internal inspections at intervals not to exceed 3 months and the retention of records of such inspections for 2 years;

(4) The applicant submits to the board a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(5) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the board a description of such procedures including:

(i) instrumentation to be used,

(ii) method of performing tests, and

(iii) pertinent experience of the individual who will perform the test; and

(6) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.26; filed May 26, 1978, 3:30 pm: 1 IR 148; filed Feb 29, 1984, 10:10 am: 7 IR 856; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-12 Specific licenses of broad scope

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.[10/]

[10/] Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(a) The different types of broad licenses are set forth below:

(1) A “Type A specific license of broad scope” is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A “Type B specific license of broad scope” is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D, 410 IAC 5-3-29, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, 410 IAC 5-3-29, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide,

determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, 410 IAC 5-3-29, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Schedule D, 410 IAC 5-3-29, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule D, 410 IAC 5-3-29, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Schedule D, 410 IAC 5-3-29, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(b) An application for a Type A specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management and persons trained and experienced in the safe use of radioactive material;

(ii) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(iii) The establishment of appropriate administrative procedures to assure:

(A) Control of procurement and use of radioactive material;

(B) Completion of safety evaluations of proposed uses of radiactive *[sic.]* material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(C) Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 410 IAC 5-3-12(b)(3)(iii)(B) prior to use of the radioactive material.

(c) An application for a Type B specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10; and

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(i) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

(ii) The establishment of appropriate administrative procedures to assure:

(A) Control of procurement and use of radioactive material,

(B) Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(C) Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 410 IAC 5-3-12(c)(2)(ii)(B) prior to use of the radioactive material.

(d) An application for a Type C specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(i) A college degree at the bachelor level, or equivalent training experience, in the physical or biological sciences or in engineering, and

(ii) At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

(e) Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to 410 IAC 5-3-12 shall not:

(i) Conduct tracer studies in the environment involving direct release of radioactive material;

(ii) Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

(iii) Conduct activities for which a specific license issued by the board under 410 IAC 5-3-11, 410 IAC 5-3-13 or 410 IAC 5-3-12.5 is required; or

(iv) Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under 410 IAC 5-3-12 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 410 IAC 5-3-12(d).

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.27; filed May 26, 1978, 3:30 pm: 1 IR 152; filed Feb 29, 1984, 10:10 am: 7 IR 861; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-12.5 Specific licenses for source material milling

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12.5. In addition to the requirements set forth in 410 IAC 5-3-9, a specific license for source material milling will be issued if the applicant submits to the board a satisfactory application as described herein and meets the other conditions specified below: (a) An application for a license to receive title to, receive, possess, and use source material for milling or byproduct material as defined in 410 IAC 5-1-2 shall address the following:

(1) Description of the proposed project or action;

(2) Area/site characteristics including geology, topography, hydrology, and meteorology;

(3) Radiological and nonradiological impacts of the proposed project or action, including waterway and groundwater impacts;

(4) Environmental effects of accidents;

(5) Long-term impacts including decommissioning, decontamination, and reclamation; and

(6) Site and project alternatives.

(b) Pursuant to 410 IAC 5-3-10(e), the applicant shall not commence construction of the project until the board has weighed the environmental, economic, technical, and other benefits against the environmental costs and has concluded that the issuance of the license is appropriate.

(c) At least 1 full year prior to any major site construction, a preoperational monitoring program shall be conducted to provide complete baseline data on a milling site and its environs. Throughout the construction and operating phases of the mill, an operational monitoring program shall be conducted to measure or evaluate compliance with applicable standards and regulations; to evaluate performance of control systems and procedures; to evaluate environmental impacts of operation; and to detect potential long-term effects.

(d) Prior to issuance of the license, the applicant shall establish financial surety arrangements consistent with the requirements of 410 IAC 5-3-10(f).

(1) The amount of funds to be ensured by financial surety arrangements shall be based on board-approved cost estimates in an approved plan for decontamination and decommissioning of mill buildings and the milling site to levels which would allow unrestricted use of these areas upon decommissioning, and the reclamation of tailings and/or waste disposal areas. The licensee shall submit this plan in conjunction with an environmental report that addresses the expected environmental impacts of the milling operation, decommissioning and tailings reclamation, and that evaluates alternatives for mitigating these impacts. In establishing specific surety arrangements, the licensee's cost estimates shall take into account total costs that would

be incurred if an independent contractor were hired to perform the decommissioning and reclamation work. In order to avoid unnecessary duplication and expense, the board may accept financial sureties that have been consolidated with financial surety arrangements established to meet requirements of other federal or state agencies and/or local governing bodies for such decommissioning, decontamination, reclamation, and long-term site surveillance, provided such arrangements are considered adequate to satisfy these requirements and that portion of the surety which covers the decommissioning and reclamation of the mill, mill tailings site and associated areas, and the long-term funding charge are clearly identified. The licensee's surety mechanism will be reviewed annually by the board to assure that sufficient funds will be available for completion of the reclamation plan if the work had to be performed by an independent contractor. The amount of surety liability should be adjusted to recognize any increases or decreases resulting from inflation, changes in engineering plans, activities performed, and any other conditions affecting costs. Regardless of whether reclamation is phased through the life of the operation or takes place at the end of operations, an appropriate portion of surety liability shall be retained until final compliance with the reclamation plan is determined. This will yield a surety that is at least sufficient at all times to cover the costs of decommissioning, decontamination, and reclamation of the areas that are expected to be disturbed before the next license renewal. The term of the surety mechanism must be open ended, unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety instrument which is written for a specified period of time (e.g., 5 years) which must be automatically renewed unless the surety agent notifies the beneficiary (the state regulatory agency) and the principal (the licensee) some reasonable time (e.g., 90 days) prior to the renewal date of their intention not to renew. In such a situation, the surety requirement still exists and the licensee would be required to submit an acceptable replacement surety within a brief period of time to allow at least 60 days for the regulatory agency to collect.

(2) The total amount of funds for reclamation or long-term surveillance and control shall be transferred to the United States if title and custody of such material and its disposal site is transferred to the United States upon termination of a license. Such funds include, but are not limited to, sums collected for long-term surveillance and control. Such funds do not, however, include monies held as surety where no default has occurred, and the reclamation or other bonded activity has been performed.

(e) The applicant shall provide procedures describing the means employed to meet the following requirements during the operational phase of any project.

(1) Milling operations shall be conducted so that all effluent releases are below the limits of 410 IAC 5-4 and are as low as is reasonably achievable.

(2) The mill operator shall conduct daily inspection of any tailings or waste retention systems. Such inspections shall be conducted by a qualified engineer or scientist. Records of such inspections shall be maintained for review by the board.

(3) The mill operator shall immediately notify the board of the following:

(i) Any failure in a tailings or waste retention system which results in a release of tailings or waste into unrestricted areas, and

(ii) Any unusual conditions or conditions not contemplated in the design of the retention system which, if not corrected, could lead to failure of the system and result in a release of tailings or waste into unrestricted areas.

(f) Continued Surveillance Requirements for Source Material Mills Having Reclaimed Residues.

(1) The final disposition of tailings or wastes at source material milling sites should be such that the need for ongoing active maintenance is not necessary to preserve isolation. As a minimum, annual site inspections shall be conducted by the government agency retaining ultimate custody of the site where tailings or wastes are stored to confirm the integrity of the stabilized tailings or waste systems and to determine the need, if any, for maintenance and/or monitoring. Results of the inspection shall be reported to the U.S. Nuclear Regulatory Commission within 60 days following each inspection. The U.S. Nuclear Regulatory Commission may require more frequent site inspections, if, on the basis of a site-specific evaluation, such a need appears necessary due to the features of a particular tailings or waste disposal system.

(2) A minimum charge of $250,000 in 1978 dollars to cover the costs of long-term surveillance shall be paid by each mill operator to the board prior to the termination of a uranium or thorium mill license. If site surveillance or control requirements at a particular site are determined, on the basis of a site-specific evaluation, to be significantly greater than those specified in 410 IAC 5-3-13(f)(1), additional funding requirements may be specified by the board. The total charge to cover the costs of long-term surveillance shall be such that, with an assumed 1 percent annual real interest rate, the collected funds will yield interest in the amount sufficient to cover the annual costs of site surveillance. The charge will be reviewed annually to recognize or adjust for inflation.

(Indiana State Department of Health; 410 IAC 5-3-12.5; filed Feb 29, 1984, 10:10 am: 7 IR 863; readopted filed Jul 11, 2001, 2:23

p.m.: 24 IR 4234)

410 IAC 5-3-13 Specific licenses to manufacture, repair, or distribute products containing radioactive materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. (a) Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations. (1) In addition to the requirements set forth in 410 IAC 5-3-10, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 410 IAC 5-3-4(a)(1) will be issued if:

(i) The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

(ii) The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Schedule A, 410 IAC 5-3-26, that reconcentration of the radioactive material in concentrations exceeding those in Schedule A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Each person licensed under 410 IAC 5-3-13(a) shall file an annual report with the board which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to 410 IAC 5-3-13(a) during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

(b) Licensing the Distribution of Radioactive Material in Exempt Quantities.[10/]

(1) An application for a specific license to distribute NARM to persons exempted from 410 IAC 5 pursuant to 410 IAC 5-3-4(b) will be approved if:

(i) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(ii) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(iii) The applicant submits copies of prototype labels and brochures and the board approves such labels and brochures.

(2) The license issued under 410 IAC 5-3-13(b)(1) is subject to the following conditions:

(i) No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

(ii) Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 410 IAC 5-3-4(b). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(A) Identifies the radionuclide and the quantity of radioactivity, and

(B) Bears the words “Radioactive Material.”

(iv) In addition to the labeling information required by 410 IAC 5-3-13(b)(2)(iii), the label affixed to the immediate

container, or an accompanying brochure, shall:

(A) State that the contents are exempt from licensing state requirements;

(B) Bear the words "Radioactive Material–Not for Human Use–Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited–Exempt Quantities Should Not Be Combined;" and

(C) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(3) Each person licensed under 410 IAC 5-3-13(b) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 410 IAC 5-3-4 or the equivalent regulations of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the board. Each report shall cover the year ending June 30, and shall be filed within thirty (30) days thereafter. If no transfers of radioactive material have been made pursuant to 410 IAC 5-3-13(b) during the reporting period, the report shall so indicate.

[10/] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(c) Licensing the Incorporation of Naturally-Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 410 IAC 5-3-4(c)(3) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie.

(d) Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed Under 410 IAC 5-3-7(d).

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 410 IAC 5-3-7(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state will be approved if:

(i) The applicant satisfies the general requirements of 410 IAC 5-3-10;

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(A) The device can be safely operated by persons not having training in radiological protection;

(B) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in 410 IAC 5-4-2(a); and

(C) Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rems
Other organs	50 rems; and

(iii) Each device bears a durable, legible, clearly visible label or labels approved by the board, which contain in a clearly identified and separate statement:

(A) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;

(B) The requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(C) The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(aa) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[11/], are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(bb) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____[11/], are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION-RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the board will consider information which includes, but is not limited to:

(i) Primary containment or source capsule;

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype test;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material; and

(x) Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 410 IAC 5-3-7(d), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in the table in 410 IAC 5-4-2(a).

(4) Each person licensed under 410 IAC 5-3-13(d) to distribute devices to generally licensed persons shall:

(i) Furnish a copy of the general license contained in 410 IAC 5-3-7(d) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 410 IAC 5-3-7(d);

(ii) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, agreement state's or licensing state's regulation equivalent to 410 IAC 5-3-7(d), or alternatively, furnish a copy of the general license contained in 410 IAC 5-3-7(d) to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the agreement state or the licensing state. If a copy of the general license in 410 IAC 5-3-7(d) is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear

Regulatory Commission, agreement state or licensing state under requirements substantially the same as those in 410 IAC 5-3-7(d);

(iii) Report to the board all transfers of such devices to persons for use under the general license in 410 IAC 5-3-7(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to the persons generally licensed under 410 IAC 5-3-7(d) during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

(iv) Furnish reports to other agencies:

(A) Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31;

(B) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 410 IAC 5-3-13(d) for use under a general license in that state's regulations equivalent to 410 IAC 5-3-7(d);

(C) Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person;

(D) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission;

(E) If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency.

(v) Keep records showing the name, address, and the point of contact for each general licensee to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 410 IAC 5-3-7(d), or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The records should show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person and compliance with the report requirements of 410 IAC 5-3-13(d)(4).

[11/] The model, serial number, and name of manufacturer or distributor may be omitted from this label provided the information is elsewhere specified and labeling affixed to the device.

(e) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 410 IAC 5-3-7(e) will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10, and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32 or their equivalent.

(f) Special Requirements for License to Manufacture Calibration Sources Containing Americium-241, Plutonium, or Radium-226 for Distribution to Persons Generally Licensed Under 410 IAC 5-3-7(g). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under 410 IAC 5-3-7(g) will be approved if:

(1) The applicant satisfies the general requirement of 410 IAC 5-3-10, and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

(g) Manufacture and Distribution of Radioactive Material for Medical Use Under General License. In addition to requirements set forth in 410 IAC 5-3-10, a specific license authorizing the distribution of radioactive material for use by physicians under the general license in 410 IAC 5-3-7(h) will be issued if:

(1) The applicant submits evidence that the radioactive material is to be manufactured, labeled and packaged in accordance

with a new drug application which the Commissioner of Food and Drugs, Food and Drug Administration, has approved, or in accordance with a license for a biologic product issued by the Secretary, U.S. Department of Health and Human Services; and

(2) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to the container or appears in the leaflet or brochure which accompanies the package:

(i) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority,

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Name of manufacturer

(ii) This radioactive drug may be received, possessed, and used only by physicians licensed (to dispense drugs) in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of a licensing state.

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Name of manufacturer

(h) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 410 IAC 5-3-7(i) will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

(i) Carbon-14 in units not exceeding 10 microcuries each;

(ii) Cobalt-57 in units not exceeding 10 microcuries each;

(iii) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(iv) Iodine-125 in units not exceeding 10 microcuries each;

(v) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcuries of americium-241 each;

(vi) Iodine-131 in units not exceeding 10 microcuries each;

(vii) Iron-59 in units not exceeding 20 microcuries each;

(viii) Selenium-75 in units not exceeding 10 microcuries each;

(3) Each prepackaged unit bears a durable, clearly visible label:

(i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries of iodine-125, iodine-131, selenium-75, cobalt-57, or carbon-14; 50 microcuries of hydrogen-3 (tritium); 20 microcuries of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each; and

(ii) Displaying the radiation caution symbol described in 410 IAC 5-4-11(a)(1) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) One of the following statements, or a substantially similar statement which contains the information called for in the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(i) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

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Name of manufacturer

(ii) This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only in in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and

transfer are subject to the regulations and a general license of a licensing state.

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Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source, must also contain directions to the licensee regarding the waste disposal requirements set out in 410 IAC 5-4-16.

(i) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 410 IAC 5-3-10 will be approved if:

(1) The applicant satisfies the general requirements of 410 IAC 5-3-10, and

(2) The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

(j) Manufacture and Distribution of Radiopharmaceuticials *[sic.]* Containing Radioactive Material for Medical Use Under Group Licenses. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to 410 IAC 5-3-11(c) for the uses listed in Group I, Group II, IV, or V of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant submits evidence that:

(i) The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

(ii) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

(4)(i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the board for distribution to persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group I, Group II, Group IV, and Group V, as appropriate, or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state.

(ii) The labels, leaflets, or brochures required by 410 IAC 5-3-13(j)(4)(i) are in addition to the labeling required by the Food and Drug Administration and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(k) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.[12/] An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 410 IAC 5-3-11(c) for the uses listed in Group III of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(2) The applicant submits evidence that:

(i) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application approved by the Food and Drug Administration or a "Notice of Claimed Investigational Exemption for a New Drug" that has been accepted by the FDA, or

(ii) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent

kit, contains:

(i) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

(ii) A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the board pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group III or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The labels, leaflets or brochures required by 410 IAC 5-3-13(k) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

[12/] Although the board does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the board for use by persons licensed pursuant to 410 IAC 5-3-11(c) and Group III of Schedule C, 410 IAC 5-3-28, may submit the pertinent information specified in 410 IAC 5-3-13(k).

(l) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 410 IAC 5-3-11(c) for use as a calibration or reference source or for the uses listed in Group VI of Schedule C, 410 IAC 5-3-28, will be approved if:

(1) The applicant satisfies the general requirements in 410 IAC 5-3-10;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The radioactive material contained, its chemical and physical form, and amount,

(ii) Details of design and construction of the source or device,

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) For devices containing radioactive material, the radiation profile of a prototype device,

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) Procedures and standards for calibrating sources and devices,

(vii) Legend and methods for labeling sources and devices as to their radioactive content, and

(viii) Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label; and

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the name of source or device is licensed by the board for distribution to persons licensed pursuant to 410 IAC 5-3-11(c) and Schedule C, 410 IAC 5-3-28, Group VI or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, provided, that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source.

(4) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(5) In determining the acceptable interval for test of leakage of radioactive material, the board will consider information that includes, but is not limited to:

(i) Primary containment or source capsule;

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype tests;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material; and

(x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(m) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 410 IAC 5-3-6(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

(i) The applicant satisfies the general requirements specified in 410 IAC 5-3-10;

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in 410 IAC 5-4-2(a); and

(iii) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the board will approve an application for a specific license under 410 IAC 5-3-13(m) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The board may deny any application for a specific license under 410 IAC 5-3-13(m) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 410 IAC 5-3-13(m)(1) shall:

(i) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) Label or mark each unit to:

(A) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(B) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;

(iii) Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: “Depleted Uranium”;

(iv)(A) Furnish a copy of the general license contained in 410 IAC 5-3-6(d) and a copy of board form “W,” 410 IAC 5-3-32, to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 410 IAC 5-3-6(d); or

(B) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 410 IAC 5-3-6(d) and a copy of the U.S. Nuclear Regulatory Commission's or agreement state's certificate; or alternatively, furnish a copy of the general license contained in 410 IAC 5-3-6(d) and a copy of board form “W,” 410 IAC 5-3-32, to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 410 IAC 5-3-6(d).

(v) Report to the board all transfers of industrial products or devices to persons for use under the general license in 410 IAC 5-3-6(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the board and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 410 IAC 5-3-6(d) during the reporting period, the report shall so indicate;

(vi)(A) Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40.

(B) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 410 IAC 5-3-13(m) for use under a general license in that state's regulations equivalent to 410 IAC 5-3-6(d).

(C) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

(D) If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

(E) If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency.

(vii) Keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 410 IAC 5-3-6(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of 2 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.28; filed May 26, 1978, 3:30 pm: 1 IR 154; filed Feb 29, 1984, 10:10 am: 7 IR 865; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-14 Issuance of specific licenses; incorporation of additional requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. (a) Upon a determination that an application meets the requirements of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and 410 IAC 5, the board will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The board may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to 410 IAC 5-3-14 as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or property;

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) Prevent loss or theft of material subject to 410 IAC 5-3.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.30; filed May 26, 1978, 3:30 pm: 1 IR 162; filed Feb 29, 1984, 10:10 am: 7 IR 874; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-15 Terms and conditions of licenses; transfer

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. (a) Each license issued pursuant to 410 IAC 5-3 shall be subject to all the provisions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, now or hereafter in effect, and to all rules, regulations, and orders of the board.

(b) No license issued or granted under 410 IAC 5-3 and no right to possess or utilize radioactive material granted by any license issued pursuant to 410 IAC 5-3 shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the board shall, after securing full information find that the transfer is in accordance with the provisions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, and shall give its consent in writing.

(c) Each person licensed by the board pursuant to 410 IAC 5-3 shall confine his use and possession of the material licensed

to the locations and purposes authorized in the license. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.31; filed May 26, 1978, 3:30 pm: 1 IR 162; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-16 Expiration of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. Except as provided in 410 IAC 5-3-17(b), each specific license shall expire at the end of the specified day in the month and year stated therein. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.32; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-17 Renewal of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. (a) Applications for renewal of specific licenses shall be filed in accordance with 410 IAC 5-3-9.

(b) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the board. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.33; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-18 Amendment of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. Applications for amendment of a license shall be filed in accordance with 410 IAC 5-3-9 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.34; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-19 Criteria for renewal or amendment of licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 19. In considering an application by a licensee to renew or amend his license, the board will apply the criteria set forth in 410 IAC 5-3-10, 410 IAC 5-3-11, 410 IAC 5-3-12, or 410 IAC 5-3-13, as applicable. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.35; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-20 United States nuclear regulatory commission license; expiration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. Persons Possessing a License for Source, Byproduct or Special Nuclear Material in Quantities Not Sufficient to Form A Critical Mass on Effective Date of 410 IAC 5. Any person who, on the effective date of 410 IAC 5, possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under 410 IAC 5-3 and IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, such license to expire either 90 days after receipt from the board of a notice of expiration of such license, or on the date of expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.36; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-21 Naturally-occurring and accelerator-produced radioactive material; expiration of license

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 21. Persons Possessing Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) on Effective Date of 410 IAC 5. Any person who, on the effective date of 410 IAC 5, possesses NARM for which a specific license is required by IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* or 410 IAC 5-3 shall be deemed to possess such a license issued under IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and 410 IAC 5-3. Such license shall expire 90 days after the effective date of 410 IAC 5; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the board. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.37; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 875; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-22 Transfer of material

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 22. (a) No licensee shall transfer radioactive material except as authorized pursuant to 410 IAC 5-3-22(c).

(b) Except as otherwise provided in his license and subject to the provisions of 410 IAC 5-3-22(c) and (d), any licensee may transfer radioactive material:

(1) To the board;[13/]

(2) To the U.S. Department of Energy;

(3) To any person exempt from 410 IAC 5-3 to the extent permitted under such exemption;

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the board, an agreement state or a licensing state; or

(5) As otherwise authorized by the board in writing.

[13/] A licensee may transfer material to the board only after receiving prior approval from the board.

(c) Before transferring radioactive material to a specific licensee of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's *[sic.]* license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(d) Any of the following methods for the verification required by 410 IAC 5-3-22(c) is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate;

(2) The transferor may possess a written certification that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other information compiled by a reporting service from official records of the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in 410 IAC 5-3-22(d)(1) to (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the board, the U.S. Nuclear Regulatory Commission, or an agreement state or a licensing state that the transferee is licensed to receive the radioactive material.

(e) Shipment and transport of radioactive material shall be in accordance with the provisions of 410 IAC 5-3-25. *(Indiana*

State Department of Health; Rule HRH-2,PT C,Sec C.40; filed May 26, 1978, 3:30 pm: 1 IR 163; filed Feb 29, 1984, 10:10 am: 7 IR 876; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-23 Modification of license terms and condition; suspension or revocation of license

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 23. (a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, or by reason of rules, regulations, and orders issued by the board.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the board to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, or of the license, or of any rule, regulation, or order of the board.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) The board may terminate a specific license upon request submitted by the licensee to the board in writing. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.50; filed May 26, 1978, 3:30 pm: 1 IR 164; filed Feb 29, 1984, 10:10 am: 7 IR 877; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-24 Reciprocal licensure

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 24. (a) Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass. (1) Subject to 410 IAC 5, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or any agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:

(i) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) The out-of-state licensee notifies the board in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the *[sic.]* day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the board, obtain permission to proceed sooner. The board may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 410 IAC 5-3-24(a)(1);

(iii) The out-of-state licensee complies with all applicable rules of the board and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the board;

(iv) The out-of-state licensee supplies such other information as the board may request; and

(v) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 410 IAC 5-3-24(a)(1) except by transfer to a person:

(A) Specifically licensed by the board or by the U.S. Nuclear Regulatory Commission to receive such material, or

(B) Exempt from the requirements for a license for such material under 410 IAC 5-3-4(a).

(2) Notwithstanding the provisions of 410 IAC 5-3-24(a)(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 410 IAC 5-3-7(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in Indiana provided that:

(i) Such person shall file a report with the board within 30 days after the end of each calendar quarter in which any device is transferred to or installed in Indiana. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

(iii) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 410 IAC 5-3-7(d).

(3) The board may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(b) Licenses of Naturally-Occurring and Accelerator-Produced Radioactive Material.

(1) Subject to 410 IAC 5, any person who holds a specific license from a licensing state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within Indiana for a period not in excess of 180 days in any calendar year provided that:

(i) The licensing document does not limit the activity authorized by such document to specified installations or locations;

(ii) The out-of-state licensee notifies the board in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the board, obtain permission to proceed sooner. The board may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in 410 IAC 5-3-24(b)(1);

(iii) The out-of-state licensee complies with all applicable rules of the board and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the board;

(iv) The out-of-state licensee supplies such other information as the board may request; and

(v) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in 410 IAC 5-3-24(b)(1) except by transfer to a person:

(A) Specifically licensed by the board or by another licensing state to receive such material, or

(B) Exempt from the requirements for a license for such material under 410 IAC 5-3-4.

(2) Notwithstanding the provisions of 410 IAC 5-3-24(b)(1), any person who holds a specific license issued by a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in 410 IAC 5-3-7(d)(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in Indiana provided that:

(i) Such person shall file a report with the board within 30 days after the end of each calendar quarter in which any device is transferred to or installed in Indiana. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(ii) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a licensing state;

(iii) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(iv) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in 410 IAC 5-3-7(d).

(3) The board may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a licensing state or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.90; filed May 26, 1978, 3:30 pm: 1 IR 164; filed Feb 29, 1984, 10:10 am: 7 IR 877; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-25 Transportation of radioactive materials

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25. No person shall deliver radioactive material to a carrier for transport or transport radioactive material except as authorized in a general or specific license issued by the board or as exempted in 410 IAC 5-3-25.1. *(Indiana State Department of Health; Rule HRH-2,PT C,Sec C.100; filed May 26, 1978, 3:30 pm: 1 IR 166; filed Feb 29, 1984, 10:10 am: 7 IR 879; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-25.1 Exemption of transporters

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25.1. (a) Common, contract and private carriers, freight forwarders, and warehousemen who are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), are exempt from 410 IAC 5 to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto. Common, contract and private carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 410 IAC 5-3-25 and other applicable sections of 410 IAC 5.

(b) Any licensee is exempt from 410 IAC 5-3-25 to the extent that he delivers to a carrier for transport packages each of which contains radioactive material having a specific activity less than, or equal to, 0.002 microcurie per gram.

(c) Any licensee who delivers radioactive material to a carrier for transport, where such transport is subject to the regulations of the U.S. Postal Service, is exempt from the provisions of 410 IAC 5-3-25. *(Indiana State Department of Health; 410 IAC 5-3-25.1; filed Feb 29, 1984, 10:10 am: 7 IR 879; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-25.2 General licenses for carriers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25.2. (a) A general license is hereby issued to any common or contract carrier not exempt under 410 IAC 5-3-25.1 to receive, possess, transport, and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[14/]

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[14/]

[14/] Any notification of incidents referred to in those U.S. Department of Transportation requirements shall be filed with, or made to, the board.

(c) Persons who transport radioactive material pursuant to the general licenses in 410 IAC 5-3-25.2(a) or (b) are exempt from

the requirements of 410 IAC 5-4 and 410 IAC 5-10 to the extent that they transport radioactive material. *(Indiana State Department of Health; 410 IAC 5-3-25.2; filed Feb 29, 1984, 10:10 am: 7 IR 879; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-25.3 General licenses for delivery of materials to carriers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25.3. A general license is hereby issued to deliver radioactive material to a carrier[15/] for transport provided that:

(a) The licensee complies with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the packaging of radioactive material, and to the monitoring, marking, and labeling of those packages;

(b) The licensee has established procedures for safely opening and closing packages in which radioactive material is transported and to assure that, prior to the delivery to a carrier for transport, each package is properly closed for transport; and

(c) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

[15/] For the purpose of 410 IAC 5, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material to a carrier for transport. *(Indiana State Department of Health; 410 IAC 5-3-25.3; filed Feb 29, 1984, 10:10 am: 7 IR 880; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-25.4 Advance notice of transport of nuclear waste

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25.4. (a) Prior to the transport of any nuclear waste outside of the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee,[16/] of each state through which the waste will be transported. For the purpose of 410 IAC 5-3-25.4 "nuclear waste" means any large quantity of source, byproduct, or special nuclear material required to be in Type B packaging while transported to, through, or across state boundaries to a disposal site, or to a collection point for transport to a disposal site.

[16/] A list of the mailing addresses of the governors and governor's designees is available upon request from the Director, Office of State Programs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(b) Each advance notification required by 410 IAC 5-3-25.4 shall contain the following information:

(1) the name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

(2) a description of the nuclear waste contained in the shipment as required by the regulations of the U.S. Department of Transportation, 49 CFR 172.202 and 172.203(d);

(3) the point of origin of the shipment and the 7-day period during which departure of the shipment is estimated to occur;

(4) the 7-day period during which arrival of the shipment at state boundaries is estimated to occur;

(5) the destination of the shipment, and the 7-day period during which arrival of the shipment is estimated to occur; and

(6) a point of contact with a telephone number for current shipment information.

(c) The notification required by 410 IAC 5-3-25.4 shall be made in writing to the office of each appropriate governor or governor's designee and to the board. A notification delivered by mail must be postmarked at least 7 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least 4 days before the beginning of the 7-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for 1 year.

(d) The licensee shall notify each appropriate governor, or governor's designee, and the board of any changes to schedule information provided pursuant to 410 IAC 5-3-25.4. Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for 1 year a record of the name of the individual contacted.

(e) Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the board. A copy of this notice shall be retained by the licensee for 1 year. *(Indiana State Department of Health; 410 IAC 5-3-25.4; filed Feb 29, 1984, 10:10 am: 7 IR 880; readopted*

filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-26 Schedule of exempt concentrations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 26.

SCHEDULE A

EXEMPT CONCENTRATIONS

Element (atomic number)	Isotope	Column I Gas concentration μCi/ml[1/]	Column II Liquid and solid concentration μCi/ml[2/]
Antimony (51)	Sb-122		3×10^{-4}
	Sb-124		2×10^{-4}
	Sb-125		1×10^{-3}
Argon (18)	Ar-37	1×10^{-3}	
	Ar-41	4×10^{-7}	
Arsenic (33)	As-73		5×10^{-3}
	As-74		5×10^{-4}
	As-76		2×10^{-4}
	As-77		8×10^{-4}
Barium (56)	Ba-131		2×10^{-3}
	Ba-140		3×10^{-4}
Beryllium (4)	Be-7		2×10^{-2}
Bismuth (83)	Bi-206		4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109		2×10^{-3}
	Cd-115m		3×10^{-4}
	Cd-115		3×10^{-4}
Calcium (20)	Ca-45		9×10^{-5}
	Ca-47		5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141		9×10^{-4}
	Ce-143		4×10^{-4}
	Ce-144		1×10^{-4}
Cesium (55)	Cs-131		2×10^{-2}
	Cs-134m		6×10^{-2}
	Cs-134		9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51		2×10^{-2}
Cobalt (27)	Co-57		5×10^{-3}
	Co-58		1×10^{-3}
	Co-60		5×10^{-4}

Copper (29)	Cu-64		3×10^{-3}
Dysprosium (66)	Dy-165		4×10^{-3}
	Dy-166		4×10^{-4}
Erbium (68)	Er-169		9×10^{-4}
	Er-171		1×10^{-3}
Europium (63)	Eu-152		6×10^{-4}
	(T_r=9.2 h)		
	Eu-155		2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153		2×10^{-3}
	Gd-159		8×10^{-4}
Gallium (31)	Ga-72		4×10^{-4}
Germanium (32)	Ge-71		2×10^{-2}
Gold (79)	Au-196		2×10^{-3}
	Au-198		5×10^{-4}
	Au-199		2×10^{-3}
Hafnium (72)	Hf-181		7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m		1×10^{-2}
	In-114m		2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190		2×10^{-3}
	Ir-192		4×10^{-4}
	Ir-194		3×10^{-4}
Iron (26)	Fe-55		8×10^{-3}
	Fe-59		6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	
	Kr-85	3×10^{-6}	
Lanthanum (57)	La-140		2×10^{-4}
Lead (82)	Pb-203		4×10^{-3}
Lutetium (71)	Lu-177		1×10^{-3}
Manganese (25)	Mn-52		3×10^{-4}
	Mn-54		1×10^{-3}
	Mn-56		1×10^{-3}
Mercury (80)	Hg-197m		2×10^{-3}
	Hg-197		3×10^{-3}

	Hg-203	2×10^{-4}
Molybdenum (42)	Mo-99	2×10^{-3}
Neodymium (60)	Nd-147	6×10^{-4}
	Nd-149	3×10^{-3}
Nickel (28)	Ni-65	1×10^{-3}
Niobium	Nb-95	1×10^{-3}
(Columbium) (41)	Nb-97	9×10^{-3}
Osmium (76)	Os-185	7×10^{-4}
	Os-191m	3×10^{-2}
	Os-191	2×10^{-3}
	Os-193	6×10^{-4}
Palladium (46)	Pd-103	3×10^{-3}
	Pd-109	9×10^{-4}
Phosphorus (15)	P-32	2×10^{-4}
Platinum (78)	Pt-191	1×10^{-3}
	Pt-193m	1×10^{-2}
	Pt-197m	1×10^{-2}
	Pt-197	1×10^{-3}
Potassium (19)	K-42	3×10^{-3}
Praseodymium (59)	Pr-142	3×10^{-4}
	Pr-143	5×10^{-4}
Promethium (61)	Pm-147	2×10^{-3}
	Pm-149	4×10^{-4}
Rhenium (75)	Re-183	6×10^{-3}
	Re-186	9×10^{-4}
	Re-188	6×10^{-4}
Rhodium (45)	Rh-103m	1×10^{-1}
	Rh-105	1×10^{-3}
Rubidium (37)	Rb-86	7×10^{-4}
Ruthenium (44)	Ru-97	4×10^{-3}
	Ru-103	8×10^{-4}
	Ru-105	1×10^{-3}
	Ru-106	1×10^{-4}
Samarium (62)	Sm-153	8×10^{-4}
Scandium (21)	Sc-46	4×10^{-4}
	Sc-47	9×10^{-4}
	Sc-48	3×10^{-4}
Selenium (34)	Se-75	3×10^{-3}
Silicon (14)	Si-31	9×10^{-3}
Silver (47)	Ag-105	1×10^{-3}

	Ag-110m		3×10^{-4}
	Ag-111		4×10^{-4}
Sodium (11)	Na-24		2×10^{-3}
Strontium (38)	Sr-85		1×10^{-3}
	Sr-89		1×10^{-4}
	Sr-91		7×10^{-4}
	Sr-92		7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182		4×10^{-4}
Technetium (43)	Tc-96m		1×10^{-1}
	Tc-96		1×10^{-3}
Tellurium (52)	Te-125m		2×10^{-3}
	Te-127m		6×10^{-4}
	Te-127		3×10^{-3}
	Te-129m		3×10^{-4}
	Te-131m		6×10^{-4}
	Te-132		3×10^{-4}
Terbium (65)	Tb-160		4×10^{-4}
Thallium (81)	Tl-200		4×10^{-3}
	Tl-201		3×10^{-3}
	Tl-202		1×10^{-3}
	Tl-204		1×10^{-3}
Thulium (69)	Tm-170		5×10^{-4}
	Tm-171		5×10^{-3}
Tin (50)	Sn-113		9×10^{-4}
	Sn-125		2×10^{-4}
Tungsten	W-181		4×10^{-3}
(Wolfram) (74)	W-187		7×10^{-4}
Vanadium (23)	V-48		3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	
	Xe-133	3×10^{-6}	
	Xe-135	1×10^{-6}	
Ytterbium (70)	Yb-175		1×10^{-3}
Yttrium (39)	Y-90		2×10^{-4}
	Y-91m		3×10^{-2}
	Y-91		3×10^{-4}
	Y-92		6×10^{-4}
	Y-93		3×10^{-4}
Zinc (30)	Zn-65		1×10^{-3}
	Zn-69m		7×10^{-4}

	Zn-69		2×10^{-2}
Zirconium (40)	Zr-95		6×10^{-4}
	Zr-97		2×10^{-4}
Beta and/or gamma emitting radioactive material not listed above with half-life of less than 3 years.		1×10^{-10}	1×10^{-6}

[1/]Values are given in Column I only for those materials normally used as gases.

[2/]μCi/g are for solids.

NOTE 1: Many radioisotopes transform into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 410 IAC 5-3-4 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1".

EXAMPLE:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

NOTE 3: To convert μCi/ml to SI units of megabecquerels per liter multiply the above values by 37.

EXAMPLE: Zirconium (40) Zr-97 (2×10^{-4} μCi/ml multiplied by 37 is equivalent to 74×10^{-4} MB/q/l). *(Indiana State Department of Health; Rule HRH-2,PT C,Schedule A; filed May 26, 1978, 3:30 pm: 1 IR 168; filed Feb 29, 1984, 10:10 am: 7 IR 881; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-27 Schedule of exempt quantities

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 27.

SCHEDULE B

EXEMPT QUANTITIES

Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100
Antimony-124 (Sb 124)	10
Antimony-125 (Sb 125)	10
Arsenic-73 (As 73)	100
Arsenic-74 (As 74)	10
Arsenic-76 (As 76)	10
Arsenic-77 (As 77)	100
Barium-131 (Ba 131)	10
Barium-133 (Ba 133)	10
Barium-140 (Ba 140)	10
Bismuth-210 (Bi 210)	1

Bromine-82 (Br 82)	10
Cadmium-109 (Cd 109)	10
Cadmium-115m (Cd 115m)	10
Cadmium-115 (Cd 115)	100
Calcium-45 (Ca 45)	10
Calcium-47 (Ca 47)	10
Carbon-14 (C 14)	100
Cerium-141 (Ce 141)	100
Cerium-143 (Ce 143)	100
Cerium-144 (Ce 144)	1
Cesium-129 (Cs 129)	100
Cesium-131 (Cs 131)	1,000
Cesium-134m (Cs 134m)	100
Cesium-134 (Cs 134)	1
Cesium-135 (Cs 135)	10
Cesium-136 (Cs 136)	10
Cesium-137 (Cs 137)	10
Chlorine-36 (Cl 36)	10
Chlorine-38 (Cl 38)	10
Chromium-51 (Cr 51)	1,000
Cobalt-57 (Co 57)	100
Cobalt-58m (Co 58m)	10
Cobalt-58 (Co 58)	10
Cobalt-60 (Co 60)	1
Copper-64 (Cu 64)	100
Dysprosium-165 (Dy 165)	10
Dysprosium-166 (Dy 166)	100
Erbium-169 (Er 169)	100
Erbium-171 (Er 171)	100
Europium-152 (Eu 152) 9.2h	100
Europium-152 (Eu 152) 13 yr	1
Europium-154 (Eu 154)	1
Europium-155 (Eu 155)	10
Flourine-18 *[sic., Fluorine]* (F 18)	1,000
Gadolinium-153 (Gd 153)	10
Gadolinium-159 (Gd 159)	100
Gallium-67 (Ga 67)	100
Gallium-72 (Ga 72)	10
Germanium-68 (Ge 68)	100
Germanium-71 (Ge 71)	100

Gold-195 (Au 195)	100
Gold-198 (Au 198)	100
Gold-199 (Au 199)	100
Hafnium-181 (Hf 181)	10
Holmium-166 (Ho 166)	100
Hydrogen-3 (H 3)	1,000
Indium-111 (In 111)	100
Indium-113m (In 113m)	100
Indium-114m (In 114m)	10
Indium-115m (In 115m)	100
Indium-115 (In 115)	10
Iodine-123 (I 123)	100
Iodine-125 (I 125)	1
Iodine-126 (I 126)	1
Iodine-129 (I 129)	0.
Iodine-131 (I 131)	1
Iodine-132 (I 132)	10
Iodine-133 (I 133)	1
Iodine-134 (I 134)	10
Iodine-135 (I 135)	10
Iridium-192 (Ir 192)	10
Iridium-194 (Ir 194)	100
Iron-52 (Fe 52)	10
Iron-55 (Fe 55)	100
Iron-59 (Fe 59)	10
Krypton-85 (Kr 85)	100
Krypton-87 (Kr 87)	10
Lanthanum-140 (La 140)	10
Lutetium-177 (Lu 177)	100
Manganese-52 (Mn 52)	10
Manganese-54 (Mn 54)	10
Manganese-56 (Mn 56)	10
Mercury-197m (Hg 197m)	100
Mercury-197 (Hg 197)	100
Mercury-203 (Hg 203)	10
Molybdenum-99 (Mo 99)	100
Neodymium-147 (Nd 147)	100
Neodymium-149 (Nd 149)	100
Nickel-59 (Ni 59)	100
Nickel-63 (Ni 63)	10

Nickel-65 (Ni 65)	100
Niobium-93m (Nb 93m)	10
Niobium-95 (Nb 95)	10
Niobium-97 (Nb 97)	10
Osmium-185 (Os 185)	10
Osmium-191m (Os 191m)	100
Osmium-191 (Os 191)	100
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 142)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Radium-226 (Ra 226)	1
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10

Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000

Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-88 (Y 88)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

NOTE 1: For purposes of 410 IAC 5-3-10(f)(1)(ii) where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in Schedule B for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed 1.

EXAMPLE:

$$\frac{\text{Amt. of Isotope A possessed}}{1000 \times \text{Schedule B quantity for Isotope A}} + \frac{\text{Amt. of Isotope B Possessed}}{1000 \times \text{Schedule B quantity for Isotope B}} \leq 1$$

NOTE 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (10μCi mulitiplied *[sic.]* by 37 is equivalent to 370 kBq). *(Indiana State Department of Health; Rule HRH-2,PT C,Schedule B; filed May 26, 1978, 3:30 pm: 1 IR 168; filed Feb 29, 1984, 10:10 am: 7 IR 883; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-28 Schedule of medical use groups

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 28. Schedule C

Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion (does not include uses involving imaging and tumor localizations)

(1) Chromium-51 as sodium chromate or labeled human serum albumin.
(2) Cobalt-57 as labeled cyanocobalamin.
(3) Cobalt-58 as labeled cyanocobalamin.
(4) Cobalt-60 as labeled cyanocobalamin.
(5) Iodine-123 as sodium iodide.
(6) Iodine-125 as sodium iodide, iodinated human serum albumin, oleic acid, or sodium iothalamate.
(7) Iodine-131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate.
(8) Iron-59 as citrate.
(9) Potassium-42 as chloride.

(10) Sodium-24 as chloride.
(11) Technetium-99m as pertechnetate.
(12) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group II. Use of prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localizations

(1) Chromium-51 as human serum albumin.
(2) Fluorine-18 in solution.
(3) Gallium-67 as citrate.
(4) Gold-198 in colloidal form.
(5) Indium-113m as chloride.
(6) Iodine-123 as sodium iodide.
(7) Iodine-125 as sodium iodide or fibrinogen.
(8) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate.
(9) Mercury-197 as chlormerodrin.
(10) Mercury-203 as chlormerodrin.
(11) Selenium-75 as selenomethionine.
(12) Strontium-85 as nitrate.
(13) Strontium-87m as chloride.
(14) Technetium-99m as pertechnetate, sulfur colloid, or macroaggregated human serum albumin.
(15) Thallium-201 as chloride.
(16) Ytterbium-169 as pentatate sodium.
(17) Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in (3) of Group III.
(18) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging except those in gaseous forms for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses

(1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate.
(2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in (3) and (6) of this group.
(3) Reagent kits for preparation of technetium-99m labeled:
    (i) sulfur colloid;
    (ii) pentatate sodium;
    (iii) human serum albumin microspheres;
    (iv) polyphosphates;
    (v) macroaggregated human serum albumin;
    (vi) etidronate sodium;
    (vii) stannous pyrophosphate;
    (viii) human serum albumin;
    (ix) medronate sodium;
    (x) gluceptate sodium; and
    (xi) oxidronate sodium.
(4) Tin-113/indium-113m generators for the elution of indium-113m as chloride.
(5) Yttrium-87/strontium-87m generators for the elution of strontium-87m.
(6) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety

(1) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction.
(2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.
(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.
(4) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety

(1) Gold-198 as colloid for intracavitary treatment of malignant effusions.
(2) Iodine-131 as iodide for treatment of thyroid carcinoma.
(3) Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or a "New Drug Application" (NDA) has been accepted by the Food and Drug Administration (FDA).

Group VI. Use of sources and devices containing radioactive material for certain medical uses

(1) Americium-241 as a sealed source in a device for bone mineral analysis.
(2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.
(3) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.
(4) Gold-198 as seeds for interstitial treatment of cancer.
(5) Iodine-125 as a sealed source in a device for bone mineral analysis.
(6) Iodine-125 as seeds for interstitial treatment of cancer.
(7) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.
(8) Radon-222 as seeds for topical, interstitial, and intracavitary treatment of cancer.
(9) Radium-226 as a sealed source for topical, interstitial, and intracavitary treatment of cancer.
(10) Strontium-90 sealed in an applicator for treatment of superficial eye conditions.

(Indiana State Department of Health; Rule HRH-2,PT C,Schedule C; filed May 26, 1978, 3:30 pm: 1 IR 170; filed Feb 29, 1984, 10:10 am: 7 IR 885; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-3-29 Schedule of limits for broad licenses

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 29.

SCHEDULE D

LIMITS FOR BROAD LICENSES

Radioactive Material	Col.I curies	Col.II curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001

Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01

Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1

Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01

Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01

Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

NOTE 1: to convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

EXAMPLE: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq). *(Indiana State Department of Health; Rule HRH-2,PT C,Schedule E; filed May 26, 1978, 3:30 pm: 1 IR 172; filed Feb 29, 1984, 10:10 am: 7 IR 889; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-30 Certification of medical use under general license (form U)

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 30. Board Form "U"

(Date)

CERTIFICATE-MEDICAL USE OF RADIOACTIVE MATERIAL UNDER GENERAL LICENSE

410 IAC 5-3-7(h) establishes a general license authorizing physicians to possess certain small quantities of I-125, I-131, Co-57, Co-58, Co-60, and Cr-51 for specified diagnostic uses. Possession of radioactive material under 410 IAC 5-3-7(h) is not authorized until the physician has filed board form U and received from the board a validated copy of board form U with certification number assigned.

INSTRUCTIONS

Submit this form in triplicate to the Radiological Health Section, Indiana State Board of Health. A certification number will be assigned and a validated copy of board form U will be returned. Please print or type your name and address (including ZIP Code), within the lines below:

Certification Number:

(Leave this space blank-number to be assigned by the board)

I am a duly licensed physician [authorized to dispense drugs] in the practice of medicine. My Indiana license number is: _____.

CERTIFICATE

I hereby certify that:

1. All information in this certificate is true and complete.
2. I have appropriate radiation measuring instruments to carry out the diagnostic procedures for which I will use radioactive material under the general license of 410 IAC 5-3-7(h) and I am competent in the use of such instruments.
3. I understand that board rules require that any change in the information furnished on this certificate be reported to the board within 30 days from the date of such change.

4. I have read and understand the provisions of 410 IAC 5-3-7(h) of the Indiana Rule for Radiation Control [410 IAC 5]; and I understand that I am required to comply with those provisions as to all radioactive material which I receive, possess, use, or transfer under the general license for which this certificate is filed with the board:

Date: _____ By: _____

(Signature of person filing form)

CONDITIONS AND LIMITATIONS OF
GENERAL LICENSE 410 IAC 5-3-7(h)

Medical Diagnostic Uses

(1) A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provisions of 410 IAC 5-3-7(h)(2), (3), and (4), the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with the specific license issued by the board pursuant to 410 IAC 5-3-13(g) or by the U.S. Nuclear Regulatory Commission, any agreement state, or a licensing state pursuant to equivalent regulations authorizing distribution to persons generally licensed pursuant to 410 IAC 5-3-7(h) or its equivalent:

(i) chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time;

(ii) cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;

(iii) cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(iv) cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

(v) iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(vi) iodine-131 as sodium iodide for measurement of thyroid uptake; and

(vii) iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.

(2) No physician shall receive, possess, use or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) until he has filed board form "U," "Certificate–Medical Use of Radioactive Material Under General License" with the board and received from the board a validated copy of the board form "U" with certification number assigned. The generally licensed physician shall furnish on board form "U" the following information and such other information as may be required by that form:

(i) name and address of the generally licensed physician;

(ii) a statement that the generally licensed physician is a duly licensed physician [authorized to dispense drugs] in the practice of medicine in this state; and

(iii) a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of 410 IAC 5-3-7(h) and that he is competent in the use of such instruments.

(3) A physician who receives, possesses or uses a pharmaceutical containing radioactive material pursuant to the general license established by 410 IAC 5-3-7(h)(1) shall comply with the following:

(i) he shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(h)(1) more than

(A) 200 microcuries of iodine-131,

(B) 200 microcuries of iodine-125,

(C) 5 microcuries of cobalt-57,

(D) 5 microcuries of cobalt-58,

(E) 5 microcuries of cobalt-60, and

(F) 200 microcuries of chromium-51;

(ii) he shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;

(iii) he shall use the pharmaceutical only for the uses authorized by 410 IAC 5-3-7(h)(1);

(iv) he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and

(v) he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(4) The generally licensed physician possessing or using radioactive material under the general license of 410 IAC 5-3-7(h)(1) shall report in duplicate to the board, any changes in the information furnished by him in the "Certificate–Medical Use of Radioactive Material Under General License," board form "U." The report shall be submitted within 30 days after the effective date of such change.

(5) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(h)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the radioactive material covered by the general license.

NOTE: 410 IAC 5-3-13(g) requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to include one of the following statements in the label affixed to the container or in the leaflet or brochure which accompanies the radiopharmaceutical:

This radioactive drug may be received, possessed, and used only by physicians licensed [to dispense drugs] in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license or its equivalent of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

(Name of Manufacturer)

This radioactive drug may be received, possessed, and used only by physicians licensed [to dispense drugs] in the practice of medicine. Its receipt, possession, use, and transfer are subject to the rules and a general license or its equivalent of a licensing state.

_____

(Name of Manufacturer)

NOTE

If larger quantities or other forms of radioactive material than those specified in the general license of 410 IAC 5-3-7(h) are required, the physician should file an "Application for Radioactive Material License," and obtain a specific radioactive material license. Copies of application and certification forms may be obtained from the Radiological Health Section, Indiana State Board of Health. *(Indiana State Department of Health; 410 IAC 5-3-30; filed Feb 29, 1984, 10:10 am: 7 IR 891; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-31 Certification of in vitro testing under general license (form V)

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 31. Board Form "V"

(Date)

CERTIFICATE–IN VITRO TESTING WITH
RADIOACTIVE MATERIAL UNDER
GENERAL LICENSE

410 IAC 5-3-7(i)(1) establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to possess certain small quantities of radioactive material for in vitro clinical or laboratory tests not involving the internal or external administration of the radioactive material or the radiation therefrom to human beings or animals. Possession of radioactive material under 410 IAC 5-3-7(i) is not authorized until the physician, veterinarian, clinical laboratory, or hospital has filed board form V and received from the board a validated copy of board form V with certification number.

INSTRUCTIONS

Submit this form in triplicate to the Radiological Health Section, Indiana State Board of Health. A certification number will be assigned and a validated copy of board form V will be returned.

_____

1. Please print or type within the lines, below, the name and address (including ZIP Code) of the physician, veterinarian, clinical laboratory, or hospital for whom or for which this form is filed.

2. I hereby apply for a certification pursuant to 410 IAC 5-3-7(i) for use of radioactive material for (Please check one):

a. Myself, a duly licensed physician [authorized to dispense drugs] in the practice of medicine.

b. The above-named clinical laboratory.

c. The above-named hospital.

d. Myself, a duly licensed veterinarian.

3. To be completed by the board.

Certification number:

(Leave this space blank–number to be assigned by the board)

4. If place of use is different from address in item 1, please give complete address:

_____

5. Certification:

I hereby certify that:

a. All information in this certification is true and complete.

b. Appropriate radiation measuring instruments are available to carry out the tests for which radioactive material will be used under the general license of 410 IAC 5-3-7(i). The tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive material.

c. I understand that board rules require that any change in the information furnished on this certificate be reported to the board, within 30 days from the effective date of such change.

d. I have read and understand the provisions of 410 IAC 5-3-7(i); and I understand that compliance with those provisions is required as to all radioactive material which is received, acquired, possessed, used, or transferred under the general license for which this certificate is filed with the board.

Date: _____ By: _____

(Signature of person filing form)

_____

(Printed name and title of position of person filing form)

CONDITIONS AND LIMITATIONS OF GENERAL LICENSE 410 IAC 5-3-7(i)

General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 410 IAC 5-3-7(i)(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) Carbon-14, in units not exceeding 10 microcuries each.

(ii) Cobalt-57, in units not exceeding 10 microcuries each.

(iii) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each.

(iv) Iodine-125, in units not exceeding 10 microcuries each.

(v) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(vi) Iodine-131, in units not exceeding 10 microcuries each.

(vii) Iron-59, in units not exceeding 20 microcuries each.

(viii) Selenium-75, in units not exceeding 10 microcuries each.

(2) No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) until he has filed board form "V," "Certificate–In Vitro Testing with Radioactive Material Under General License," with the board and received from the board a validated copy of board form "V" with certification number assigned, or until he has been authorized pursuant to 410 IAC 5-3-11(c)(3) to use radioactive material under the general license in 410 IAC 5-3-7(i). The physician, veterinarian, clinical laboratory, or hospital shall furnish on board form "V" the following information and such other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory, or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 410 IAC 5-3-7(i)(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by 410 IAC 5-3-7(i)(1) shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in 410 IAC 5-3-7(i)(1), at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-175, iron-59, and/or cobalt-57 in excess of 200 microcuries.

(ii) The general licensee shall store the radioactive material until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the uses authorized by 410 IAC 5-3-7(i)(1).

(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the board, the U.S. Nuclear Regulatory Commission, any agreement state, or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in 410 IAC 5-3-7(i)(1)(viii) as required by 410 IAC 5-4-16.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 410 IAC 5-3-7(i)(1):

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 410 IAC 5-3-13(h) or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under 410 IAC 5-3-7(i) or its equivalent, and

(ii) Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on the label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

(A) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the rules and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

Name of Manufacturer

(B) This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

_____

Name of Manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general

license of 410 IAC 5-3-7(i)(1) shall report in writing to the board, any changes in the information furnished by him in the "Certificate–In Vitro Testing with Radioactive Material Under General License," board form "V." The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 410 IAC 5-3-7(i)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 410 IAC 5-3-7(i)(1)(viii) shall comply with the provisions of 410 IAC 5-4-16, 410 IAC 5-4-22, and 410 IAC 5-4-23.

NOTE

If larger quantities or other forms of radioactive material than those specified in the general license of 410 IAC 5-3-7(i) are required, an "Application for Radioactive Material License," should be filed to obtain a specific radioactive material license. Copies of application and certification forms may be obtained from the Radiological Health Section, Indiana State Board of Health. *(Indiana State Department of Health; 410 IAC 5-3-31; filed Feb 29, 1984, 10:10 am: 7 IR 893; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-3-32 Certification of use of depleted uranium under general license (form W)

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 32. Board Form "W"

(Date)

REGISTRATION CERTIFICATE–USE OF DEPLETED URANIUM UNDER GENERAL LICENSE

410 IAC 5-3-6(d) establishes a general license authorizing the use of depleted uranium contained in industrial products or devices for mass-volume applications. This form W shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium.

INSTRUCTIONS

1. Submit this form in triplicate to:
   Radiological Health Section
   Indiana State Board of Health
   1330 West Michigan Street
   Indianapolis, IN 46206
2. Please print or type the name and address (including ZIP Code) of the registrant for whom this form is filed. Position the first letter of the address below the left dot and do not extend the address beyond the right dot. (A file number will be assigned and a copy of form W will be returned.)
3. I hereby file form W pursuant to 410 IAC 5-3-6(d), for use of depleted uranium contained in industrial products or devices for mass-volume applications.
4. To be completed by the board.

FILE NUMBER: (Leave this space blank–number to be assigned by board.)

5. Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d).

_____

6. Certification:

   I hereby certify that:

   a. All information in this registration certificate is true and complete.

   b. The registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.

c. I understand that board rules require that any changes in information furnished by a registrant on this registration certificate be reported in writing to the board within 30 days after the effective date of such change.

d. I understand that the registrant is required to comply with the provisions of 410 IAC 5-3-6(d) (reprinted as part of this form) with respect to all depleted uranium which he receives, acquires, uses, or transfers under the general license for which this registration certificate is filed with the board.

Date:_____ By: _____

(Signature of person filing form)

_____

(Printed name and title of person filing form)

Depleted Uranium in Industrial Products and Devices

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 410 IAC 5-3-6(d)(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 410 IAC 5-3-6(d)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 410 IAC 5-3-13(m) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(3)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) shall file board form W "Registration Certificate–Use of Depleted Uranium Under General License," with the board. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on board form W the following information and such other information as may be required by that form:

(A) Name and address of the registrant;

(B) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 410 IAC 5-3-6(d)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 410 IAC 5-3-6(d)(3)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by 410 IAC 5-3-6(d)(1) shall report in writing to the board any changes in information furnished by him in board form W "Registration Certificate–Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1):

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

(ii) Shall not abandon such depleted uranium.

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 410 IAC 5-3-22. In the case where the transferee receives the depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form W. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 410 IAC 5-3-6(d)(1), the transferor shall furnish the transferee a copy of 410 IAC 5 and a copy of board form W accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 410 IAC 5.

(iv) Within 30 days of any transfer, shall report in writing to the board the name and address of the person receiving the depleted uranium pursuant to such transfer.

(v) Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 410 IAC 5-3-6(d)(1) is exempt from the requirements of 410 IAC 5-4 and 410 IAC 5-10 with respect to the

depleted uranium covered by that general license.
(Indiana State Department of Health; 410 IAC 5-3-32; filed Feb 29, 1984, 10:10 am: 7 IR 895; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 4. Protection and Exposure Standards

410 IAC 5-4-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. (a) 410 IAC 5-4-1 establishes standards for protection against radiation hazards. Except as otherwise specifically provided, 410 IAC 5-4 applies to all licensees or registrants. It is the purpose of 410 IAC 5-4 to control the possession, use, and transfer of sources of radiation by any licensee or registrant in such a manner that the total dose to an individual does not exceed the standards of radiation protection prescribed in 410 IAC 5-4. Nothing in 410 IAC 5-4 shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy.

(b) In addition to complying with the rules set forth in 410 IAC 5-4, every reasonable effort should be made to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable. The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socio-economic considerations, and in relation to the utilization of ionizing radiation in the public interest. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.1; filed May 26, 1978, 3:30 pm: 1 IR 174; filed Feb 29, 1984, 10:10 am: 7 IR 897; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-2 Radiation dose to individuals in restricted areas[1/]

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) In accordance with the provisions of 410 IAC 5-4-3(a), and except as provided in 410 IAC 5-4-2(b), no licensee or registrant shall possess, use, receive, or transfer sources of radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from all sources of radiation in the licensee's or registrant's possession a total occupational dose in excess of the standards specified in the following table:

	Rems per Calendar Quarter
Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	1 1/4
Hands and forearms; feet and ankles	18 3/4
Skin of whole body	7 1/2

[1/] For determining the doses specified in 410 IAC 5-4-2 a dose from x or gamma rays up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

(b) A licensee or registrant may permit an individual in a restricted area to receive a total occupational dose to the whole body greater than that permitted under 410 IAC 5-4-2(a), provided:

(1) During any calendar quarter, the total occupational dose to the whole body from sources of radiation in the licensee's or registrant's possession shall not exceed 3 rems;

(2) The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5(N-18) rems where "N" equals the individual's age in years at his last birthday; and

(3) The licensee or registrant has determined the individual's accumulated occupational dose to the whole body on board form "Y" or on a clear and legible record containing all the information required in that form and has otherwise complied with the requirements of 410 IAC 5-4-3. As used in 410 IAC 5-4-2(b), "dose to the whole body" shall be deemed to include any dose to the whole body, gonads, active bloodforming organs, head and trunk, or lens of eye.

(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.101; filed May 26, 1978, 3:30 pm: 1 IR 174; filed Feb 29, 1984, 10:10 am: 7 IR 897; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-4-3 Disclosure of prior exposure; certification for excess exposure (form Y)

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a)(1) Each licensee or registrant shall require any individual, prior to first entry of the individual into the licensee's or registrant's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of 1 calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in 410 IAC 5-4-2(a) and 410 IAC 5-4-5(a), to disclose in a written, signed statement, either:

(i) That the individual had no prior occupational dose during the current calendar quarter, or

(ii) The nature and amount of any occupational dose which the individual may have received during the specifically identified current calendar quarter, from sources of radiation possessed or controlled by other persons.

(2) Each licensee or registrant shall maintain records of such statements until the board authorizes disposition.

(b) Before permitting, pursuant to 410 IAC 5-4-2(b), any individual in a restricted area to receive an occupational radiation dose in excess of the standards specified in 410 IAC 5-4-2(a), each licensee or registrant shall:

(1) obtain a certificate on board form "Y" or on a clear and legible record containing all the information required in that form, signed by the individual, showing each period of time after the individual attained the age of 18 in which the individual received an occupational dose of radiation; and

(2) calculate on board form "Y" in accordance with the instructions appearing therein, or on a clear and legible record containing all the information required in that form, the previously accumulated occupational dose received by the individual and the additional dose allowed for that individual under 410 IAC 5-4-2(b).

(c)(1) In the preparation of board form "Y," or a clear and legible record containing all the information required in that form, the licensee or registrant shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the licensee or registrant obtains such reports, he shall use the dose shown in the report in preparing the form. In any case where a licensee or registrant is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose specified in whichever of the following columns that apply:

Part of Body	Column 1 Assumed Dose in Rems for Calendar Quarters Prior to January 1, 1961	Column 2 Assumed Dose in Rems for Calendar Quarters Beginning on or After January 1, 1961
Whole body, gonads, active blood-forming organs, head and trunk, lens of eye	3¾	1¼

(2) The licensee or registrant shall retain and preserve records used in preparing board form "Y" until the board authorizes their disposition. If calculation of the individual's accumulated occupational dose for all periods prior to January 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in 410 IAC 5-4-2(b)(2), the excess may be disregarded. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.102; filed May 26, 1978, 3:30 pm: 1 IR 175; filed Feb 29, 1984, 10:10 am: 7 IR 897; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-4 Airborne radiation exposure; restricted areas

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. (a)(1) No licensee or registrant shall possess, use, or transfer radioactive material in such a manner as to permit any individual in a restricted area to inhale a quantity of radioactive material in any period of 1 calendar quarter greater than the quantity which would result from inhalation for 40 hours per week for 13 weeks at uniform concentrations of radioactive material in air specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1.[2/3/4/] If the radioactive material is of such form that intake by absorption through the skin is likely, individual exposures to radioactive material shall be controlled so that the uptake of radioactive material by any organ from either inhalation or absorption or both routes of intake[5/6/] in any calendar quarter does not exceed that which would result from inhaling such radioactive material for 40 hours per week for 13 weeks at uniform concentrations specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1.

(2) No licensee or registrant shall possess, use, or transfer mixtures of U-234, U-235, and U-238 in soluble form in such a manner as to permit any individual in a restricted area to inhale a quantity of such material in excess of the intake limits specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1. If such soluble uranium is of a form such that absorption through the skin is likely, individual exposures to such material shall be controlled so that the uptake of such material by any organ from either inhalation or absorption or both routes of intake[5/] does not exceed that which would result from inhaling such material at the limits specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 and footnote 5 thereto.

(3) For purposes of determining compliance with the requirements of 410 IAC 5-4-4 the licensee or registrant shall use suitable measurements of concentrations of radioactive material in air for detecting and evaluating airborne radioactivity in restricted areas and in addition, as appropriate, shall use measurements of radioactivity in the body, measurements of radioactivity excreted from the body or any combination of such measurements as may be necessary for timely detection and assessment of individual intakes of radioactivity by exposed individuals. It is assumed that an individual inhales radioactive material at the airborne concentration in which he is present unless he uses respiratory protective equipment pursuant to 410 IAC 5-4-4(c). When assessment of a particular individual's intake of radioactive material is necessary, intakes less than those which would result from inhalation for 2 hours in any 1 day or for 10 hours in any 1 week at uniform concentrations specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 need not be included in such assessment, provided that for any assessment in excess of these amounts the entire amount is included.

[2/] Since the concentration specified for tritium oxide vapor assumes equal intakes by skin absorption and inhalation, the total intake permitted is twice that which would result from inhalation alone at the concentration specified in H-3 (S) in Appendix A, 410 IAC 5-4-27, Table I, Column 1 for 40 hours per week for 13 weeks.

[3/] For radon-222, the limiting quantity is that inhaled in a period of one calendar year. For radioactive material designated "Sub" in the "Isotope" column of the table, the concentration value specified is based upon exposure to the material as an external radiation source. Individual exposures to these materials may be accounted for as part of the limitation on individual dose in 410 IAC 5-4-2. These materials shall be subject to the precautionary procedures required in 410 IAC 5-4-4(b)(1).

[4/] Multiply the concentration values specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 by 6.3×10^8 milliliters to obtain the quarterly quantity limit. Multiply the concentration value specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 by 2.5×10^9 milliliters to obtain the annual quantity limit for Rn-222.

[5/] Significant intake by ingestion or injection is presumed to occur only as a result of circumstances such as accident, inadvertence, poor procedure, or similar special conditions. Such intakes must be evaluated and accounted for by techniques and procedures as may be appropriate to the circumstances of the occurrence. Exposures so evaluated shall be included in determining whether the limitation on individual exposures in 410 IAC 5-4-4(a)(1) has been exceeded.

[6/] Regulatory guidance on assessment of individual intakes of radioactive material is given in U.S. Nuclear Regulatory Commission Regulatory Guide 8.9, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program." Single copies of Regulatory Guide 8.9 are available from the Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, upon written request.

(b)(1) The licensee or registrant shall, as a precautionary procedure, use process or other engineering controls, to the extent practicable, to limit concentrations of radioactive materials in air to levels below those which delimit an airborne radioactivity area as defined in 410 IAC 5-1-2.

(2) When it is impracticable to apply process or other engineering controls to limit concentrations of radioactive material in air below those defined in 410 IAC 5-1-2, other precautionary procedures, such as increased surveillance, limitation of working times, or provision of respiratory protective equipment, shall be used to maintain intake of radioactive material by any individual within any period of 7 consecutive days as far below that intake of radioactive material which would result from inhalation of such material for 40 hours at the uniform concentrations specified in Appendix A, 410 IAC 5-4-27, Table I, Column 1 as is reasonably achievable. Whenever the intake of radioactive material by any individual exceeds this 40-hour control measure, the licensee shall

make such evaluations and take such actions as are necessary to assure against recurrence. The licensee shall maintain records of such occurrences, evaluations, and actions taken in a clear and readily identifiable form suitable for summary review and evaluation.

(c) When respiratory protective equipment is used to limit the inhalation of airborne radioactive material pursuant to 410 IAC 5-4-4(b)(2), the licensee may make allowance for such use in estimating exposures of individuals to such materials provided that such equipment is used as stipulated in U.S. Nuclear Regulatory Commission Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection."[7/]

[7/] Single copies of U.S. Nuclear Regulatory Commission Regulatory Guide 8.15 are available from the Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, upon written request.

(d) Notwithstanding the provisions of 410 IAC 5-4-4(b) and (c), the board may impose further restrictions:

(1) On the extent to which a licensee may make allowance for use of respirators in lieu of provision of process, containment, ventilation, or other engineering controls, if application of such controls is found to be practicable; and

(2) As might be necessary to assure that the respiratory protective program of the licensee is adequate in limiting exposures of personnel to airborne radioactive material.

(e) The licensee or registrant shall notify, in writing, the board at least 30 days before the date that respiratory protective equipment is first used under the provisions of 410 IAC 5-4-4.

(f) A licensee or registrant who is authorized to make allowance for use of respiratory protective equipment shall bring his respiratory protective program into conformance with the requirements of 410 IAC 5-4-4(c) within 1 year. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.103; filed May 26, 1978, 3:30 pm: 1 IR 175; filed Feb 29, 1984, 10:10 am: 7 IR 898; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-5 Exposure of minors[8/]

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) No licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to receive in any period of 1 calendar quarter from all sources of radiation in such licensee's or registrant's possession a dose in excess of 10 percent of the standards specified in the table in 410 IAC 5-4-2(a).

(b) No licensee or registrant shall possess, use, or transfer radioactive material in such a manner as to cause any individual within a restricted area, who is under 18 years of age to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Appendix A, 410 IAC 5-4-27, Table II. For purposes of this paragraph, concentrations may be averaged over periods not greater than a week.

(c) The provisions of 410 IAC 5-4-4(b)(2) and 410 IAC 5-4-4(c) shall apply to exposures subject to 410 IAC 5-4-5(b) except that the references in 410 IAC 5-4-4(b)(2) and 410 IAC 5-4-4(c) to Appendix A, 410 IAC 5-4-27, Table I, Column 1 shall be deemed to be references to Appendix A, 410 IAC 5-4-27, Table II, Column 1.

[8/] For determining the doses specified in 410 IAC 5-4-5, a dose from x or gamma radiation up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.104; filed May 26, 1978, 3:30 pm: 1 IR 177; filed Feb 29, 1984, 10:10 am: 7 IR 900; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-6 Permissible levels of radiation from external sources in unrestricted areas[9/]

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Except as authorized by the board pursuant to 410 IAC 5-4-6(b) no licensee or registrant shall possess, use, or transfer sources of radiation in such a manner as to create in any unrestricted area from such sources of radiation in his possession:

(1) Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any 1 hour; or

(2) Radiation levels which, if an individual were continuously present in the area could result in his receiving a dose in excess of 100 millirems in any 7 consecutive days.

(b) Any person may apply to the board for proposed limits upon levels of radiation in unrestricted areas in excess of those

specified in 410 IAC 5-4-6(a) resulting from the applicant's possession or use of sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The board will approve the proposed limits if the applicant demonstrates to the satisfaction of the board that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of 1 calendar year in excess of 0.5 rem.

[9/] It is the intent of 410 IAC 5-4-6 to limit radiation levels so that it is unlikely that individuals in unrestricted areas would receive a dose to the whole body in excess of 0.5 rem in any one year. If in specific instances, it is determined by the board that this intent is not met, the board may, pursuant to 410 IAC 5-1-7, impose such additional requirements on the licensee or registrant as may be necessary to meet the intent. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.105; filed May 26, 1978, 3:30 pm: 1 IR 177; filed Feb 29, 1984, 10:10 am: 7 IR 900; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-7 Effluent concentration limits in unrestricted areas

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) A licensee or registrant shall not possess, use, or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix A, 410 IAC 5-4-27, Table II, except as authorized pursuant to 410 IAC 5-4-17 or 410 IAC 5-4-7(b). For purposes of 410 IAC 5-4-7, concentrations may be averaged over a period not greater than 1 year.

(b) An application for a license or amendment may include proposed limits higher than those specified in 410 IAC 5-4-7(a). The board will approve the proposed limits if the applicant demonstrates:

(1) That the applicant has made a reasonable effort to minimize the radioactivity contained in effluents to unrestricted areas; and

(2) That it is not likely that radioactive material discharged in the effluent would result in the exposure of an individual to concentrations of radioactive material in air or water exceeding the limits specified in Appendix A, 410 IAC 5-4-27, Table II.

(c) An application for higher limits pursuant to 410 IAC 5-4-7(b) shall include information demonstrating that the applicant has made a reasonable effort to minimize the radioactivity discharged in effluents to unrestricted areas, and shall include, as pertinent:

(1) Information as to flow rates, total volume of effluent, peak concentration of each radionuclide in the effluent, and concentration of each radionuclide in the effluent averaged over a period of 1 year at the point where the effluent leaves a stack, tube, pipe, or similar conduit;

(2) A description of the properties of the effluents, including:

(i) Chemical composition,

(ii) Physical characteristics, including suspended solids content in liquid effluents, and nature of gas or aerosol for air effluents,

(iii) The hydrogen ion concentration (pH) of liquid effluents, and

(iv) The size range of particulates in effluents released into air;

(3) A description of the anticipated human occupancy in the unrestricted area where the highest concentration of radioactive material from the effluent is expected, and, in the case of a river or stream, a description of water uses downstream from the point of release of the effluent;

(4) Information as to the highest concentration of each radionuclide in an unrestricted area, including anticipated concentrations averaged over a period of 1 year:

(i) In air at any point of human occupancy, or

(ii) In water at points of use downstream from the point of release of the effluent;

(5) The background concentration of radionuclides in the receiving river or stream prior to the release of liquid effluent;

(6) A description of the environmental monitoring equipment, including sensitivity of the system, and procedures and calculations to determine concentrations of radionuclides in the unrestricted area and possible reconcentrations of radionuclides; and

(7) A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release.

(d) For the purposes of 410 IAC 5-4-7, the concentration limits in Appendix A, 410 IAC 5-4-27, Table II, shall apply at the

boundary of the restricted area. The concentration of radioactive material discharged through a stack, pipe or similar conduit may be determined with respect to the point where the material leaves the conduit. If the conduit discharges within the restricted area, the concentration at the boundary may be determined by applying appropriate factors for dilution, dispersion, or decay between the point of discharge and the boundary.

(e) In addition to limiting concentrations in effluent streams, the board may limit quantities of radioactive material released in air or water during a specified period of time if it appears that the daily intake of radioactive material from air, water, or food by a suitable sample of an exposed population group, averaged over a period not exceeding 1 year, would otherwise exceed the daily intake resulting from continuous exposure to air or water containing one-third (1/3) the concentration of radioactive material specified in Appendix A, 410 IAC 5-4-27, Table II.

(f) The provisions of 410 IAC 5-4-7 do not apply to disposal of radioactive material into sanitary sewerage systems, which is governed by 410 IAC 5-4-18.

(g) In addition to other requirements of this part *[410 IAC 5-4]*, licensees engaged in uranium fuel cycle operations subject to the provisions of 410 IAC 5-3-13 shall also comply with the provisions of 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations." *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.106; filed May 26, 1978, 3:30 pm: 1 IR 177; filed Feb 29, 1984, 10:10 am: 7 IR 901; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-8 Bioassay services

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the board may incorporate license provisions or issue an order requiring a licensee or registrant to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the board. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.107; filed May 26, 1978, 3:30 pm: 1 IR 178; filed Feb 29, 1984, 10:10 am: 7 IR 902; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-9 Surveys

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. Each licensee or registrant shall make or cause to be made such surveys as may be necessary for him to establish compliance with 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.201; filed May 26, 1978, 3:30 pm: 1 IR 178; filed Feb 29, 1984, 10:10 am: 7 IR 902; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-10 Personnel monitoring requirements[9.5/]

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. Each licensee or registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by:

(a) Each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 410 IAC 5-4-2(a);

(b) Each individual under 18 years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any calendar quarter in excess of 5 percent of the applicable value specified in 410 IAC 5-4-2(a);

(c) Each individual who enters a high radiation area.

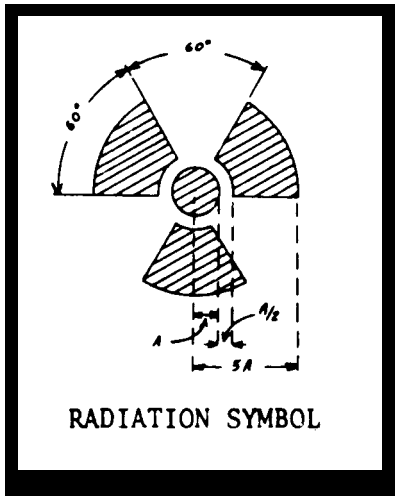
[9.5/] After July 1, 1984, all required personnel monitoring equipment must be obtained from personnel dosimetry processors having an accreditation program approved by the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Bureau of Standards. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.202; filed May 26, 1978, 3:30 pm: 1 IR 178; filed Feb 29, 1984, 10:10 am: 7 IR 902; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-11 Caution signs and labels; alarm signals

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. (a) General.

(1) Except as otherwise authorized by the board, symbols prescribed by 410 IAC 5-4-11 shall use the conventional radiation caution colors (magenta or purple on yellow background). The symbol prescribed by this section is the conventional three-blade design:



RADIATION SYMBOL

(A) Cross-hatch area is to be magenta or purple.

(B) Background is to be yellow.

(2) In addition to the contents of signs and labels prescribed in this section, a licensee or registrant may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation.

(b) Radiation Areas. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
RADIATION AREA

(c) High Radiation Areas.

(1) Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
HIGH RADIATION AREA

(2) Each entrance or access point to a high radiation area shall be:

(i) Equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in 1 hour upon entry into the area; or

(ii) Equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the licensee or a supervisor of the activity are made aware of the entry; or

(iii) Maintained locked except during periods when access to the area is required, with positive control over each individual entry.

(3) The controls required by 410 IAC 5-4-11(c)(2) shall be established in such a way that no individual will be prevented from leaving a high radiation area.

(4) In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by 410 IAC 5-4-11(c)(2).

(5) Any licensee or registrant may apply to the board for approval of methods not included in 410 IAC 5-4-11(c)(2) and (4)

for controlling access to high radiation areas. The board will approve the proposed alternatives if the licensee or registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of 410 IAC 5-4-11(c)(3) is met.

(6) Each area in which there may exist radiation levels in excess of 500 rems in 1 hour at 1 meter from a sealed radioactive source that is used to irradiate materials shall have entry control devices and alarms meeting the criteria specified in Section 20.203(c)(6) of 10 CFR Part 20.

(7) The requirements of 410 IAC 5-4-11(c)(6) shall not apply to radioactive sources that are used in teletherapy, industrial radiography, or in completely self-contained irradiators. In the case of open field irradiators in which certain of the criteria specified in 410 IAC 5-4-11(c)(6) are impracticable, equivalent protection shall be provided by license conditions.

(d) Airborne Radioactivity Areas. Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
AIRBORNE RADIOACTIVITY AREA

(e) Additional Requirements.

(1) Each area or room in which any radioactive material, other than natural uranium or thorium, is used or stored in an amount exceeding 10 times the quantity of radioactive material specified in Appendix B, 410 IAC 5-4-28, shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
RADIOACTIVE MATERIAL

(2) Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity specified in Appendix B, 410 IAC 5-4-28, shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION[10/]
RADIOACTIVE MATERIAL

(f) Containers.

(1) Except as provided in 410 IAC 5-4-11(f)(3) each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents.

(2) A label required pursuant to 410 IAC 5-4-11(f)(1) shall bear the radiation caution symbol and the words:

CAUTION[10/]
RADIOACTIVE MATERIAL

It shall also provide sufficient information[11/] to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures.

(3) Notwithstanding the provisions of 410 IAC 5-4-11(f)(1) labeling is not required:

(i) For containers that do not contain radioactive material in quantities greater than the applicable quantities listed in Appendix B, 410 IAC 5-4-28;

(ii) For containers containing only natural uranium or thorium in quantities no greater than 10 times the applicable quantities listed in Appendix B, 410 IAC 5-4-28;

(iii) For containers that do not contain radioactive material in concentrations greater than the applicable concentrations listed in Appendix A, 410 IAC 5-4-27, Table I, Column 2;

(iv) For containers when they are attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established by 410 IAC 5-4;

(v) For containers when they are in transport and packaged and labeled in accordance with regulations published by the U.S. Department of Transportation;

(vi) For containers which are accessible only to individuals authorized to handle or use them[12/] or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record; and

(vii) For manufacturing and process equipment such as piping and tanks.

(4) Each licensee or registrant shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.

(g) All radiation machines shall be labeled in a manner which cautions individuals that radiation is produced when the machine is being operated.

[10/] Or "Danger."

[11/] As appropriate, the information will include radiation levels, kinds of material, estimate of activity, date for which activity is estimated, etc.

[12/] For example, containers in locations such as water-filled canals, storage vaults, or hot cells. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.203; filed May 26, 1978, 3:30 pm: 1 IR 178; filed Feb 29, 1984, 10:10 am: 7 IR 903; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-12 Exceptions to posting requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. Notwithstanding the provisions of 410 IAC 5-4-11:

(a) A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level 12 inches from the surface of the source container or housing does not exceed 5 millirem per hour.

(b) Rooms or other areas in hospitals are not required to be posted with caution signs, and control of entrance or access thereto pursuant to 410 IAC 5-4-11(c) is not required, because of the presence of patients containing radioactive material provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in 410 IAC 5-4.

(c) Caution signs are not required to be posted in areas or rooms containing radioactive material for periods of less than 8 hours provided that (1) the material is constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in 410 IAC 5-4, and (2) such area or room is subject to the licensee's or registrant's control.

(d) A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive material prepared for transport and packaged and labeled in accordance with regulations of the U.S. Department of Transportation. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.204; filed May 26, 1978, 3:30 pm: 1 IR 180; filed Feb 29, 1984, 10:10 am: 7 IR 904; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-13 Instruction of personnel

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. Instructions required for individuals working in or frequenting any portion of a restricted area are specified in 410 IAC 5-10-3. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.205; filed May 26, 1978, 3:30 pm: 1 IR 180; filed Feb 29, 1984, 10:10 am: 7 IR 905; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-14 Storage of radiation sources

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. (a) Sources of radiation shall be secured against unauthorized removal from the place of storage.

(b) Sources of radiation in an unrestricted area and not in storage shall be tended under the constant surveillance and immediate control of the licensee or registrant. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.206; filed May 26, 1978, 3:30 pm: 1 IR 180; filed Feb 29, 1984, 10:10 am: 7 IR 905; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-15 Procedures for receiving packages

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. (a)(1) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of the Type A quantities specified in the table of exempt and type A quantities in this section shall:

(i) Make arrangements to receive the package when it is offered for delivery by the carrier if the package is to be delivered

to the licensee's or registrant's facility by the carrier; or

(ii) Make arrangements to receive notification from the carrier of the arrival of the package, at the time of arrival if the package is to be picked up by the licensee or registrant at the carrier's terminal.

(2) Each licensee or registrant who picks up a package of radioactive material from a carrier's terminal shall pick up the package expeditiously upon receipt of notification from the carrier of its arrival.

(b)(1) Each licensee or registrant, upon receipt of a package of radioactive material, shall monitor the external surfaces of the package for radioactive contamination caused by leakage of the radioactive contents. The monitoring shall be performed as soon as practicable after receipt, but no later than 3 hours after the package is received at the licensee's facility if received during the licensee's normal working hours or 18 hours if received after normal working hours. Such monitoring need not be performed on:

(i) Packages containing no more than the exempt quantity specified in the table of exempt and type A quantities in this section;

(ii) Packages containing no more than 10 millicuries of radioactive material consisting solely of tritium, carbon-14, sulfur-35, or iodine-125;

(iii) Packages containing only radioactive material as gases or in special form;

(iv) Packages containing only radioactive material in other than liquid form, including Mo-99/Tc-99m generators, and not exceeding the Type A quantity limit specified in the table following 410 IAC 5-4-15(b); and

(v) Packages containing only radionuclides with half-lives of less than 30 days and a total quantity of no more than 100 millicuries.

(2) If removable radioactive contamination in excess of 0.01 microcurie (22,200 transformations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package, the licensee or registrant shall immediately notify by telephone or mailagram, the final delivering carrier and the board.

Table of Exempt and Type A Quantities

Transport Group [13/]	Exempt Quantity Limit (Millicuries)	Type A Quantity Limit (Curies)
I	0.01	0.001
II	0.1	0.050
III	1	3
IV	1	20
V	1	20
VI	1	1,000
VII	25,000	1,000
Special form [13/]	1	20

[13/]The definitions of “transport group” and “special form” are specified in 410 IAC 5-1-2.

(c)(1) Each licensee or registrant, upon receipt of a package containing quantities of radioactive material in excess of the Type A quantities specified in the table of exempt and type A quantities above, other than those transported by exclusive use vehicle, shall monitor the radiation levels external to the package. The package shall be monitored as soon as practicable after receipt, but no later than three hours after the package is received at the licensee's facility if received during the licensee's normal working hours or 18 hours if received after normal working hours.

(2) If radiation levels are found on the external surface of the package in excess of 200 millirems per hour, or in excess of 10 millirems per hour at 3 feet from the external surface of the package, the licensee or registrant shall immediately notify, by telephone and telegraph, the final delivering carrier and the board.

(d) Each licensee or registrant shall establish and maintain procedures for safely opening packages in which radioactive material is received and shall assure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.207; filed May 26, 1978, 3:30 pm: 1 IR 180; filed Feb 29, 1984, 10:10 am: 7 IR 905; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-16 Waste disposal; general provisions

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 16. General Requirement. No licensee or registrant shall dispose of any radioactive material except:

(a) By transfer to an authorized recipient as provided in 410 IAC 5-3-22, or

(b) As authorized pursuant to 410 IAC 5-4-7, 410 IAC 5-4-17, 410 IAC 5-4-18 or 410 IAC 5-4-19. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.301; filed May 26, 1978, 3:30 pm: 1 IR 181; filed Feb 29, 1984, 10:10 am: 7 IR 906; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-17 Approval of proposed disposal procedures

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. (a) Any person may apply to the board for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this section. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal. The application, where appropriate, should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meterological, and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

(b) The board will not approve any application for a license to receive radioactive material from other persons for disposal on land not owned by a state or the federal government. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.302; filed May 26, 1978, 3:30 pm: 1 IR 181; filed Feb 29, 1984, 10:10 am: 7 IR 906; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-18 Release into sanitary sewerage system

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. (a) No licensee or registrant shall discharge radioactive material into a sanitary sewerage system unless:

(1) it is readily soluble or dispersible in water;

(2) the quantity of any radioactive material released into the system by the licensee in any one day does not exceed the larger of:

(i) The quantity which, if diluted by the average daily quantity of sewage released into the sewer by the licensee, will result in an average concentration not greater than the limits specified in Appendix A, 410 IAC 5-4-27, Table I, Column 2, or

(ii) 10 times the quantity of such material specified in Appendix B, 410 IAC 5-4-28;

(3) The quantity of any radioactive material released in any one month, if diluted by the average monthly quantity of water released by the licensee, will not result in an average concentration exceeding the limits specified in Appendix A, 410 IAC 5-4-27, Table I, Column 2; and

(4) The gross quantity of radioactive material, excluding hydrogen-3 and carbon-14, released into the sewage system by the licensee does not exceed 1 curie per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary sewage system may not exceed 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14.

(b) No licensee or registrant shall discharge radioactive material into an individual sewage disposal system used for the treatment of wastewater serving only a single dwelling, office building, industrial plant, or institution except as specifically approved by the board pursuant to 410 IAC 5-4-7 and 410 IAC 5-4-17.

(c) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in 410 IAC 5-4-18. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.303; filed May 26, 1978, 3:30 pm: 1 IR 181; filed Feb 29, 1984, 10:10 am: 7 IR 907; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-19 Burial in soil

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 19. No licensee shall dispose of radioactive material by burial in soil except as specifically approved by the board

pursuant to 410 IAC 5-4-17. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.304; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 907; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-20 Incineration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. No licensee shall incinerate radioactive material for the purpose of disposal or preparation for disposal except as specifically approved by the board pursuant to 410 IAC 5-4-7 and 410 IAC 5-4-17. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.305; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 907; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-20.5 Exceptions to disposal requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20.5. (a) Any licensee or registrant may dispose of the following radioactive material without regard to its radioactivity:

(1) 0.05 microcurie or less of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting, and

(2) 0.05 microcurie or less of hydrogen-3 or carbon-14 per gram of animal tissue averaged over the weight of the entire animal; provided, however, tissue may not be disposed of under 410 IAC 5-4-20.5 in a manner that would permit its use either as food for humans or as animal feed.

(b) Nothing in 410 IAC 5-4-20.5(a), however, relieves the licensee or registrant of maintaining records showing the receipt, transfer and disposal of such radioactive material as specified in 410 IAC 5-1-4.

(c) Nothing in 410 IAC 5-4-20.5(a) relieves the licensee or registrant from complying with other applicable federal, state, and local rules and regulations governing any other toxic or hazardous property of these materials. *(Indiana State Department of Health; 410 IAC 5-4-20.5; filed Feb 29, 1984, 10:10 am: 7 IR 907; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-21 Recordkeeping requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 21. (a) Each licensee or registrant shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under 410 IAC 5-4-10. Such records shall be kept on board form "Z", in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by board form "Z". The doses entered on the forms or records shall be for periods of time not exceeding 1 calendar quarter.

(b) Each licensee or registrant shall maintain records in the same units used in 410 IAC 5-4, showing the results of surveys required by 410 IAC 5-4-9, monitoring required by 410 IAC 5-4-15(b) and (c), and disposals made under 410 IAC 5-4-17, 410 IAC 5-4-18, and 410 IAC 5-4-19.

(c)(1) Records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of 410 IAC 5-4-21(a) and records of bioassays, including results of whole body counting examinations, made pursuant to 410 IAC 5-4-8 shall be preserved until the board authorizes their disposition.

(2) Records of the results of surveys and monitoring which must be maintained pursuant to 410 IAC 5-4-21(b) shall be preserved for 2 years after the completion of the survey except that the following records shall be maintained until the board authorizes their disposition:

(i) records of the results of surveys to determine compliance with 410 IAC 5-4-4(a);

(ii) in the absence of personnel monitoring data, records of the results of surveys to determine external radiation dose; and

(iii) records of the results of surveys used to evaluate the release of radioactive effluents to the environment.

(3) Records of disposal of licensed material made pursuant to 410 IAC 5-4-17, 410 IAC 5-4-18 or 410 IAC 5-4-19 shall be maintained until the board authorizes their disposition.

(4) Records which must be maintained pursuant to 410 IAC 5-4-21 may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a

clear and legible copy after storage for the period specified by board rules.

(5) If there is a conflict between the board's rules in 410 IAC 5-4-21, license condition, or other written board approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in 410 IAC 5-4-21 for such records shall apply unless the board, pursuant to 410 IAC 5-1-3(a), has granted a specific exemption from the record retention requirements specified in 410 IAC 5-4-21.

(d) The discontinuance of, or curtailment of, activities does not relieve the licensee or registrant of responsibility for retaining all records required by 410 IAC 5-4-21. A licensee or registrant may, however, request the board to accept such records. The acceptance of the records by the board relieves the licensee or registrant of subsequent responsibility only in respect to their preservation as required by 410 IAC 5-4-21. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.401; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 908; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-22 Theft or loss of sources; reporting

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 22. Each licensee or registrant shall report by telephone or mailgram to the board the theft or loss of any source of radiation immediately after such occurrence becomes known. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.402; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 908; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-23 Incident reports

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 23. (a) Immediate Notification. Each licensee or registrant shall immediately notify the board by telephone and telegraph of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause:

(1) a dose to the whole body of any individual of 25 rems or more of radiation; a dose to the skin of the whole body of any individual of 150 rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of any individual of 375 rems or more of radiation; or

(2) the release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in Appendix A, 410 IAC 5-4-27, Table II; or

(3) a loss of 1 working week or more of the operation of any facilities affected; or

(4) damage to property in excess of $200,000.

(b) Twenty-four Hour Notification. Each licensee or registrant shall within 24 hours notify the board by telephone or mailgram of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause:

(1) A dose to the whole body of any individual of 5 rems or more of radiation; a dose to the skin of the whole body of any individual of 30 rems or more of radiation; or a dose to the feet, ankles, hands, or forearms of 75 rems or more of radiation; or

(2) The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limits specified for such materials in Appendix A, 410 IAC 5-4-27, Table II; or

(3) A loss of 1 day or more of the operation of any facilities affected; or

(4) Damage to property in excess of $2,000.

(c) Any report filed with the board pursuant to 410 IAC 5-4-23 shall be prepared in such a manner that names of individuals who have received excessive doses will be stated in a separate part of the report. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.403; filed May 26, 1978, 3:30 pm: 1 IR 182; filed Feb 29, 1984, 10:10 am: 7 IR 909; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-24 Overexposure reports

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 24. (a) In addition to any notification required by 410 IAC 5-4-23, each licensee or registrant shall make a report in

writing within 30 days to the board of:

(1) each exposure of an individual to radiation in excess of the applicable standards in 410 IAC 5-4-2 or 410 IAC 5-4-5(a) or the license;

(2) each exposure of an individual to radioactive material in excess of the applicable limits in 410 IAC 5-4-4(a)(1), 410 IAC 5-4-4(a)(2), 410 IAC 5-4-5(b) or the license;

(3) levels of radiation or concentrations of radioactive material in a restricted area in excess of any other applicable limit in the license;

(4) any incident for which notification is required by 410 IAC 5-4-23; and

(5) levels of radiation or concentrations of radioactive material, whether or not involving excessive exposure of any individual, in an unrestricted area in excess of 10 times any applicable limit set forth in this part *[410 IAC 5-4]* or in the license.

(b) Each report required under 410 IAC 5-4-24 shall describe the extent of exposure of individuals to radiation or to radioactive material, including estimates of each individual's exposure as required by 410 IAC 5-4-24; levels of radiation and concentrations of radioactive material involved; the cause of the exposure, levels or concentrations; and corrective steps taken or planned to assure against a recurrence.

(c) Any report filed with the board pursuant to 410 IAC 5-4-24 shall include for each individual exposed the name, social security number, and the date of birth, and an estimate of the individual's dose. The report shall be prepared so that this information is stated in a separate part of the report. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.405; filed May 26, 1978, 3:30 pm: 1 IR 183; filed Feb 29, 1984, 10:10 am: 7 IR 909; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-25 Vacating premises; decontamination

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25. Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the board in writing of intent to vacate. When deemed necessary by the board, the licensee or registrant shall decontaminate the premises in such a manner as the board may specify. *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.407; filed May 26, 1978, 3:30 pm: 1 IR 183; filed Feb 29, 1984, 10:10 am: 7 IR 910; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-26 Notice and report to exposed individuals

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 26. (a) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 410 IAC 5-10-4.

(b) When a licensee or registrant is required pursuant to 410 IAC 5-4-24 to report to the board any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the board, and shall comply with the provisions of 410 IAC 5-10-4(a). *(Indiana State Department of Health; Rule HRH-2,PT D,Sec D.408; filed May 26, 1978, 3:30 pm: 1 IR 183; filed Feb 29, 1984, 10:10 am: 7 IR 910; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-4-27 Concentrations in air and water above natural background; Appendix A

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 27.

APPENDIX A
CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Actinium (89)	Ac-227	S	20×10^{-12}	6×10^{-5}	8×10^{-14}	2×10^{-6}
		I	3×10^{-11}	9×10^{-3}	9×10^{-13}	3×10^{-4}
	Ac-228	S	8×10^{-8}	3×10^{-3}	3×10^{-9}	9×10^{-5}
		I	2×10^{-8}	3×10^{-3}	6×10^{-10}	9×10^{-5}
Americium (95)	Am-241	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Am-242m	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	3×10^{-10}	3×10^{-3}	9×10^{-12}	9×10^{-5}
	Am-242	S	4×10^{-8}	4×10^{-3}	1×10^{-9}	1×10^{-4}
		I	5×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
	Am-243	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Am-244	S	4×10^{-6}	1×10^{-1}	1×10^{-7}	5×10^{-3}
		I	2×10^{-5}	1×10^{-1}	8×10^{-7}	5×10^{-3}
Antimony (51)	Sb-122	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
	Sb-124	S	2×10^{-7}	7×10^{-4}	5×10^{-9}	2×10^{-5}
		I	2×10^{-8}	7×10^{-4}	7×10^{-10}	2×10^{-5}
	Sb-125	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	3×10^{-8}	3×10^{-3}	9×10^{-10}	1×10^{-4}
Argon (18)	Ar-37	Sub[2/]	6×10^{-3}	_____	1×10^{-4}	_____
	Ar-41	Sub	2×10^{-6}	_____	4×10^{-8}	_____
Arsenic (33)	As-73	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	5×10^{-4}
		I	4×10^{-7}	1×10^{-2}	1×10^{-8}	5×10^{-4}
	As-74	S	3×10^{-7}	2×10^{-3}	1×10^{-10}	5×10^{-5}
		I	1×10^{-7}	2×10^{-3}	4×10^{-9}	5×10^{-5}
	As-76	S	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
		I	1×10^{-7}	6×10^{-4}	3×10^{-9}	2×10^{-5}
	As-77	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Astatine (85)	At-211	S	7×10^{-9}	5×10^{-5}	2×10^{-10}	2×10^{-6}
		I	3×10^{-8}	2×10^{-3}	1×10^{-9}	7×10^{-5}
Barium (56)	Ba-131	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Ba-140	S	1×10^{-7}	8×10^{-4}	4×10^{-9}	3×10^{-5}
		I	4×10^{-8}	7×10^{-4}	1×10^{-9}	2×10^{-5}
Berkelium (97)	Bk-249	S	9×10^{-10}	2×10^{-2}	3×10^{-11}	6×10^{-4}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	1×10^{-7}	2×10^{-2}	4×10^{-9}	6×10^{-4}
	Bk-250	S	1×10^{-7}	6×10^{-3}	5×10^{-9}	2×10^{-4}
		I	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
Beryllium (4)	Be-7	S	6×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
		I	1×10^{-6}	5×10^{-2}	4×10^{-8}	2×10^{-3}
Bismuth (83)	Bi-206	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
		I	1×10^{-7}	1×10^{-3}	5×10^{-9}	4×10^{-5}
	Bi-207	S	2×10^{-7}	2×10^{-3}	6×10^{-9}	6×10^{-5}
		I	1×10^{-8}	2×10^{-3}	5×10^{-10}	6×10^{-5}
	Bi-210	S	6×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
		I	6×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
	Bi-212	S	1×10^{-7}	1×10^{-2}	3×10^{-9}	4×10^{-4}
		I	2×10^{-7}	1×10^{-2}	7×10^{-9}	4×10^{-4}
Bromine (35)	Br-82	S	1×10^{-6}	8×10^{-3}	4×10^{-8}	3×10^{-4}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Cadmium (48)	Cd-109	S	5×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
		I	7×10^{-8}	5×10^{-3}	3×10^{-9}	2×10^{-4}
	Cd-115m	S	4×10^{-8}	7×10^{-4}	1×10^{-9}	3×10^{-5}
		I	4×10^{-8}	7×10^{-4}	1×10^{-9}	3×10^{-5}
	Cd-115	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Calcium (20)	Ca-45	S	3×10^{-8}	3×10^{-4}	1×10^{-9}	9×10^{-6}
		I	1×10^{-7}	5×10^{-3}	4×10^{-9}	2×10^{-4}
	Ca-47	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	3×10^{-5}
Californium (98)	Cf-249	S	2×10^{-12}	1×10^{-4}	5×10^{-14}	4×10^{-6}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	2×10^{-5}
	Cf-250	S	5×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-5}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	3×10^{-5}
	Cf-251	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}
	Cf-252	S	6×10^{-12}	2×10^{-4}	2×10^{-13}	7×10^{-6}
		I	3×10^{-11}	2×10^{-4}	1×10^{-12}	7×10^{-6}
	Cf-253	S	8×10^{-10}	4×10^{-3}	3×10^{-11}	1×10^{-4}
		I	8×10^{-10}	4×10^{-3}	3×10^{-11}	1×10^{-4}
	Cf-254	S	5×10^{-12}	4×10^{-6}	2×10^{-13}	1×10^{-7}
		I	5×10^{-12}	4×10^{-6}	2×10^{-13}	1×10^{-7}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Carbon (6)	C-14	S	4×10^{-6}	2×10^{-2}	1×10^{-7}	8×10^{-4}
	(Co_2)	Sub[2/]	5×10^{-5}	_____	1×10^{-6}	_____
Cerium (58)	Ce-141	S	4×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	2×10^{-7}	3×10^{-3}	5×10^{-9}	9×10^{-5}
	Ce-143	S	3×10^{-7}	1×10^{-3}	9×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
	Ce-144	S	1×10^{-8}	3×10^{-4}	3×10^{-10}	1×10^{-5}
		I	6×10^{-9}	3×10^{-4}	2×10^{-10}	1×10^{-5}
Cesium (55)	Cs-131	S	1×10^{-5}	7×10^{-2}	4×10^{-7}	2×10^{-3}
		I	3×10^{-6}	3×10^{-2}	1×10^{-7}	9×10^{-4}
	Cs-134m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	6×10^{-3}
		I	6×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
	Cs-134	S	4×10^{-8}	3×10^{-4}	1×10^{-9}	9×10^{-6}
		I	1×10^{-8}	1×10^{-3}	4×10^{-10}	4×10^{-5}
	Cs-135	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	9×10^{-8}	7×10^{-3}	3×10^{-9}	2×10^{-4}
	Cs-136	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	9×10^{-5}
		I	2×10^{-7}	2×10^{-3}	6×10^{-9}	6×10^{-5}
	Cs-137	S	6×10^{-8}	4×10^{-4}	2×10^{-9}	2×10^{-5}
		I	1×10^{-8}	1×10^{-3}	5×10^{-10}	4×10^{-5}
Chlorine (17)	Cl-36	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
		I	2×10^{-8}	2×10^{-3}	8×10^{-10}	6×10^{-5}
	Cl-38	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	7×10^{-8}	4×10^{-4}
Chromium (24)	Cr-51	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	2×10^{-6}	5×10^{-2}	8×10^{-8}	2×10^{-3}
Cobalt (27)	Co-57	S	3×10^{-6}	2×10^{-2}	1×10^{-7}	5×10^{-4}
		I	2×10^{-7}	1×10^{-2}	6×10^{-9}	4×10^{-4}
	Co-58m	S	2×10^{-5}	8×10^{-2}	6×10^{-7}	3×10^{-3}
		I	9×10^{-6}	6×10^{-2}	3×10^{-7}	2×10^{-3}
	Co-58	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-8}	3×10^{-3}	2×10^{-9}	9×10^{-5}
	Co-60	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	5×10^{-5}
		I	9×10^{-9}	1×10^{-3}	3×10^{-10}	3×10^{-5}
Copper (29)	Cu-64	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	3×10^{-4}
		I	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
Curium (96)	Cm-242	S	1×10^{-10}	7×10^{-4}	4×10^{-12}	2×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	2×10^{-10}	7×10^{-4}	6×10^{-12}	2×10^{-5}
	Cm-243	S	6×10^{-12}	1×10^{-4}	2×10^{-13}	5×10^{-6}
		I	1×10^{-10}	7×10^{-4}	3×10^{-12}	2×10^{-5}
	Cm-244	S	9×10^{-12}	2×10^{-4}	3×10^{-13}	7×10^{-6}
		I	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}
	Cm-245	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Cm-246	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	Cm-247	S	5×10^{-12}	1×10^{-4}	2×10^{-13}	4×10^{-6}
		I	1×10^{-10}	6×10^{-4}	4×10^{-12}	2×10^{-5}
	Cm-248	S	6×10^{-13}	1×10^{-5}	2×10^{-14}	4×10^{-7}
		I	1×10^{-11}	4×10^{-5}	4×10^{-13}	1×10^{-6}
	Cm-249	S	1×10^{-5}	6×10^{-2}	4×10^{-7}	2×10^{-3}
		I	1×10^{-5}	6×10^{-2}	4×10^{-7}	2×10^{-3}
Dysprosium (66)	Dy-165	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	7×10^{-8}	4×10^{-4}
	Dy-166	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
Einsteinium (99)	Es-253	S	8×10^{-10}	7×10^{-4}	3×10^{-11}	2×10^{-5}
		I	6×10^{-10}	7×10^{-4}	2×10^{-11}	2×10^{-5}
	Es-254m	S	5×10^{-9}	5×10^{-4}	2×10^{-10}	2×10^{-5}
		I	6×10^{-9}	5×10^{-4}	2×10^{-10}	2×10^{-5}
	Es-254	S	2×10^{-11}	4×10^{-4}	6×10^{-13}	1×10^{-5}
		I	1×10^{-10}	4×10^{-4}	4×10^{-12}	1×10^{-5}
	Es-255	S	5×10^{-10}	8×10^{-4}	2×10^{-11}	3×10^{-5}
		I	4×10^{-10}	8×10^{-4}	1×10^{-11}	3×10^{-5}
Erbium (68)	Er-169	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	4×10^{-7}	3×10^{-3}	1×10^{-8}	9×10^{-5}
	Er-171	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Europium (63)	Eu-152	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	(T_r=9.2 hrs)	I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Eu-152	S	1×10^{-8}	2×10^{-3}	4×10^{-10}	8×10^{-5}
	(T_r=13 yrs)	I	2×10^{-8}	2×10^{-3}	6×10^{-10}	8×10^{-5}
	Eu-154	S	4×10^{-9}	6×10^{-4}	1×10^{-10}	2×10^{-5}
		I	7×10^{-9}	6×10^{-4}	2×10^{-10}	2×10^{-5}

APPENDIX A
CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
	Eu-155	S	9×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}
		I	7×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}
Fermium (100)	Fm-254	S	6×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
		I	7×10^{-8}	4×10^{-3}	2×10^{-9}	1×10^{-4}
	Fm-255	S	2×10^{-8}	1×10^{-3}	6×10^{-10}	3×10^{-5}
		I	1×10^{-8}	1×10^{-3}	4×10^{-10}	3×10^{-5}
	Fm-256	S	3×10^{-9}	3×10^{-5}	1×10^{-10}	9×10^{-7}
		I	2×10^{-9}	3×10^{-5}	6×10^{-11}	9×10^{-7}
Fluorine (9)	F-18	S	5×10^{-6}	2×10^{-2}	2×10^{-7}	8×10^{-4}
		I	3×10^{-6}	1×10^{-2}	9×10^{-8}	5×10^{-4}
Gadolinium (64)	Gd-153	S	2×10^{-7}	6×10^{-3}	8×10^{-9}	2×10^{-4}
		I	9×10^{-8}	6×10^{-3}	3×10^{-9}	2×10^{-4}
	Gd-159	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Gallium (31)	Ga-72	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
Germanium (32)	Ge-68	S	7×10^{-7}	3×10^{-3}	2×10^{-7}	9×10^{-4}
		I	2×10^{-8}	3×10^{-3}	5×10^{-9}	9×10^{-4}
	Ge-71	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}
		I	6×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
Gold (79)	Au-195	S	2×10^{-7}	7×10^{-4}	7×10^{-8}	2×10^{-4}
		I	6×10^{-8}	7×10^{-4}	2×10^{-8}	2×10^{-4}
	Au-196	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	6×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
	Au-198	S	3×10^{-7}	2×10^{-3}	1×10^{-8}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Au-199	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	8×10^{-7}	4×10^{-3}	3×10^{-8}	2×10^{-4}
Hafnium (72)	Hf-181	S	4×10^{-8}	2×10^{-3}	1×10^{-9}	7×10^{-5}
		I	7×10^{-8}	2×10^{-3}	3×10^{-9}	7×10^{-5}
Holmium (67)	Ho-166	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
Hydrogen (1)	H-3	S	5×10^{-6}	1×10^{-1}	2×10^{-7}	3×10^{-3}
		I	5×10^{-6}	1×10^{-1}	2×10^{-7}	3×10^{-3}
		Sub[2/]	2×10^{-3}	_____	4×10^{-5}	_____
Indium (49)	In-113m	S	8×10^{-6}	4×10^{-2}	3×10^{-7}	1×10^{-3}
		I	7×10^{-6}	4×10^{-2}	2×10^{-7}	1×10^{-3}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
	In-114m	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	2×10^{-8}	5×10^{-4}	7×10^{-10}	2×10^{-5}
	In-115m	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	4×10^{-4}
	In-115	S	2×10^{-7}	3×10^{-3}	9×10^{-9}	9×10^{-5}
		I	3×10^{-8}	3×10^{-3}	1×10^{-9}	9×10^{-5}
Iodine (53)	I-125	S	5×10^{-9}	4×10^{-5}	8×10^{-11}	2×10^{-7}
		I	2×10^{-7}	6×10^{-3}	6×10^{-9}	2×10^{-4}
	I-126	S	8×10^{-9}	5×10^{-5}	9×10^{-11}	3×10^{-7}
		I	3×10^{-7}	3×10^{-3}	1×10^{-8}	9×10^{-5}
	I-129	S	2×10^{-9}	1×10^{-5}	2×10^{-11}	6×10^{-8}
		I	7×10^{-8}	6×10^{-3}	2×10^{-9}	2×10^{-4}
	I-131	S	9×10^{-9}	6×10^{-5}	1×10^{-10}	3×10^{-7}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	I-132	S	2×10^{-7}	2×10^{-3}	3×10^{-9}	8×10^{-6}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	I-133	S	3×10^{-8}	2×10^{-4}	4×10^{-10}	1×10^{-6}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
	I-134	S	5×10^{-7}	4×10^{-3}	6×10^{-9}	2×10^{-5}
		I	3×10^{-6}	2×10^{-2}	1×10^{-7}	6×10^{-4}
	I-135	S	1×10^{-7}	7×10^{-4}	1×10^{-9}	4×10^{-6}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
Iridium (77)	Ir-190	S	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Ir-192	S	1×10^{-7}	1×10^{-3}	4×10^{-9}	4×10^{-5}
		I	3×10^{-8}	1×10^{-3}	9×10^{-10}	4×10^{-5}
	Ir-194	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
Iron (26)	Fe-55	S	9×10^{-7}	2×10^{-2}	3×10^{-8}	8×10^{-4}
		I	1×10^{-6}	7×10^{-2}	3×10^{-8}	2×10^{-3}
	Fe-59	S	1×10^{-7}	2×10^{-3}	5×10^{-9}	6×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	5×10^{-5}
Krypton (36)	Kr-85m	Sub[2/]	6×10^{-6}	_____	1×10^{-7}	_____
	Kr-85	Sub	1×10^{-5}	_____	3×10^{-7}	_____
	Kr-87	Sub	1×10^{-6}	_____	2×10^{-8}	_____
	Kr-88	Sub	1×10^{-6}	_____	2×10^{-8}	_____
Lanthanum (57)	La-140	S	2×10^{-7}	7×10^{-4}	5×10^{-9}	2×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	1×10^{-7}	7×10^{-4}	4×10^{-9}	2×10^{-5}
Lead (82)	Pb-203	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	4×10^{-4}
	Pb-210	S	1×10^{-10}	4×10^{-6}	4×10^{-12}	1×10^{-7}
		I	2×10^{-10}	5×10^{-3}	8×10^{-12}	2×10^{-4}
	Pb-212	S	2×10^{-8}	6×10^{-4}	6×10^{-10}	2×10^{-5}
		I	2×10^{-8}	5×10^{-4}	7×10^{-10}	2×10^{-5}
Lutetium (71)	Lu-177	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Manganese (25)	Mn-52	S	2×10^{-7}	1×10^{-3}	7×10^{-9}	3×10^{-5}
		I	1×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
	Mn-54	S	4×10^{-7}	4×10^{-3}	1×10^{-8}	1×10^{-4}
		I	4×10^{-8}	3×10^{-3}	1×10^{-9}	1×10^{-4}
	Mn-56	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Mercury (80)	Hg-197m	S	7×10^{-7}	6×10^{-3}	3×10^{-8}	2×10^{-4}
		I	8×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Hg-197	S	1×10^{-6}	9×10^{-3}	4×10^{-8}	3×10^{-4}
		I	3×10^{-6}	1×10^{-2}	9×10^{-8}	5×10^{-4}
	Hg-203	S	7×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
Molybdenum (42)	Mo-99	S	7×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
		I	2×10^{-7}	1×10^{-3}	7×10^{-9}	4×10^{-5}
Neodymium (60)	Nd-144	S	8×10^{-11}	2×10^{-3}	3×10^{-12}	7×10^{-5}
		I	3×10^{-10}	2×10^{-3}	1×10^{-11}	8×10^{-5}
	Nd-147	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	2×10^{-3}	8×10^{-9}	6×10^{-5}
	Nd-149	S	2×10^{-6}	8×10^{-3}	6×10^{-8}	3×10^{-4}
		I	1×10^{-6}	8×10^{-3}	5×10^{-8}	3×10^{-4}
Neptunium (93)	Np-237	S	4×10^{-12}	9×10^{-5}	1×10^{-13}	3×10^{-6}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
	Np-239	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	7×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
Nickel (28)	Ni-59	S	5×10^{-7}	6×10^{-3}	2×10^{-8}	2×10^{-4}
		I	8×10^{-7}	6×10^{-2}	3×10^{-8}	2×10^{-3}
	Ni-63	S	6×10^{-8}	8×10^{-4}	2×10^{-9}	3×10^{-5}
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	7×10^{-4}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
	Ni-65	S	9×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Niobium (41)	Nb-93m	S	1×10^{-7}	1×10^{-2}	4×10^{-9}	4×10^{-4}
		I	2×10^{-7}	1×10^{-2}	5×10^{-9}	4×10^{-4}
	Nb-95	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	1×10^{-7}	3×10^{-3}	3×10^{-9}	1×10^{-4}
	Nb-97	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
Osmium (76)	Os-185	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	7×10^{-5}
	Os-191m	S	2×10^{-5}	7×10^{-2}	6×10^{-7}	3×10^{-3}
		I	9×10^{-6}	7×10^{-2}	3×10^{-7}	2×10^{-3}
	Os-191	S	1×10^{-6}	5×10^{-3}	4×10^{-8}	2×10^{-4}
		I	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
	Os-193	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	3×10^{-7}	2×10^{-3}	9×10^{-9}	5×10^{-5}
Palladium (46)	Pd-103	S	1×10^{-6}	1×10^{-2}	5×10^{-8}	3×10^{-4}
		I	7×10^{-7}	8×10^{-3}	3×10^{-8}	3×10^{-4}
	Pd-109	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
Phosphorus (15)	P-32	S	7×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	8×10^{-8}	7×10^{-4}	3×10^{-9}	2×10^{-5}
Platinum (78)	Pt-191	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
	Pt-193m	S	7×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
	Pt-193	S	1×10^{-6}	3×10^{-2}	4×10^{-8}	9×10^{-4}
		I	3×10^{-7}	5×10^{-2}	1×10^{-8}	2×10^{-3}
	Pt-197m	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	1×10^{-3}
		I	5×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
	Pt-197	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Plutonium (94)	Pu-238	S	2×10^{-12}	1×10^{-4}	7×10^{-14}	5×10^{-6}
		I	3×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu-239	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}
		I	4×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu-240	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	4×10^{-11}	8×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu-241	S	9×10^{-11}	7×10^{-3}	3×10^{-12}	2×10^{-4}
		I	4×10^{-8}	4×10^{-2}	1×10^{-9}	1×10^{-3}
	Pu-242	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	5×10^{-6}
		I	4×10^{-11}	9×10^{-4}	1×10^{-12}	3×10^{-5}
	Pu-243	S	2×10^{-6}	1×10^{-2}	6×10^{-8}	3×10^{-4}
		I	2×10^{-6}	1×10^{-2}	8×10^{-8}	3×10^{-4}
	Pu-244	S	2×10^{-12}	1×10^{-4}	6×10^{-14}	4×10^{-6}
		I	3×10^{-11}	3×10^{-4}	1×10^{-12}	1×10^{-5}
Polonium (84)	Po-210	S	5×10^{-10}	2×10^{-5}	2×10^{-11}	7×10^{-7}
		I	2×10^{-10}	8×10^{-4}	7×10^{-12}	3×10^{-5}
Potassium (19)	K-42	S	2×10^{-6}	9×10^{-3}	7×10^{-8}	3×10^{-4}
		I	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
Praseodymium (59)	Pr-142	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	2×10^{-7}	9×10^{-4}	5×10^{-9}	3×10^{-5}
	Pr-143	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	5×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	5×10^{-5}
Promethium (61)	Pm-147	S	6×10^{-8}	6×10^{-3}	2×10^{-9}	2×10^{-4}
		I	1×10^{-7}	6×10^{-3}	3×10^{-9}	2×10^{-4}
	Pm-149	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
Protactinium (91)	Pa-230	S	2×10^{-9}	7×10^{-3}	6×10^{-11}	2×10^{-4}
		I	8×10^{-10}	7×10^{-3}	3×10^{-11}	2×10^{-4}
	Pa-231	S	1×10^{-12}	3×10^{-5}	4×10^{-14}	9×10^{-7}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	2×10^{-5}
	Pa-233	S	6×10^{-7}	4×10^{-3}	2×10^{-8}	1×10^{-4}
		I	2×10^{-7}	3×10^{-3}	6×10^{-9}	1×10^{-4}
Radium (88)	Ra-223	S	2×10^{-9}	2×10^{-5}	6×10^{-11}	7×10^{-7}
		I	2×10^{-10}	1×10^{-4}	8×10^{-12}	4×10^{-6}
	Ra-224	S	5×10^{-9}	7×10^{-5}	2×10^{-10}	2×10^{-6}
		I	7×10^{-10}	2×10^{-4}	2×10^{-11}	5×10^{-6}
	Ra-226	S	3×10^{-11}	4×10^{-7}	3×10^{-12}	3×10^{-8}
		I	5×10^{-11}	9×10^{-4}	2×10^{-12}	3×10^{-5}
	Ra-228	S	7×10^{-11}	8×10^{-7}	2×10^{-12}	3×10^{-8}
		I	4×10^{-11}	7×10^{-4}	1×10^{-12}	3×10^{-5}
Radon (86)	Rn-220	S	3×10^{-7}	_____	1×10^{-8}	_____
		I	_____	_____	_____	_____

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
	Rn-222[3/]	S	3×10^{-8}	_____	3×10^{-9}	_____
Rhenium (75)	Re-183	S	3×10^{-6}	2×10^{-2}	9×10^{-8}	6×10^{-4}
		I	2×10^{-7}	8×10^{-3}	5×10^{-9}	3×10^{-4}
	Re-186	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Re-187	S	9×10^{-6}	7×10^{-2}	3×10^{-7}	3×10^{-3}
		I	5×10^{-7}	4×10^{-2}	2×10^{-8}	2×10^{-3}
	Re-188	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
Rhodium (45)	Rh-103m	S	8×10^{-5}	4×10^{-1}	3×10^{-6}	1×10^{-2}
		I	6×10^{-5}	3×10^{-1}	2×10^{-6}	1×10^{-2}
	Rh-105	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Rubidium (37)	Rb-86	S	3×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
		I	7×10^{-8}	7×10^{-4}	2×10^{-9}	2×10^{-5}
	Rb-87	S	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	7×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
Ruthenium (44)	Ru-97	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-6}	1×10^{-2}	6×10^{-8}	3×10^{-4}
	Ru-103	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	8×10^{-8}	2×10^{-3}	3×10^{-9}	8×10^{-5}
	Ru-105	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
	Ru-106	S	8×10^{-8}	4×10^{-4}	3×10^{-9}	1×10^{-5}
		I	6×10^{-9}	3×10^{-4}	2×10^{-10}	1×10^{-5}
Samarium (62)	Sm-147	S	7×10^{-11}	2×10^{-3}	2×10^{-12}	6×10^{-5}
		I	3×10^{-10}	2×10^{-3}	9×10^{-12}	7×10^{-5}
	Sm-151	S	6×10^{-8}	1×10^{-2}	2×10^{-9}	4×10^{-4}
		I	1×10^{-7}	1×10^{-2}	5×10^{-9}	4×10^{-4}
	Sm-153	S	5×10^{-7}	2×10^{-3}	2×10^{-8}	8×10^{-5}
		I	4×10^{-7}	2×10^{-3}	1×10^{-8}	8×10^{-5}
Scandium (21)	Sc-46	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
		I	2×10^{-8}	1×10^{-3}	8×10^{-10}	4×10^{-5}
	Sc-57	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
		I	5×10^{-7}	3×10^{-3}	2×10^{-8}	9×10^{-5}
	Sc-48	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Selenium (34)	Se-75	S	1×10^{-6}	9×10^{-3}	4×10^{-8}	3×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	3×10^{-4}
Silicon (14)	Si-31	S	6×10^{-6}	3×10^{-2}	2×10^{-7}	9×10^{-4}
		I	1×10^{-6}	6×10^{-3}	3×10^{-8}	2×10^{-4}
Silver (47)	Ag-105	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	8×10^{-8}	3×10^{-3}	3×10^{-9}	1×10^{-4}
	Ag-110m	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	1×10^{-8}	9×10^{-4}	3×10^{-10}	3×10^{-5}
	Ag-111	S	3×10^{-7}	1×10^{-3}	1×10^{-8}	4×10^{-5}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	4×10^{-5}
Sodium (11)	Na-22	S	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
		I	9×10^{-9}	9×10^{-4}	3×10^{-10}	3×10^{-5}
	Na-24	S	1×10^{-6}	6×10^{-3}	4×10^{-8}	2×10^{-4}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
Strontium (38)	Sr-85m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	7×10^{-3}
		I	3×10^{-5}	2×10^{-1}	1×10^{-6}	7×10^{-3}
	Sr-85	S	2×10^{-7}	3×10^{-3}	8×10^{-9}	1×10^{-4}
		I	1×10^{-7}	5×10^{-3}	4×10^{-9}	2×10^{-4}
	Sr-89	S	3×10^{-8}	3×10^{-4}	3×10^{-10}	3×10^{-6}
		I	4×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
	Sr-90	S	1×10^{-9}	1×10^{-5}	3×10^{-11}	3×10^{-7}
		I	5×10^{-9}	1×10^{-3}	2×10^{-10}	4×10^{-5}
	Sr-91	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	1×10^{-3}	9×10^{-9}	5×10^{-5}
	Sr-92	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
Sulfur (16)	S-35	S	3×10^{-7}	2×10^{-3}	9×10^{-9}	6×10^{-5}
		I	3×10^{-7}	8×10^{-3}	9×10^{-9}	3×10^{-4}
Tantalum (73)	Ta-182	S	4×10^{-8}	1×10^{-3}	1×10^{-9}	4×10^{-5}
		I	2×10^{-8}	1×10^{-3}	7×10^{-10}	4×10^{-5}
Technetium (43)	Tc-96m	S	8×10^{-5}	4×10^{-1}	3×10^{-6}	1×10^{-2}
		I	3×10^{-5}	3×10^{-1}	1×10^{-6}	1×10^{-2}
	Tc-96	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	2×10^{-7}	1×10^{-3}	8×10^{-9}	5×10^{-5}
	Tc-97m	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	2×10^{-7}	5×10^{-3}	5×10^{-9}	2×10^{-4}
	Tc-97	S	1×10^{-5}	5×10^{-2}	4×10^{-7}	2×10^{-3}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	8×10^{-4}
	Tc-99m	S	4×10^{-5}	2×10^{-1}	1×10^{-6}	6×10^{-3}
		I	1×10^{-5}	8×10^{-2}	5×10^{-7}	3×10^{-3}
	Tc-00	S	2×10^{-6}	1×10^{-2}	7×10^{-8}	3×10^{-4}
		I	6×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
Tellurium (52)	Te-125m	S	4×10^{-7}	5×10^{-3}	1×10^{-8}	2×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
	Te-127m	S	1×10^{-7}	2×10^{-3}	5×10^{-9}	6×10^{-5}
		I	4×10^{-8}	2×10^{-3}	1×10^{-9}	5×10^{-5}
	Te-127	S	2×10^{-6}	8×10^{-3}	6×10^{-8}	3×10^{-4}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Te-129m	S	8×10^{-8}	1×10^{-3}	3×10^{-9}	3×10^{-5}
		I	3×10^{-8}	6×10^{-4}	1×10^{-9}	2×10^{-5}
	Te-129	S	5×10^{-6}	2×10^{-2}	2×10^{-7}	8×10^{-4}
		I	4×10^{-6}	2×10^{-2}	1×10^{-7}	8×10^{-4}
	Te-131m	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	4×10^{-5}
	Te-132	S	2×10^{-7}	9×10^{-4}	7×10^{-9}	3×10^{-5}
		I	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
Terbium (65)	Tb-165	S	1×10^{-7}	1×10^{-3}	3×10^{-9}	4×10^{-5}
		I	3×10^{-8}	1×10^{-3}	1×10^{-9}	4×10^{-5}
Thallium (81)	Tl-200	S	3×10^{-6}	1×10^{-2}	9×10^{-8}	4×10^{-4}
		I	1×10^{-6}	7×10^{-3}	4×10^{-8}	2×10^{-4}
	Tl-201	S	2×10^{-6}	9×10^{-3}	7×10^{-8}	3×10^{-4}
		I	9×10^{-7}	5×10^{-3}	3×10^{-8}	2×10^{-4}
	Tl-202	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	2×10^{-7}	2×10^{-3}	8×10^{-9}	7×10^{-5}
	Tl-204	S	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	3×10^{-8}	2×10^{-3}	9×10^{-10}	6×10^{-5}
Thorium (90)	Th-227	S	3×10^{-10}	5×10^{-4}	1×10^{-11}	2×10^{-5}
		I	2×10^{-10}	5×10^{-4}	6×10^{-12}	2×10^{-5}
	Th-228	S	9×10^{-12}	2×10^{-4}	3×10^{-13}	7×10^{-6}
		I	6×10^{-12}	4×10^{-4}	2×10^{-13}	1×10^{-5}
	Th-230	S	2×10^{-12}	5×10^{-5}	8×10^{-14}	2×10^{-6}
		I	1×10^{-11}	9×10^{-4}	3×10^{-13}	3×10^{-5}
	Th-231	S	1×10^{-6}	7×10^{-3}	5×10^{-8}	2×10^{-4}
		I	1×10^{-6}	7×10^{-3}	7×10^{-8}	2×10^{-4}

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CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
	Th-232	S	3×10^{-11}	5×10^{-5}	1×10^{-12}	2×10^{-6}
		I	3×10^{-11}	1×10^{-3}	1×10^{-12}	4×10^{-5}
	Th-nat-ural	S	6×10^{-11}	6×10^{-5}	2×10^{-12}	2×10^{-6}
		I	6×10^{-11}	6×10^{-4}	2×10^{-12}	2×10^{-5}
	Th-234	S	6×10^{-8}	5×10^{-4}	2×10^{-9}	2×10^{-5}
		I	3×10^{-8}	5×10^{-4}	1×10^{-9}	2×10^{-5}
Thulium (69)	Tm-170	S	4×10^{-8}	1×10^{-3}	1×10^{-9}	5×10^{-5}
		I	3×10^{-8}	1×10^{-3}	1×10^{-9}	5×10^{-5}
	Tm-171	S	1×10^{-7}	1×10^{-2}	4×10^{-9}	5×10^{-4}
		I	2×10^{-7}	1×10^{-2}	8×10^{-9}	5×10^{-4}
Tin (50)	Sn-113	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	9×10^{-5}
		I	5×10^{-8}	2×10^{-3}	2×10^{-9}	8×10^{-5}
	Sn-125	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	8×10^{-8}	5×10^{-4}	3×10^{-9}	2×10^{-5}
Tungsten (74)	W-181	S	2×10^{-6}	1×10^{-2}	8×10^{-8}	4×10^{-4}
		I	1×10^{-7}	1×10^{-2}	4×10^{-9}	3×10^{-4}
	W-185	S	8×10^{-7}	4×10^{-3}	3×10^{-8}	1×10^{-4}
		I	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
	W-187	S	4×10^{-7}	2×10^{-3}	2×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
Uranium (92)	U-230	S	3×10^{-10}	1×10^{-4}	1×10^{-11}	5×10^{-6}
		I	1×10^{-10}	1×10^{-4}	4×10^{-12}	5×10^{-6}
	U-232	S	1×10^{-10}	8×10^{-4}	3×10^{-12}	3×10^{-5}
		I	3×10^{-11}	8×10^{-4}	9×10^{-13}	3×10^{-5}
	U-233	S	5×10^{-10}	9×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
	U-234	S[4/]	6×10^{-10}	9×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	9×10^{-4}	4×10^{-12}	3×10^{-5}
	U-235	S[4/]	5×10^{-10}	8×10^{-4}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	8×10^{-4}	4×10^{-12}	3×10^{-5}
	U-236	S	6×10^{-10}	1×10^{-3}	2×10^{-11}	3×10^{-5}
		I	1×10^{-10}	1×10^{-3}	4×10^{-12}	3×10^{-5}
	U-238	S[4/]	7×10^{-11}	1×10^{-3}	3×10^{-12}	4×10^{-5}
		I	1×10^{-10}	1×10^{-3}	5×10^{-12}	4×10^{-5}
	U-240	S	2×10^{-7}	1×10^{-3}	8×10^{-9}	3×10^{-5}
		I	2×10^{-7}	1×10^{-3}	6×10^{-9}	3×10^{-5}
	U-natural	S[4/]	1×10^{-10}	1×10^{-3}	5×10^{-12}	3×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]		Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
		I	1×10^{-10}	1×10^{-3}	5×10^{-12}	3×10^{-5}
Vanadium (23)	V-48	S	2×10^{-7}	9×10^{-4}	6×10^{-9}	3×10^{-5}
		I	6×10^{-8}	8×10^{-4}	2×10^{-9}	3×10^{-5}
Xenon (54)	Xe-131m	Sub[2/]	2×10^{-5}	_____	4×10^{-7}	_____
	Xe-133m	Sub	1×10^{-5}	_____	3×10^{-7}	_____
	Xe-133	Sub	1×10^{-5}	_____	3×10^{-7}	_____
	Xe-135	Sub	4×10^{-6}	_____	1×10^{-7}	_____
Ytterbium (70)	Yb-175	S	7×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
		I	6×10^{-7}	3×10^{-3}	2×10^{-8}	1×10^{-4}
Yttrium (39)	Y-88	S	1×10^{-7}	2×10^{-4}	4×10^{-8}	8×10^{-5}
		I	5×10^{-8}	2×10^{-4}	2×10^{-8}	8×10^{-5}
	Y-90	S	1×10^{-7}	6×10^{-4}	4×10^{-9}	2×10^{-5}
		I	1×10^{-7}	6×10^{-4}	3×10^{-9}	2×10^{-5}
	Y-91m	S	2×10^{-5}	1×10^{-1}	8×10^{-7}	3×10^{-3}
		I	2×10^{-5}	1×10^{-1}	6×10^{-7}	3×10^{-3}
	Y-91	S	4×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
		I	3×10^{-8}	8×10^{-4}	1×10^{-9}	3×10^{-5}
	Y-92	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Y-93	S	2×10^{-7}	8×10^{-4}	6×10^{-9}	3×10^{-5}
		I	1×10^{-7}	8×10^{-4}	5×10^{-9}	3×10^{-5}
Zinc (30)	Zn-65	S	1×10^{-7}	3×10^{-3}	4×10^{-9}	1×10^{-4}
		I	6×10^{-8}	5×10^{-3}	2×10^{-9}	2×10^{-4}
	Zn-69m	S	4×10^{-7}	2×10^{-3}	1×10^{-8}	7×10^{-5}
		I	3×10^{-7}	2×10^{-3}	1×10^{-8}	6×10^{-5}
	Zn-69	S	7×10^{-6}	5×10^{-2}	2×10^{-7}	2×10^{-3}
		I	9×10^{-6}	5×10^{-2}	3×10^{-7}	2×10^{-3}
Zirconium (40)	Zr-93	S	1×10^{-7}	2×10^{-2}	4×10^{-9}	8×10^{-4}
		I	3×10^{-7}	2×10^{-2}	1×10^{-8}	8×10^{-4}
	Zr-95	S	1×10^{-7}	2×10^{-3}	4×10^{-9}	6×10^{-5}
		I	3×10^{-8}	2×10^{-3}	1×10^{-9}	6×10^{-5}
	Zr-97	S	1×10^{-7}	5×10^{-4}	4×10^{-9}	2×10^{-5}
		I	9×10^{-8}	5×10^{-4}	3×10^{-9}	2×10^{-5}

APPENDIX A

CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND

Element (atomic number)	Isotope[1/]	Table I Column 1 Air (μCi/ml)	Table I Column 2 Water (μCi/ml)	Table II Column 1 Air (μCi/ml)	Table II Column 2 Water (μCi/ml)
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours. ***	Sub[2/]	1×10^{-6}	_____	3×10^{-8}	_____
Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours.		3×10^{-9}	9×10^{-5}	1×10^{-10}	3×10^{-6}
Any single radionuclide not listed above, which decays by alpha emission or spontaneous fission.		6×10^{-13}	4×10^{-7}	$2\times^{-14}$	3×10^{-8}

[1/]Soluble (S); Insoluble (I).

[2/]"Sub" means that values given are for submersion in a semispherical infinite cloud of airborne material.

[3/]These radon concentrations are appropriate for protection from radon-222 combined with its short-lived daughters. Alternatively, the value in Table I may be replaced by 1/3 "working level." (A "working level" is defined as any combinations of short-lived radon-222 daughters, polonium-218, lead-214, bismuth-214, and polonium-214 in 1 liter of air, without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3×10^5 MeV of alpha particle energy.) The Table II value may be replaced by 1/30th of a "working level." The limit on radon-222 concentrations in restricted areas may be based on an annual average.

[4/]For soluble mixtures of U-238, U-234 and U-235 in air, chemical toxicity may be the limiting factor. If the percent by weight (enrichment) of U-235 is less than 5, the concentration value for a 40-hour workweek, Table I, is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8×10^{-3} SA μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The concentration value for Table II is 0.007 milligrams uranium per cubic meter of air. The specific activity for natural uranium is 6.77×10^{-7} curies per gram uranium. The specific activity for other mixtures of U-238, U-235 and U-234, if not known, shall be:

$SA = 3.6 \times 10^{-7}$ curies/gram U U-depeleted

$SA = (0.4 + 0.38\ E + 0.0034\ E^2)$ $10^{-6}\ E \geq 0.72$

where E is the percentage by weight of U-235, expressed as percent.

Note: In any case where there is a mixture in air or water of more than one radionuclide, the limiting values for purposes of this appendix should be determined as follows:

1. If the identity and concentration of each radionuclide in the mixture are known, the limiting values should be derived as follows: Determine, for each radionuclide in the mixture, the ratio between the quantity present in the mixture and the limit otherwise established in Appendix "A" for the specific radionuclide when not in a mixture. The sum of such ratios for all the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Example: If radionuclides a, b, and c are present in concentrations C_a, C_b, and C_c, and if the applicable maximum permissible concentrations (MPC's) are MPC_a, MPC_b, and MPC_c respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_a}{MPC_a} + \frac{C_b}{MPC_b} + \frac{C_c}{MPC_c} \leq 1$$

2. If either the identity or the concentration of any radionuclide in the mixture is not known, the limiting values for purposes of Appendix "A" shall be:

a. For purposes of Table I, Col. 1 . . . . . 6×10^{-13}
b. For purposes of Table I, Col. 2 . . . . . 4×10^{-7}
c. For purposes of Table II, Col. 1 . . . . . 2×10^{-14}
d. For purposes of Table II, Col. 2 . . . . . 3×10^{-8}

3. If any of the conditions specified below are met, the corresponding values specified below may be used in lieu of those specified in paragraph 2 above.

a. If the identity of each radionuclide in the mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the concentration limit for the mixture is the limit specified in Appendix "A" for the radionuclide in the mixture having the lowest concentration limit: or

b. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in Appendix "A" are not present in the mixture, the concentration limit for the mixture is the lowest concentration limit specified in Appendix "A" for any radionuclide which is not known to be absent from the mixture; or

c. Radionuclide	Table I		Table II	
	Column 1 Air (μCi/ml)	Column 2 Water (μCi/ml)	Column 1 Air (μCi/ml)	Column 2 Water (μCi/ml)
If it is known that Sr-90, I-125, I-126, I-129, I-131, (I-133 Table II only), Pb-210, Po-210, At-211, Ra-223, Ra-224, Ra-226, Ac-227, Ra-228, Th-230, Pa-231, Th-232, Th-nat, Cm-248, Cf-254, and Fm-256 are not present	_____	9×10^{-5}	_____	3×10^{-6}
If it is known that Sr-90, I-125, I-126, I-129, (I-131, I-133, Table II only), Pb-210, Po-210, Ra-223, Ra-226, Ra-228, Pa-231, Th-nat, Cm-248, Cf-254, and Fm-256 are not present	_____	6×10^{-5}	_____	2×10^{-6}
If it is known that Sr-90, I-129, (I-125, I-126, I-131, Table II only), Pb-210, Ra-226, Ra-228, Cm-248, and Cf-254 are not present	_____	2×10^{-5}	_____	6×10^{-7}
If it is known that (I-129, Table II only), Ra-226, and Ra-228 are not present	_____	3×10^{-6}	_____	1×10^{-7}
If it is known that alpha-emitters and Sr-90, I-129, Pb-210, Ac-227, Ra-228, Pa-230, Pu-241, and Bk-249 are not present	3×10^{-9}	_____	1×10^{-10}	_____
If it is known that alpha-emitters and Pb-210, Ac-227, Ra-228, and Pu-241 are not present	3×10^{-10}	_____	1×10^{-11}	_____
If it is known that alpha-emitters and Ac-227 are not present	3×10^{-11}	_____	1×10^{-12}	_____
If it is known that Ac-227, Th-230, Pa-231, Pu-238, Pu-239, Pu-240, Pu-242, Pu-244, Cm-248, Cf-249 and Cf-251 are not present	3×10^{-12}	_____	1×10^{-13}	_____

4. If a mixture of radionuclides consists of uranium and its daughter products in ore dust prior to chemical separation of the uranium from the ore, the values specified below may be used for uranium and its daughters through radium-226, instead of those from paragraphs 1, 2, or 3 above.

a. For purposes of Table I, Column 1, 1×10^{-10} μCi/ml gross alpha activity; or 5×10^{-11} μCi/ml natural uranium; or 75 micrograms per cubic meter of air natural uranium.

b. For purposes of Table II, Column 1, 3×10^{-12} μCi/ml gross alpha activity; 2×10^{-12} μCi/ml natural uranium; or 3 micrograms per cubic meter of air natural uranium.

5. For purposes of this note, a radionuclide may be considered as not present in a mixture if (a) the ratio of the concentration of that radionuclide in the mixture (C_a) to the concentration limit for that radionuclide specified in Table II of Appendix "A" (MPC_a) does not exceed 1/10, (i.e., $C_a/MPC_a \leq 1/10$) and (b) the sum of such ratios for all radionuclides considered as not present in the mixture does not exceed 1/4, (i.e., $C_a/MPC_a + C_b/MPC_b + ... \leq 1/4$).

Note: To convert μCi/ml to SI unnts *[sic.]* of megabecquerels per liter, multiply the above values by 37.

Example: Zirconium (40) Zr-97 S (Table I, Column 1-Air) (1×10^{-7} μCi/ml multiplied by 37 is equivalent to 37×10^{-7} MBq/1.)

(Indiana State Department of Health; Rule HRH-2,PT D,Appendix A; filed May 26, 1978, 3:30 pm: 1 IR 184; filed Feb 29, 1984, 10:10 am: 7 IR 910; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-4-28 Appendix B; table for use with 410 IAC 5-4-11, 410 IAC 5-4-18, 410 IAC 5-4-19

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 28.

Part D

APPENDIX B

Material	Microcuries
Americium-241	0.01
Antinomy-122	100
Antinomy-124	10
Antinomy-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10

Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10

Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10

Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-22	10
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10

Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[1/]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2/]	100
Uranium-233	0.01
Uranium-234/235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

[1/]Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[2/]Based on alpha disintegration rate of U-238, U-234, and U-235.

NOTE: For purposes of 410 IAC 5-4-11, 410 IAC 5-4-18, and 410 IAC 5-4-19, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may exceed "1" (i.e., "unity").

Example: For purposes of 410 IAC 5-4-19, if a particular batch contains 20,000 μCi of Au-198 and 50,000 μCi of C-14, it may also include not more than 300 μCi of I-131. This limit was determined as follows:

20,000 μCi Au-198/100,000 μCi + 50,000 μCi C-14/100,00 *[sic.]* μCi
+ 300 μCi I-131/1,000 μCi = 1

The denominator in each of the above ratios was obtained by multiplying the figure in the table by 1,000 as provided in 410 IAC 5-4-19.

Note: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by 37.

Example: Zirconium-97 (10 μCi)(37) = 370 kBq. (10 μCi multiplied by 37 is equivalent to 370 kBq) *(Indiana State Department of Health; Rule HRH-2,PT D,Appendix B; filed May 26, 1978, 3:30 pm: 1 IR 197; filed Feb 29, 1984, 10:10 am: 7 IR 924; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 5. Non-Medical Radiography

410 IAC 5-5-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. The requirements in 410 IAC 5-5 establish radiation safety requirements for persons utilizing sources of radiation for non-medical radiography (i.e., industrial radiography, ionizing radiation gauging devices, NARM, and any other non-medical use). The requirements of 410 IAC 5-5 are in addition to, and not in substitution for, the other requirements of 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.1; filed May 26, 1978, 3:30 pm: 1 IR 199; filed Feb 29, 1984, 10:10 am: 7 IR 926; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-2 Applicability of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. The requirements in 410 IAC 5-5 apply to all registrants who use sources of radiation for non-medical radiography. Except for those requirements of 410 IAC 5-5 clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by 410 IAC 5-5. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.2; filed May 26, 1978, 3:30 pm: 1 IR 199; filed Feb 29, 1984, 10:10 am: 7 IR 927; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-3 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. As used in 410 IAC 5-5, the following definitions apply:

"ANSI" means the American National Standards Institute.

"Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography and shielded room radiography.

(1) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the limitations specified in 410 IAC 5-4-6.

(i) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independent of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airlines, railroads, bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(ii) "Certified cabinet x-ray system" means an x-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

(2) "Shielded-room radiography" means industrial radiography conducted in a room so shielded that radiation levels at every location on the exterior meet the limitations specified in 410 IAC 5-4-6.

"Gamma radiography" means industrial radiography using radioactive material that emits gamma rays (i.e., Ir 192, Co 60, Cs 137).

"Industrial radiography" means the use of penetrating radiation, such as x-rays, gamma rays, or neutrons, to make pictures of the insides of objects (i.e., metal castings or welds).

"Ionizing radiation gauging device" (gauge) means a mechanism designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative chemical composition.

"NARM" means any naturally occurring or accelerator produced radioactive material. It does not include by-product, source, or special nuclear material.

"Permanent radiographic installation" means an installation or structure designed or intended for radiography and in which radiography is regularly performed.

"Personal supervision" means supervision such that the supervisor is physically present at the site where sources of radiation and associated equipment are being used, watching the performance of the radiographer's assistant and in such proximity that contact can be maintained and immediate assistance given as required.

"Radiographer" means any individual who performs or provides personal supervision of industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of 410 IAC 5 and all license (and/or registration) conditions.

"Radiographer's assistant" means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

"Storage container" means a device in which sealed sources are transported or stored.

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed in a specific license or certificate of registration. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.3; filed May 26, 1978, 3:30 pm: 1 IR 199; filed Feb 29, 1984, 10:10 am: 7 IR 927; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-3.1 Additional requirements; safety programs

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3.1. (a) Ionizing radiation gauging devices shall comply with applicable sections of ANSI N538 or its equivalent, in addition to 410 IAC 5-5-8 and other applicable sections of 410 IAC 5.

(b) The board may impose any additional requirement for the specific application of an ionizing radiation source to protect the health and safety of an employee and/or the public. The board shall weigh the impact of any such requirement against the hazards created without such a requirement, before imposing any additional requirements.

(c) All non-medical users of "NARM" and/or devices that produce x-rays either as part of their design or incidental to other

design functions shall have an adequate radiation safety program.

(1) The adequacy of the program will be evaluated by the board.

(2) The program must meet the intent of 410 IAC 5.

(3) The program shall keep personnel exposure ALARA (as low as reasonably achievable).

(4) The program shall take under consideration the education and training of the personnel utilizing or in the environs of the radiation device.

(Indiana State Department of Health; 410 IAC 5-5-3.1; filed Feb 29, 1984, 10:10 am: 7 IR 928; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-5-3.2 Enclosed radiography; special provisions and exemptions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3.2. (a) Systems for enclosed radiography designed to allow admittance of individuals shall:

(1) Comply with 410 IAC 5-5-11, 410 IAC 5-5-11.5, 410 IAC 5-5-12, 410 IAC 5-5-13, 410 IAC 5-5-15, 410 IAC 5-5-16, and 410 IAC 5-5-18 of 410 IAC 5-5 and 410 IAC 5-4-6.

(2) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter and reports of the results must be maintained for inspection by the board.

(3) Be evaluated at intervals not to exceed 1 year to assure compliance with the applicable requirements as specified in 410 IAC 5-5-3.2(a)(1). Records of these evaluations shall be maintained for inspection by the board for a period of 2 years after the evaluation.

(b) Cabinet x-ray systems designed to exclude individuals are exempt from the requirements of 410 IAC 5-5-3.2 except that:

(1) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of instructions in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subdivision shall be maintained for inspection by the board until disposition is authorized by the board;

(2) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, must be conducted and recorded in accordance with 410 IAC 5-5-11.5; and

(3) The registrant shall perform or have done an evaluation, at intervals not to exceed 1 year, to determine conformance with 410 IAC 5-4-6. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed 1 year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the board for a period of 2 years after the evaluation.

(c) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the board pursuant to 410 IAC 5-1-3(a). *(Indiana State Department of Health; 410 IAC 5-5-3.2; filed Feb 29, 1984, 10:10 am: 7 IR 928; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-4 Radiation limits for exposure devices and storage containers for gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. Radiographic exposure devices measuring less than 10 cm from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at 15 cm from any exterior surface of the device. Radiographic exposure devices measuring a minimum of 10 cm from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and 10 milliroentgens per hour at 1 meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.101; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 929; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-5 Locking of sources for gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant, or as may be otherwise authorized pursuant to 410 IAC 5-5-15. Each storage container and source changer likewise shall be provided with a lock and shall be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

(b) Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.102; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 929; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-6 Security precautions for gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. Locked radiographic exposure devices, source changers, and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.103; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 929; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-7 Survey instruments for gamma and temporary job site radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by 410 IAC 5-5-7 and 410 IAC 5-4-9 of 410 IAC 5. Instrumentation required by this section shall have such a range such that 2 milliroentgens per hour through 1 roentgen per hour can be measured.

(b) Each radiation survey instrument shall be calibrated:

(1) at energies appropriate for use and at intervals not to exceed 3 months and after each instrument servicing;

(2) such that accuracy within plus or minus 20 percent traceable to a national standard can be demonstrated; and

(3) at two or more widely separated points, other than zero, on each scale.

(c) Records of these calibrations shall be maintained for two years after the calibration date for inspection by the board. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.104; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 929; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-8 Leak testing, replacement, and modification of NARM sealed sources

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) The replacement of any "NARM" sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons qualified by education and training.

(b) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 month period prior to the transfer, the sealed source shall not be put into use until tested.

(1) The board may grant exceptions to the leak test requirement for "NARM," when;

(i) The construction and history of a type of sealed source warrants a less frequent testing.

(ii) Access to the source places an undue burden on the registrant.

(2) Any "NARM" sealed source less than 100 times the quantity listed in Schedule B of 410 IAC 5-4 is excepted from leak tests.

(3) Any sealed source with a half-life less than 30 days and/or in gaseous form is excepted from leak tests.

(4) Any "NARM" sealed source 10μCi or less used as a check source is excepted.

(c) The leak test shall be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed

source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the board for 6 months after the next required leak test is performed or until the sealed source is transferred or disposed of.

(d) Any test conducted pursuant to 410 IAC 5-5-8(b) and (c) which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with rules of the board. Within 5 days after obtaining results of the test, the licensee shall file a report with the board describing the equipment involved, the test results, and the corrective action taken.

(e) A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger–Radioactive Material." *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.105; filed May 26, 1978, 3:30 pm: 1 IR 200; filed Feb 29, 1984, 10:10 am: 7 IR 930; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-9 Quarterly inventory of sealed sources for gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received or possessed by him. The records of the inventories shall be maintained for 2 years from the date of the inventory for inspection by the board and shall include the quantities and kinds of radioactive material, the location of sealed sources, and the date of the inventory. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.106; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 930; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-10 Utilization logs in gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by the board for 2 years from the date of the recorded event showing for each source of radiation the following information:

(a) A description (or make and model number) of each source of radiation or storage container in which the sealed source is located;

(b) The identity of the radiographer to whom assigned; and

(c) Locations where used and dates of use.

(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.107; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 930; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-5-11 Inspection and maintenance of industrial exposure devices and storage containers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. (a) Each licensee or registrant shall ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers are performed prior to each day of use.

(b) The licensee or registrant shall conduct a program of at least quarterly inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturers' specifications. Records of inspection and maintenance shall be maintained for inspection by the board until it authorizes their disposal.

(c) If any inspection conducted pursuant to 410 IAC 5-5-11(a) or (b) reveals damage to components critical to radiation safety, the device shall be removed from service until repairs have been made. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.108; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 931; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-11.5 Permanent installations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11.5. Permanent radiographic installations having high radiation area entrance controls of the type described in 410 IAC 5-4-11(c)(2)(ii) and (iii) and (c)(4) shall also meet the following requirements:

(a) Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

(b) The control device or alarm system shall be tested for proper operation at the beginning of each period of use. Records of these tests shall be maintained for inspection by the board until their disposal is authorized. *(Indiana State Department of Health; 410 IAC 5-5-11.5; filed Feb 29, 1984, 10:10 am: 7 IR 931; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-12 Personnel training and testing; internal audit of operating and emergency procedures

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. Training and testing (applies to all industrial radiography). (a) No licensee or registrant shall permit any individual to act as a radiographer, as defined in 410 IAC 5-5-12, until such individual:

(1) Has been instructed in the subjects outlined in 410 IAC 5-5-20 and shall have demonstrated understanding thereof;

(2) Has received copies of and instruction in the requirements contained in this section and the applicable sections of 410 IAC 5-4 and 410 IAC 5-10, appropriate license(s), and the licensee's or registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;

(3) Has demonstrated competence to use the source of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which will be employed in his assignment; and

(4) Has demonstrated an understanding of the instructions of 410 IAC 5-5-12(a) by successful completion of a written test and a field examination on the subjects covered.

(b) No licensee or registrant shall permit any individual to act as a radiographer's assistant as defined in 410 IAC 5-5-12 until such individual:

(1) Has received copies of and instruction in the licensee's or registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;

(2) Has demonstrated competence to use, under the personal supervision of the radiographer, the sources of radiation, radiographic exposure device(s), related handling tools, and radiation survey instruments which will be employed in his assignment; and

(3) Has demonstrated an understanding of the instructions in 410 IAC 5-5-12(b) by successful completion of a written or oral test and a field examination on the subjects covered.

(c) Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained for inspection by the board for 3 years following termination of employment.

(d) Each licensee or registrant shall conduct an internal audit program to ensure that the board's radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least annually. Records of internal audits shall be maintained for inspection by the board for 2 years from the date of the audit. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.201; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 931; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-13 Operating and emergency instructions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) The handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation

doses in excess of the limits established in 410 IAC 5-4;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing sources of radiation;

(e) Personnel monitoring and the use of personnel monitoring equipment including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;

(f) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;

(g) Minimizing exposure of individuals in the event of an accident;

(h) The procedure for notifying proper personnel in the event of an accident;

(i) Maintenance of records; and

(j) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.202; filed May 26, 1978, 3:30 pm: 1 IR 201; filed Feb 29, 1984, 10:10 am: 7 IR 932; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-14 Personnel monitoring in gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. (a) No licensee or registrant shall permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such individual shall wear a direct reading pocket dosimeter and either film badge or a thermoluminescent dosimeter. Pocket dosimeters shall have a range from zero to at least 200 milliroentgens and shall be recharged daily or at the start of each shift. Each film badge or thermoluminescent dosimeter shall be assigned to and worn by only one individual.

(b) Pocket dosimeters shall be read and exposures recorded daily. An individual's film badge or thermoluminescent dosimeter shall be immediately processed if his pocket dosimeter is discharged beyond its range. Reports received from the film badge or thermoluminescent dosimeter processor and records of pocket dosimeter readings shall be maintained for inspection by the board until it authorizes their disposal.

(c) Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.203; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 932; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-14.5 Supervision of radiographer assistants in gamma radiography

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14.5. Whenever a radiographer's assistant uses radiographic exposure devices, sealed sources, or related source handling tools, or conducts radiation surveys required by 410 IAC 5-5-17(b) and (c) to determine that the sealed source has returned to the shielded position after an exposure, the radiographer's assistant shall be under the personal supervision of a radiographer. *(Indiana State Department of Health; 410 IAC 5-5-14.5; filed Feb 29, 1984, 10:10 am: 7 IR 933; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-15 Security during operation

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in 410 IAC 5-1, except:

(a) Where the high radiation area is equipped with a control device or alarm system as described in 410 IAC 5-4-11(c)(2), or

(b) Where the high radiation area is locked to protect against unauthorized or accidental entry. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.301; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 933; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-16 Posting of operation areas

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. Notwithstanding any provisions in 410 IAC 5-4-12(c), areas in which radiography is being performed shall be conspicuously posted as required by 410 IAC 5-4-11(b) and (c)(1). *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.302; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 933; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-17 Surveys; records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. (a) No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation as described in 410 IAC 5-5-9 is available and used at each site where radiographic exposures are made.

(b) A physical radiation survey shall be made after each radiographic exposure utilizing radiographic exposure devices or sealed sources of radioactive material to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the guide tube.

(c) A physical radiation survey shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device or storage container as specified in 410 IAC 5-5-5.

(d) A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."

(e) Records shall be kept of the surveys required by 410 IAC 5-5-17(c). Such records shall be maintained for inspection by the board for 2 years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the board authorizes their disposition. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.303; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 933; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-18 Temporary job site records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. Each licensee or registrant conducting industrial radiography at a temporary site shall have the following records available at that site for inspection by the board:

(a) Appropriate license, (or certificate of registration) or equivalent document;

(b) Operating and emergency procedures;

(c) Applicable rules;

(d) Survey records required pursuant to 410 IAC 5-5-17 for the period of operation at the site;

(e) Daily pocket dosimeter records for the period of operation at the site; and

(f) The latest instrument calibration and leak test record for specific devices in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter. *(Indiana State Department of Health; Rule HRH-2,PT E,Sec E.304; filed May 26, 1978, 3:30 pm: 1 IR 202; filed Feb 29, 1984, 10:10 am: 7 IR 934; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-5-19 Enclosed radiography; exemption; special requirements (Repealed)

Sec. 19. *(Repealed by Indiana State Department of Health; filed Feb 29, 1984, 10:10 am: 7 IR 829)*

410 IAC 5-5-20 Instruction of radiographers; scope

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. Subjects to be Covered During the Instruction of Radiographers
(I) Fundamentals of Radiation Safety
(A) Characteristics of radiation
(B) Units of radiation dose (mrem) and quantity of radioactivity (curie)
(C) Significance of radiation dose
(1) Radiation protection standards
(2) Biological effects of radiation
(D) Levels of radiation from sources of radiation
(E) Methods of controlling radiation dose
(1) Working time
(2) Working distances
(3) Shielding
(II) Radiation Detection Instrumentation to be Used
(A) Use of radiation survey instruments
(1) Operation
(2) Calibration
(3) Limitations
(B) Survey techniques
(C) Use of personnel monitoring equipment
(1) Film badges
(2) Thermoluminescent dosimeters
(3) Pocket dosimeters
(III) Radiographic Equipment to be Used
(A) Remote handling equipment
(B) Radiographic exposure devices and sealed sources
(C) Storage containers
(D) Operation and control of x-ray equipment
(IV) The Requirements of Pertinent Federal and State Rules
(V) The Licensee's or Registrant's Written Operating and Emergency Procedures
(VI) Case Histories of Radiography Accidents *(Indiana State Department of Health; Rule HRH-2,PT E,Appendix A; filed May 26, 1978, 3:30 pm: 1 IR 203; filed Feb 29, 1984, 10:10 am: 7 IR 934; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 6. X-Rays in the Healing Arts (Repealed)

(Repealed by Indiana State Department of Health; filed Oct 29, 1993, 5:00 p.m.: 17 IR 392)

Rule 6.1. X-Rays in the Healing Arts

410 IAC 5-6.1-1 Incorporation by reference

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. The following documents are incorporated by reference as a part of this rule:
(1) 21 CFR 1020.30(c) (HHS publication FDA 88-8035, April 1988). Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. This document is available for public review at the department.
(2) 21 CFR Subchapter J (HHS publication FDA 88-8035, April 1988). Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. This document is

available for public review at the department.

(3) "A Protocol for the Determination of Absorbed Dose from High Energy Photon and Electron Beams": Medical Physics; Vol. 10; No. 6; Nov/Dec 1983; pp. 741–771. Copies may be obtained by writing to: American Institute of Physics, Single Copy Sales, 500 Sunnyside Blvd., Woodbury, New York 11791. This document is available for public review at the department.

(Indiana State Department of Health; 410 IAC 5-6.1-1; filed Oct 29, 1993, 5:00 p.m.: 17 IR 356; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-2 "ABHP" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. As used in this rule, "ABHP" means the American Board of Health Physics. *(Indiana State Department of Health; 410 IAC 5-6.1-2; filed Oct 29, 1993, 5:00 p.m.: 17 IR 356; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-3 "ABMP" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. As used in this rule, "ABMP" means the American Board of Medical Physics. *(Indiana State Department of Health; 410 IAC 5-6.1-3; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-4 "ABR" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. As used in this rule, "ABR" means the American Board of Radiology. *(Indiana State Department of Health; 410 IAC 5-6.1-4; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-5 "Absorbed dose" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. As used in this rule, "absorbed dose" means that amount of radiation which has been absorbed, measured in grays or rads. *(Indiana State Department of Health; 410 IAC 5-6.1-5; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-6 "Accessible surface" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. As used in this rule, "accessible surface" means the external surface of the enclosure or housing provided by the manufacturer. *(Indiana State Department of Health; 410 IAC 5-6.1-6; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-7 "ACR" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. As used in this rule, "ACR" means the American College of Radiology. *(Indiana State Department of Health; 410 IAC 5-6.1-7; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-8 "Air-kerma" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. As used in this rule, "air-kerma" means the sum of the initial kinetic energies of all charged particles liberated by indirectly ionizing particles in a volume element of air of known mass. *(Indiana State Department of Health; 410 IAC 5-6.1-8; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-9 "Air-kerma rate" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. As used in this rule, "air-kerma rate" means the air-kerma in a time interval. *(Indiana State Department of Health; 410 IAC 5-6.1-9; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-10 "Air-kerma strength" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. As used in this rule, "air-kerma strength" means the product of air-kerma rate in free space and the square of the distance of the calibration point from the source center along the perpendicular bisector. *(Indiana State Department of Health; 410 IAC 5-6.1-10; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-11 "Aluminum equivalent" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. As used in this rule, "aluminum equivalent" means that thickness of type 1100 aluminum alloy (compounded of ninety-nine percent (99%) aluminum, minimum, and twelve-hundredths percent (0.12%) copper, minimum) which affords the same attenuation as the material in question, under the same conditions. *(Indiana State Department of Health; 410 IAC 5-6.1-11; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-12 "Applicator" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. As used in this rule, "applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source. *(Indiana State Department of Health; 410 IAC 5-6.1-12; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-13 "ARRT" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. As used in this rule, "ARRT" means the American Registry of Radiologic Technologists. *(Indiana State Department of Health; 410 IAC 5-6.1-13; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-14 "Attenuation block" defined
Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. As used in this rule, "attenuation block" means a block or stack of aluminum equivalent material having dimensions twenty (20) cm by twenty (20) cm by three and eight-tenths (3.8) cm. *(Indiana State Department of Health; 410 IAC 5-6.1-14; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-15 "Automatic exposure control" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. As used in this rule, "automatic exposure control" means a device which automatically controls one (1) or more technique factors in order to obtain at a preselected location the required quantity of radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-15; filed Oct 29, 1993, 5:00 p.m.: 17 IR 357; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-16 "Beam axis" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. As used in this rule, "beam axis" means a line from the source through the centers of the x-ray fields. *(Indiana State Department of Health; 410 IAC 5-6.1-16; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-17 "Beam-limiting device" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. As used in this rule, "beam-limiting device" means a device which provides a means to restrict the dimensions of an x-ray field. *(Indiana State Department of Health; 410 IAC 5-6.1-17; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-18 "Beam monitoring system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. As used in this rule, "beam monitoring system" means a system which detects and measures radiation present in the useful beam. *(Indiana State Department of Health; 410 IAC 5-6.1-18; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-19 "Beam scattering filter" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 19. As used in this rule, "beam scattering filter" means a filter used to scatter a beam of electrons. *(Indiana State Department of Health; 410 IAC 5-6.1-19; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-20 "Blocking tray" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. As used in this rule, "blocking tray" means a device attached to the radiation head to support auxiliary beam-limiting material. *(Indiana State Department of Health; 410 IAC 5-6.1-20; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-21 "Calibration" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 21. As used in this rule, "calibration" means the determination of any of the following:
(1) The exposure or reading of an instrument relative to a known exposure or air-kerma.
(2) The exposure rate or air-kerma rate of the output of an x-ray or electron system.
(3) The absorbed dose rate from an x-ray or electron system.
(4) The air-kerma strength of a radioactive sealed source.

(Indiana State Department of Health; 410 IAC 5-6.1-21; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-22 "Central axis" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 22. As used in this rule, "central axis" means the line passing through the center of an x-ray system's virtual source and the center of the plane figure formed by the edges of the first beam-limiting device. *(Indiana State Department of Health; 410 IAC 5-6.1-22; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-23 "Certified component" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 23. As used in this rule, "certified component" means a component of an x-ray system which meets the requirements of 21 CFR Subchapter J. *(Indiana State Department of Health; 410 IAC 5-6.1-23; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-24 "Certified system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 24. As used in this rule, "certified system" means any x-ray system which has one (1) or more certified components. *(Indiana State Department of Health; 410 IAC 5-6.1-24; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-25 "cm" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25. As used in this rule, "cm" means centimeter. *(Indiana State Department of Health; 410 IAC 5-6.1-25; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-26 "Coefficient of variation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 26. As used in this rule, "coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{x} = \frac{1}{x}\left[\sum_{i=1}^{n} \frac{(X_i - X)}{n-1}\right]^{\frac{1}{2}}$$

Where: C = Coefficient of variation
s = Estimated standard deviation of the population
X = Mean value of observations in sample
X_i = Value of the ith observation in sample
n = Number of observations in sample

(Indiana State Department of Health; 410 IAC 5-6.1-26; filed Oct 29, 1993, 5:00 p.m.: 17 IR 358; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-27 "Commissioner" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 27. As used in this rule, "commissioner" means the department commissioner or his or her authorized representative. *(Indiana State Department of Health; 410 IAC 5-6.1-27; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-28 "Constancy check" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 28. As used in this rule, "constancy check" means a weekly procedure performed to assure that a previous calibration continues to be valid. *(Indiana State Department of Health; 410 IAC 5-6.1-28; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-29 "Contact therapy system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 29. As used in this rule, "contact therapy system" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within five (5) cm of the surface being treated. *(Indiana State Department of Health; 410 IAC 5-6.1-29; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-30 "Contrast ratio" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 30. As used in this rule, "contrast ratio" means the illumination inside the area three (3) mm from the edge of the light field (I_1), divided by the illumination outside the area three (3) mm from the edge of the light field (I_2). It is calculated using the following equation:

$$\text{Contrast ratio} = I_1/I_2$$

(Indiana State Department of Health; 410 IAC 5-6.1-30; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-31 "Control panel" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 31. As used in this rule, "control panel" means that part of the x-ray system or electron therapy system control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors. *(Indiana State Department of Health; 410 IAC 5-6.1-31; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-32 "Cooling curve" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 32. As used in this rule, "cooling curve" means the graphical relationship between heat stored and cooling time for a tube. *(Indiana State Department of Health; 410 IAC 5-6.1-32; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-33 "Dead-man switch" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 33. As used in this rule, "dead-man switch" means a control switch constructed so that its circuit remains closed only as long as the operator maintains pressure on the switch. *(Indiana State Department of Health; 410 IAC 5-6.1-33; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-34 "Department" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 34. As used in this rule, "department" means the Indiana state department of health or its authorized representative. *(Indiana State Department of Health; 410 IAC 5-6.1-34; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-35 "Diagnostic source assembly" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 35. As used in this rule, "diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached. *(Indiana State Department of Health; 410 IAC 5-6.1-35; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-36 "Diagnostic x-ray system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 36. As used in this rule, "diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for diagnosis or visualization. *(Indiana State Department of Health; 410 IAC 5-6.1-36; filed Oct 29, 1993, 5:00 p.m.: 17 IR 359; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-37 "Direct scattered radiation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 37. As used in this rule, "direct scattered radiation" means that radiation which has changed direction only by virtue of its contact with the materials irradiated by the useful beam. *(Indiana State Department of Health; 410 IAC 5-6.1-37; filed Oct 29,*

1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-38 "Dose monitoring system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 38. As used in this rule, "dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-38; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-39 "Dose monitor unit" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 39. As used in this rule, "dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated. *(Indiana State Department of Health; 410 IAC 5-6.1-39; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-40 "Field emission equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 40. As used in this rule, "field emission equipment" means equipment which uses an x-ray tube in which electrons are emitted from the cathode due solely to an electromagnetic field. *(Indiana State Department of Health; 410 IAC 5-6.1-40; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-41 "Field size" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 41. As used in this rule, "field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the fifty percent (50%) isodose line, for diagnostic applications. For therapeutic x-ray applications, "field size" means the two (2) longest perpendicular lengths, in combination, of a figure defined by the fifty percent (50%) isodose line at a cross section of the x-ray beam, measured in the plane perpendicular to the central axis of the x-ray beam at the normal treatment distance. In either case, field size is determined when material is placed in the beam so that maximum dose is achieved at the normal treatment distance. *(Indiana State Department of Health; 410 IAC 5-6.1-41; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-42 "Filter" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 42. As used in this rule, "filter" means material placed in the useful beam to absorb selected radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-42; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-43 "Fluoroscopic imaging assembly" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 43. As used in this rule, "fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the following:

(1) A diagnostic source assembly.
(2) An image receptor.
(3) An image intensifier.
(4) A spot-film device.
(5) Electrical interlocks.
(6) Appurtenances.

(Indiana State Department of Health; 410 IAC 5-6.1-43; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-44 "Focal spot" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 44. As used in this rule, "focal spot" means that area of the x-ray tube anode struck by electrons from the cathode to produce the useful beam. *(Indiana State Department of Health; 410 IAC 5-6.1-44; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-45 "Gantry" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 45. As used in this rule, "gantry" means that part of a radiation therapy system supporting and which allows movement of the radiation head. *(Indiana State Department of Health; 410 IAC 5-6.1-45; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-46 "General purpose radiographic x-ray system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 46. As used in this rule, "general purpose radiographic x-ray system" means any radiographic x-ray system which is used, or can be used, to visualize or measure any anatomical region, except fluoroscopic, intraoral dental, mammographic, special purpose, therapy, and veterinary x-ray systems. *(Indiana State Department of Health; 410 IAC 5-6.1-46; filed Oct 29, 1993, 5:00 p.m.: 17 IR 360; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-47 "Gonadal shield" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 47. As used in this rule, "gonadal shield" means a secondary protective barrier for the testes or ovaries. *(Indiana State Department of Health; 410 IAC 5-6.1-47; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-48 "Gray" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 48. As used in this rule, "gray" means a unit of measurement of radiation absorption. One (1) gray is equal to one (1) joule per kilogram, or one hundred (100) radiation absorbed doses. *(Indiana State Department of Health; 410 IAC 5-6.1-48; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-49 "Half-value layer" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 49. As used in this rule, "half-value layer" means the thickness of a specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half (1/2) of its original value. The contribution of all scattered radiation, other than any which might be present initially in the radiation beam concerned, is excluded from this definition. *(Indiana State Department of Health; 410 IAC 5-6.1-49; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-50 "Healing arts screening" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 50. As used in this rule, "healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. *(Indiana State Department of Health; 410 IAC 5-6.1-50; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-51 "Image intensifier" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 51. As used in this rule, "image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density. *(Indiana State Department of Health; 410 IAC 5-6.1-51; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-52 "Image receptor" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 52. As used in this rule, "image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. *(Indiana State Department of Health; 410 IAC 5-6.1-52; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-53 "Interruption" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 53. As used in this rule, "interruption" means temporary cessation of irradiation with the possibility that irradiation will be resumed without resetting the operating conditions on the x-ray system control panel. *(Indiana State Department of Health; 410 IAC 5-6.1-53; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-54 "Irradiation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 54. As used in this rule, "irradiation" means the exposure of matter to ionizing radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-54; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-55 "Isocenter" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 55. As used in this rule, "isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the x-ray beam passes in all conditions. *(Indiana State Department of Health; 410 IAC 5-6.1-55; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-56 "Isodose line" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 56. As used in this rule, "isodose line" means a line, usually in a plane, along which the absorbed dose is constant. *(Indiana State Department of Health; 410 IAC 5-6.1-56; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-57 "kV" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 57. As used in this rule, "kV" means kilovolts. *(Indiana State Department of Health; 410 IAC 5-6.1-57; filed Oct 29, 1993, 5:00 p.m.: 17 IR 361; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-58 "kVp" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 58. As used in this rule, "kVp" means kilovolts peak or peak tube potential, which is the maximum possible voltage drop across the tube during an exposure, measured in kV. *(Indiana State Department of Health; 410 IAC 5-6.1-58; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-59 "kWs" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 59. As used in this rule, "kWs" means kilowatt-second. *(Indiana State Department of Health; 410 IAC 5-6.1-59; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-60 "Lead equivalent" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 60. As used in this rule, "lead equivalent" means that thickness of lead which affords the same filtration of an x-ray beam as the material in question under the same conditions. *(Indiana State Department of Health; 410 IAC 5-6.1-60; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-61 "Leakage radiation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 61. As used in this rule, "leakage radiation" means all radiation emanating from the diagnostic or therapeutic source

assembly except the useful beam and that radiation produced when the exposure switch or timer is not activated. *(Indiana State Department of Health; 410 IAC 5-6.1-61; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-62 "Leakage technique factors" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 62. As used in this rule, "leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated kVp, and the maximum rated number of exposures per hour at the maximum rated kVp, with a charge per exposure of ten (10) mAs or the minimum obtainable from the system, whichever is larger.

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated kVp and the maximum rated number of x-ray pulses per hour for operation at the maximum rated kVp.

(3) For all other diagnostic or therapeutic source assemblies, the maximum rated kVp and the maximum rated continuous tube current for the maximum rated kVp.

(Indiana State Department of Health; 410 IAC 5-6.1-62; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-63 "Lux" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 63. As used in this rule, "lux" means a unit of measurement for illumination equal to one (1) lumen per square meter. *(Indiana State Department of Health; 410 IAC 5-6.1-63; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-64 "mA" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 64. As used in this rule, "mA" means milliampere. *(Indiana State Department of Health; 410 IAC 5-6.1-64; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-65 "Mammographer" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 65. As used in this rule, "mammographer" means the diagnostic x-ray machine operator with specialized training and/or education in performing mammography. *(Indiana State Department of Health; 410 IAC 5-6.1-65; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-66 "mAs" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 66. As used in this rule, "mAs" means milliampere-second. *(Indiana State Department of Health; 410 IAC 5-6.1-66; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-67 "MeV" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 67. As used in this rule, "MeV" means one million (10^6) electron volts. *(Indiana State Department of Health; 410 IAC 5-6.1-67; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-68 "Misadministration" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 68. As used in this rule, "misadministration" means the use of an x-ray therapy system or an electron therapy system as follows:

(1) Administration of radiation to the wrong individual or to the wrong treatment site.

(2) Administration of the wrong mode of treatment (electrons versus x-rays and/or stationary versus moving beam) to an individual.

(3) When a treatment prescribed for any treatment site consists of three (3) or fewer fractions, the total radiation dose actually administered at the treatment site differs from that prescribed for the site by a practitioner of the healing arts by more than ten percent (10%) of the total radiation dose prescribed for that treatment site.

(4) When the total weekly radiation dose actually administered at any treatment site differs from that prescribed for the site by a practitioner of the healing arts by more than thirty percent (30%) of the total weekly radiation dose prescribed for that treatment site.

(5) When the total radiation dose actually administered at any treatment site differs from that prescribed for the site by a practitioner of the healing arts by more than twenty percent (20%) of the total radiation dose prescribed for that treatment site.

(Indiana State Department of Health; 410 IAC 5-6.1-68; filed Oct 29, 1993, 5:00 p.m.: 17 IR 362; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-69 "mm" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 69. As used in this rule, "mm" means millimeter. *(Indiana State Department of Health; 410 IAC 5-6.1-69; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-70 "Mobile x-ray equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 70. As used in this rule, "mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled. *(Indiana State Department of Health; 410 IAC 5-6.1-70; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-71 "Moving beam therapy" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 71. As used in this rule, "moving beam therapy" means radiation therapy wherein the useful beam or the patient is moved during irradiation. Moving beam therapy includes arc therapy, skip therapy, and rotational therapy. *(Indiana State Department of Health; 410 IAC 5-6.1-71; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-72 "mR" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 72. As used in this rule, "mR" means milliroentgen. *(Indiana State Department of Health; 410 IAC 5-6.1-72; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-73 "Normal treatment distance" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 73. As used in this rule, "normal treatment distance" means the following:

(1) For electron irradiation, the virtual source-to-surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.

(2) For x-ray irradiation, the virtual source-to-isocenter distance along the central axis of the useful beam.

(3) For nonisocentric x-ray equipment, the normal treatment distance shall be that specified by the manufacturer.

(Indiana State Department of Health; 410 IAC 5-6.1-73; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-74 "Patient" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 74. As used in this rule, "patient" means an individual subjected to examination, diagnosis, or treatment by a practitioner of the healing arts. *(Indiana State Department of Health; 410 IAC 5-6.1-74; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-75 "Phantom" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 75. As used in this rule, "phantom" means a device which has characteristics similar to specific human or animal tissue with respect to the attenuation and scattering of radiation x-rays. *(Indiana State Department of Health; 410 IAC 5-6.1-75; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-76 "Portable x-ray equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 76. As used in this rule, "portable x-ray equipment" means x-ray equipment designed to be hand-carried. *(Indiana State Department of Health; 410 IAC 5-6.1-76; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-77 "Position indicating device" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 77. As used in this rule, "position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite SSD. It may also serve as a beam-limiting device. *(Indiana State Department of Health; 410 IAC 5-6.1-77; filed Oct 29, 1993, 5:00 p.m.: 17 IR 363; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-78 "Practitioner of the healing arts" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35; IC 25-10; IC 25-14; IC 25-19; IC 25-22.5

Sec. 78. As used in this rule, "practitioner of the healing arts" means one (1) of the following:
(1) A person licensed to practice medicine or osteopathic medicine by IC 25-22.5.
(2) A person licensed to practice dentistry by IC 25-14.
(3) A person licensed to practice chiropractic medicine by IC 25-10.
(4) A person licensed to practice podiatric medicine by IC 25-19.
(5) A person who is a corporate physician directly responsible for the health of Indiana employees and licensed to practice medicine in another state.

(Indiana State Department of Health; 410 IAC 5-6.1-78; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-79 "Primary dose monitoring system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 79. As used in this rule, "primary dose monitoring system" means a system which will monitor the useful beam and automatically terminate irradiation when the preselected number of dose monitor units have been acquired. *(Indiana State Department of Health; 410 IAC 5-6.1-79; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-80 "Primary protective barrier" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 80. As used in this rule, "primary protective barrier" means a protective barrier of material which is placed in the useful radiation beam to reduce radiation exposure. The term does not include filters. *(Indiana State Department of Health; 410 IAC 5-6.1-80; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-81 "Protective apron" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 81. As used in this rule, "protective apron" means an apron made of radiation absorbing materials used as a secondary protective barrier. *(Indiana State Department of Health; 410 IAC 5-6.1-81; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-82 "Protective barrier" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 82. As used in this rule, "protective barrier" means a primary or secondary protective barrier composed of radiation absorbing material used to reduce radiation exposure. *(Indiana State Department of Health; 410 IAC 5-6.1-82; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-83 "Protective glove" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 83. As used in this rule, "protective glove" means a glove made of radiation absorbing materials used as a secondary protective barrier. *(Indiana State Department of Health; 410 IAC 5-6.1-83; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-84 "Radiation detector" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 84. As used in this rule, "radiation detector" means a device which, in the presence of radiation, provides a signal or other indication suitable for use in measuring incident radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-84; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-85 "Radiation head" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 85. As used in this rule, "radiation head" means the structure from which the useful beam emerges. *(Indiana State Department of Health; 410 IAC 5-6.1-85; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-86 "Radiation therapy simulation system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 86. As used in this rule, "radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system used to target a patient for therapeutic radiation by determining the position and size of the therapeutic irradiation field. *(Indiana State Department of Health; 410 IAC 5-6.1-86; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-87 "Radiographic imaging system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 87. As used in this rule, "radiographic imaging system" means any x-ray system capable of producing a radiograph. *(Indiana State Department of Health; 410 IAC 5-6.1-87; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-88 "Rating" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 88. As used in this rule, "rating" means the operating limits specified by the manufacturer of x-ray equipment or a component thereof. *(Indiana State Department of Health; 410 IAC 5-6.1-88; filed Oct 29, 1993, 5:00 p.m.: 17 IR 364; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-89 "Scattered radiation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 89. As used in this rule, "scattered radiation" means that radiation which has changed direction by virtue of its contact with matter after emerging from the radiation head. *(Indiana State Department of Health; 410 IAC 5-6.1-89; filed Oct 29, 1993,*

5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-90 "Secondary dose monitoring system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 90. As used in this rule, "secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system. *(Indiana State Department of Health; 410 IAC 5-6.1-90; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-91 "Secondary protective barrier" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 91. As used in this rule, "secondary protective barrier" means a protective barrier sufficient to attenuate stray radiation as required, such as a protective apron, protective gloves, or a gonadal shield. *(Indiana State Department of Health; 410 IAC 5-6.1-91; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-92 "Shutter" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 92. As used in this rule, "shutter" means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly. *(Indiana State Department of Health; 410 IAC 5-6.1-92; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-93 "SID" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 93. As used in this rule, "SID" means source-image receptor distance, which is the distance from the source to the center of the input surface of the image receptor. *(Indiana State Department of Health; 410 IAC 5-6.1-93; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-94 "Source" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 94. As used in this rule, "source" means the focal spot of the x-ray tube. *(Indiana State Department of Health; 410 IAC 5-6.1-94; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-95 "Special purpose x-ray system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 95. As used in this rule, "special purpose x-ray system" means a diagnostic x-ray system designed for use on specific body regions, for example, extremities, head or neck, thoracic, abdominal, or for specialized applications, for example, pantomographic, tomographic, or cystographic systems. Specifically excluded from this definition are intraoral dental and mammographic x-ray equipment. *(Indiana State Department of Health; 410 IAC 5-6.1-95; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-96 "Spot check" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 96. As used in this rule, "spot check" means a monthly procedure performed to assure that a previous calibration continues to be valid. *(Indiana State Department of Health; 410 IAC 5-6.1-96; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-97 "Spot film" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 97. As used in this rule, "spot film" means a radiograph made during a fluoroscopic procedure. *(Indiana State Department of Health; 410 IAC 5-6.1-97; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-98 "Spot film device" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 98. As used in this rule, "spot film device" means a device used to transport and/or position an image receptor between the x-ray source and a fluoroscopic image receptor or image intensifier to make a radiograph, including a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph. *(Indiana State Department of Health; 410 IAC 5-6.1-98; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-99 "SSD" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 99. As used in this rule, "SSD" means the distance between the source and the skin of the patient. *(Indiana State Department of Health; 410 IAC 5-6.1-99; filed Oct 29, 1993, 5:00 p.m.: 17 IR 365; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-100 "Stationary beam therapy" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 100. As used in this rule, "stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation. *(Indiana State Department of Health; 410 IAC 5-6.1-100; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-101 "Stationary x-ray equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 101. As used in this rule, "stationary x-ray equipment" means x-ray equipment installed at a fixed location. *(Indiana State Department of Health; 410 IAC 5-6.1-101; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-102 "Target" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 102. As used in this rule, "target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation. *(Indiana State Department of Health; 410 IAC 5-6.1-102; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-103 "Technique factors" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 103. As used in this rule, "technique factors" means the conditions of operation. They are as follows:

(1) For capacitor energy storage equipment, kVp and mAs.

(2) For field emission equipment rated for pulsed operation, kVp and the number of x-ray pulses.

(3) For all other equipment, kVp and mAs or kVp, mA, and exposure time in seconds.

(Indiana State Department of Health; 410 IAC 5-6.1-103; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-104 "Termination of irradiation" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 104. As used in this rule, "termination of irradiation" means cessation of x-ray exposure in a manner which requires that the x-ray control be reset before further exposures can be made at the control panel. *(Indiana State Department of Health; 410 IAC 5-6.1-104; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-105 "Traceable" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 105. As used in this rule, "traceable" means that a quantity or a measurement has been compared to a national standard through intermediate steps and that all comparisons have been documented. *(Indiana State Department of Health; 410 IAC 5-6.1-105; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-106 "Tube" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 106. As used in this rule, "tube" means an electron tube used to produce x-rays. *(Indiana State Department of Health; 410 IAC 5-6.1-106; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-107 "Tube housing assembly" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 107. As used in this rule, "tube housing assembly" means the housing with the tube installed which may include a high voltage and/or filament transformer and other appurtenances. *(Indiana State Department of Health; 410 IAC 5-6.1-107; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-108 "Tube rating chart" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 108. As used in this rule, "tube rating chart" means a set of curves which specify the limits of operation for the tube in terms of technique factors as rated by the manufacturer. *(Indiana State Department of Health; 410 IAC 5-6.1-108; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-109 "Useful beam" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 109. As used in this rule, "useful beam" means those x-rays emitted from the aperture of a beam-limiting device. *(Indiana State Department of Health; 410 IAC 5-6.1-109; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-110 "Veterinarian" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 15-5-1.1; IC 16-41-35

Sec. 110. As used in this rule, "veterinarian" means a person licensed to practice veterinary medicine under IC 15-5-1.1. *(Indiana State Department of Health; 410 IAC 5-6.1-110; filed Oct 29, 1993, 5:00 p.m.: 17 IR 366; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-111 "Virtual source" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 111. As used in this rule, "virtual source" means a point from which radiation appears to originate. *(Indiana State Department of Health; 410 IAC 5-6.1-111; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-112 "Visible area" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 112. As used in this rule, "visible area" means that portion of the image receptor which x-rays are bombarding to produce a visible image. *(Indiana State Department of Health; 410 IAC 5-6.1-112; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-113 "Wedge filter" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 113. As used in this rule, "wedge filter" means a filter which can affect progressive, stepless attenuation of all or part of the useful beam. *(Indiana State Department of Health; 410 IAC 5-6.1-113; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-114 "x-ray" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 114. As used in this rule, "x-ray" means electromagnetic radiation of energy equal to or greater than one hundred twenty-four (124) electron volts produced by bombardment of a target with electrons in a vacuum. *(Indiana State Department of Health; 410 IAC 5-6.1-114; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-115 "x-ray control" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 115. As used in this rule, "x-ray control" means a device which controls input power to the x-ray high voltage generator or the tube, including devices such as timers, phototimers, automatic brightness stabilizers, and similar devices which control the technique factors of an x-ray exposure. *(Indiana State Department of Health; 410 IAC 5-6.1-115; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-116 "x-ray equipment" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 116. As used in this rule, "x-ray equipment" means an x-ray system, subsystem, or component thereof. *(Indiana State Department of Health; 410 IAC 5-6.1-116; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-117 "x-ray system" defined

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 117. As used in this rule, "x-ray system" means an assemblage of components for the controlled production of x-rays. At a minimum, an x-ray system includes the following:

(1) An x-ray high voltage generator.
(2) An x-ray control.
(3) A tube housing assembly.
(4) A beam-limiting device.
(5) Necessary supporting structures.
(6) Appurtenances.

Included in an x-ray system are mobile x-ray equipment, portable x-ray equipment, particle accelerators, and stationary x-ray equipment. *(Indiana State Department of Health; 410 IAC 5-6.1-117; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-118 General requirements for operation of x-ray equipment

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 118. (a) All individuals associated with the operation of x-ray equipment shall comply with applicable sections of 410 IAC 5-4-2, 410 IAC 5-4-3, 410 IAC 5-4-10, and this rule.

(b) The registrant shall be responsible for directing the operation of those x-ray systems under his or her administrative control. The registrant or the registrant's agent shall comply with this section in the operation of such x-ray systems.

(c) At intervals prescribed in this rule, all new and existing facilities shall be surveyed by a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector approved by the department. Such surveys shall also be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard. The survey shall be done before the x-ray system is used for diagnostic purposes, and an evaluation report, including all violations of this rule, on a form acceptable to the commissioner must be completed by the physicist or inspector and a copy forwarded to the registrant and to the commissioner within sixty (60) days of completion of the survey. The cost of this evaluation must be negotiated between

the physicist or inspector and the practitioner of the healing arts or registrant and will not be borne by the department.

(d) For each x-ray system, a notice of compliance with this rule, supplied by or approved by the commissioner, shall be prominently displayed on or near the x-ray control panel. This notice must indicate the date of full compliance and be signed by the physicist or inspector. For fluoroscopy systems, this notice may incorporate the entrance exposure posting requirement of section 119(k)(6) of this rule.

(e) For each x-ray facility, a notice of compliance with this rule, supplied by or approved by the commissioner, shall be prominently displayed in an area readily accessible to patients and visitors. This notice must indicate the date of full compliance and be signed by the physicist or inspector.

(f) At the intervals prescribed for facility inspections in this rule, the registrant shall be responsible for completing an x-ray machine registration application form. A diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector approved by the department shall be responsible for verifying that all information on the application is correct, and the form shall be submitted to the commissioner as part of the physicist's or inspector's evaluation report.

(g) On the effective date of this rule, in order to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector in accordance with this rule, an individual must be approved by the department in accordance with subsection (h), (i), (j), or (k).

(h) In order to be approved to practice as a diagnostic imaging physicist, an individual must be certified by the ABR in diagnostic radiological physics or radiological physics or the ABMP in diagnostic imaging physics or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l). In determining equivalency in accordance with this section, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in physics or applied physics or physical science.

(2) The individual shall hold a master's or doctoral degree in physics or medical physics or a physical science with the equivalent of a physics minor.

(3) The individual shall have completed formal course work in the biological sciences.

(4) The individual shall have at least three (3) years of full-time active work experience in diagnostic or radiological physics under the direction of a diagnostic or radiological physicist certified by the ABR or ABMP or a radiologist certified by the ABR.

(5) The individual shall provide as references the names of a radiologist certified by the ABR and a diagnostic or radiological physicist certified by the ABR or ABMP, both of whom are familiar with the individual's training. At least one (1) of the two (2) references shall have directed the individual's work in accordance with subdivision (4).

In addition, the applicant must demonstrate to the physicist review committee that he or she is qualified to provide oversight for the establishment and conduct of a mammography quality assurance program required by section 127 of this rule. In determining qualifications in accordance with this subsection, the physicist review committee shall do the following:

(6) Determine that the individual has formal training or experience in evaluation of mammography systems, including performing, recording, and interpreting the results of required quality control checks.

(7) Determine that the individual has adequate testing equipment available to perform the quality control checks required by section 127 of this rule.

(8) Review a sample of a mammographic x-ray facility evaluation report prepared and submitted by the individual as part of their determination of his or her qualifications.

(i) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified radiation therapy physicist is automatically approved to practice as a radiation oncology physicist. However, after the effective date of this rule, all other persons must be certified by the ABR in therapeutic radiological physics or radiological physics or the ABMP in radiation oncology physics or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l), in order to be approved to practice as a radiation oncology physicist. In determining equivalency in accordance with this subsection, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in physics or applied physics or a physical science.

(2) The individual shall hold a master's or doctoral degree in physics or medical physics or a physical science with the equivalent of a physics minor.

(3) The individual shall have completed formal course work in the biological sciences.

(4) The individual shall have at least three (3) years of full-time active work experience in radiation oncology physics, under the direction of a radiation oncology physicist or radiological physicist certified by the ABR or ABMP or a radiation oncology physician certified by the ABR.

(5) The individual shall provide as references the names of a radiation oncology physician certified by the ABR and a radiation oncology physicist certified by the ABR or ABMP, both of whom are familiar with the individual's training. At least one (1) of these references shall be from an individual who directed the individual's work in accordance with subdivision (4).

(j) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified radiation or health physicist is automatically approved to practice as a health physicist. However, after the effective date of this rule, all other persons must be certified by the ABR, the ABMP, or the ABHP or shall possess equivalent qualifications as determined by the physicist review committee established in subsection (l), in order to be approved to practice as a health physicist. In determining equivalency in accordance with this subsection, the physicist review committee shall determine the following:

(1) The individual shall hold a bachelor's degree in health physics, radiological health, a physical science, engineering, or a biological science with a minor in a physical science or engineering.

(2) The individual shall have at least three (3) years of full-time active work experience in applied health physics. A master's degree in health physics or a closely related area may substitute for one (1) year of work experience required by this subsection. A doctoral degree in health physics or a closely related area may substitute for two (2) years of work experience required by this subsection.

(k) On the effective date of this rule, any individual who has been approved previously by the department to practice as a qualified x-ray machine physicist is automatically approved to practice as an x-ray machine inspector. However, after the effective date of this rule, all other persons must have a minimum of a bachelor's degree in a physical or biological science, health physics, or radiological health and a minimum of two (2) years of experience working with x-ray systems under the direct supervision of a diagnostic imaging physicist, health physicist, or x-ray machine inspector, who has been approved by the department, in order to be approved to practice as an x-ray machine inspector.

(l) A physicist review committee is hereby created, which shall determine competency to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, and x-ray machine inspector in accordance with subsection (h), (i), (j), or (k). The physicist review committee shall be composed of a diagnostic imaging physicist and a radiation oncology physicist, both certified by the ABR or ABMP, and a radiologist certified by the ABR. The diagnostic imaging physicist, the radiation oncology physicist, and the radiologist shall be appointed to the physicist review committee by the commissioner. Approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector shall be based upon review of a completed application which demonstrates that the individual meets applicable education, training, and experience requirements of subsection (h), (i), (j), or (k).

(m) Approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector may be revoked by the commissioner for failure to perform his or her duties as required by this rule. The commissioner may audit facility evaluations performed by a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector. Any errors found as a result of such an audit shall be brought to the attention of the individual who performed the evaluation. If a subsequent audit indicates repetitive errors which have resulted in the issuance of unnecessary violation notices, or in violations not being reported to the commissioner, the commissioner may revoke that individual's approval to practice as a diagnostic imaging physicist, radiation oncology physicist, health physicist, or x-ray machine inspector.

(n) Department employees are exempt from the credentialing requirements of this section when they are conducting inspections or surveys of x-ray facilities for the commissioner.

(o) The radiation machine registration certificate issued by the commissioner in accordance with 410 IAC 5-2-6 shall be prominently displayed in an area readily accessible to patients and visitors.

(p) An x-ray system which does not comply with this rule shall not be operated for diagnostic or therapeutic purposes, if so directed by the commissioner.

(q) Individuals who will be operating the x-ray equipment shall be adequately instructed in proper operating procedures for such equipment. Diagnostic x-ray machines shall be operated only by a person who complies with applicable provisions of 410 IAC 5-11.

(r) In the vicinity of each x-ray control panel, a technique guide shall be provided for routine examinations performed utilizing that system.

(s) Written safety procedures and rules shall be available to each individual operating x-ray equipment, including any restrictions of operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(t) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. In addition to the patient being examined, others will

be protected in the following manner:

(1) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by five-tenths (0.5) mm lead equivalent.

(2) Staff and ancillary personnel shall be protected from direct scattered radiation by protective aprons or whole body protective barriers of not less than twenty-five hundredths (0.25) mm lead equivalent.

(3) Patients who cannot be removed from the room shall be protected from direct scattered radiation by whole body protective barriers of twenty-five hundredths (0.25) mm lead equivalent or shall be positioned so that portion of the body nearest to the tube head is at least two (2) meters from both the tube head and the nearest edge of the image receptor.

(u) Gonadal shielding of not less than twenty-five hundredths (0.25) mm lead equivalent shall be used for patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(v) Individuals shall not be exposed to the useful beam, except for healing arts purposes and such exposure has been authorized by a practitioner of the healing arts. This subsection specifically prohibits deliberate exposure for training, demonstration, or other nonhealing arts purposes.

(w) The following apply when a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices shall be used when the technique permits. Written safety procedures established in accordance with subsection (s) shall list individual projections where holding devices cannot be utilized.

(2) Written safety procedures established in accordance with subsection (s) shall indicate the requirements for selecting a holder and the procedure the holder shall follow.

(3) The human holder shall be protected as required by subsection (t).

(4) No individual shall be used routinely to hold film or patients.

In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than five-tenths (0.5) mm lead equivalent material.

(x) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

(y) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(z) Any registrant proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the commissioner. When requesting such approval, that person shall submit all department required information. If any submitted information becomes invalid or outdated, the commissioner shall be immediately notified.

(aa) The registrant shall maintain the following information for each x-ray system for inspection by the commissioner:

(1) Maximum rating of technique factors.

(2) Model and serial numbers of all certified components.

(3) Aluminum equivalent filtration of the useful beam, including any routine variation.

(4) Records of surveys, calibrations, maintenance, and modifications performed on the x-ray systems for the following periods:

(A) For hospitals, medical facilities, and chiropractic facilities, twenty-four (24) months.

(B) For podiatric and veterinary facilities, forty-eight (48) months.

(C) For dental facilities, seventy-two (72) months.

(5) After the effective date of this rule, a scaled drawing of the room in which a stationary x-ray system is located, which indicates the use of areas adjacent to the room, and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall indicate either of the following:

(A) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions.

(B) The type and thickness of materials or the lead equivalency of each wall, window, door, ceiling, and floor in the room.

(6) A copy of all correspondence with the commissioner regarding each x-ray machine, including a copy of all facility evaluation reports issued in compliance with this section.

(bb) Floor plans and equipment arrangements for all new diagnostic x-ray installations, or modifications of such installations, shall be evaluated with regard to shielding requirements prior to construction. A safety survey shall be performed prior to first use. Both evaluations shall be performed by a diagnostic imaging physicist or a health physicist approved by the department.

(cc) Floor plans and equipment arrangements for all new therapeutic x-ray installations, or modifications of such installations,

shall be evaluated with regard to shielding requirements prior to construction. A safety survey shall be performed prior to first use. Both evaluations shall be performed by a radiation oncology physicist or a health physicist approved by the department.

(dd) A report of each plan review and safety survey conducted in compliance with subsection (bb) or (cc) shall be submitted to the registrant and the commissioner within twenty (20) working days of completing the plan review, and the registrant shall keep a copy of the report in its files for at least as long as the registrant uses that x-ray facility. *(Indiana State Department of Health; 410 IAC 5-6.1-118; filed Oct 29, 1993, 5:00 p.m.: 17 IR 367; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-119 Diagnostic x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 119. (a) Podiatric and veterinary x-ray facilities shall be evaluated at least once each twenty-four (24) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Dental x-ray facilities shall be evaluated at least once each thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Mammography facilities shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist approved by the department. All other diagnostic x-ray systems shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Those x-ray facilities which have been evaluated within sixty (60) days after the end of the interval established in this section will be considered to be in compliance with this section as long as the evaluation occurs in the same calendar year as the date on which reevaluation is required. All diagnostic x-ray systems shall comply with this section.

(b) The x-ray control panel containing the main power switch shall bear the warning statement, legible and accessible to view, "WARNING: This x-ray system may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed.".

(c) For battery-powered generators, visual means shall be provided on the x-ray control panel to indicate whether the battery is charged adequately for proper operation.

(d) Leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed one hundred (100) mR in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm.

(e) Radiation emitted by a component other than the diagnostic source assembly shall not exceed two (2) mR in one (1) hour at five (5) cm from any accessible surface of the component when it is operated in an assembled x-ray system under any condition for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm.

(f) The half-value layer of the useful beam for a given x-ray tube voltage shall be no less than the values shown as follows:

TABLE I

Design Operating Range	Measured Voltage	Half-Value Layer Aluminum Equivalent
Below 50 kVp	30 kVp	0.3 mm
	40 kVp	0.4 mm
	49 kVp	0.5 mm
50 to 70 kVp	50 kVp	1.2 mm
	60 kVp	1.3 mm
	70 kVp	1.5 mm
	71 kVp	2.1 mm
	80 kVp	2.3 mm
	90 kVp	2.5 mm
	100 kVp	2.7 mm

110 kVp	3.0 mm
120 kVp	3.2 mm
130 kVp	3.5 mm
140 kVp	3.8 mm
150 kVp	4.1 mm

For a kVp not listed in Table I, linear interpolation shall be utilized to determine the minimum acceptable half-value layer. For capacitor energy storage x-ray systems, compliance shall be determined with the maximum charge per exposure assumed to be the kVp. The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient. The requirements of this subsection will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown as follows:

TABLE II

	Total Filtration
Operating Voltage	Aluminum Equivalent
Below 50 kVp	0.5 mm
50 to 70 kVp	1.5 mm
Above 70 kVp	2.5 mm

In addition, there must be compliance with the following:

(1) Beryllium window tubes shall have a minimum of five-tenths (0.5) mm aluminum equivalent filtration permanently installed in the useful beam.

(2) For capacitor energy storage equipment, compliance with this subsection shall be determined with the maximum quantity of charge per exposure.

(3) For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum filtration required by this subsection is in the useful beam for the kVp which has been selected.

(g) Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(h) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the x-ray system.

(i) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. For equipment having fixed technique factors, the requirement in this subsection may be met by placing permanent markings on such equipment. However, the markings shall be visible from the operator's position except in the case of spot films made by the fluoroscopist. *(Indiana State Department of Health; 410 IAC 5-6.1-119; filed Oct 29, 1993, 5:00 p.m.: 17 IR 371; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-120 Fluoroscopic x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 120. (a) Fluoroscopic x-ray systems shall be evaluated at least once each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department and shall comply with applicable sections of this rule. Radiation therapy simulation systems are exempt from compliance with subsections (c) through (e), (g) through (l), and (p) if the following are met:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room when the system is producing x-rays.

(2) Systems which do not comply with subsection (p) are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. In such cases, procedures shall require that the timer be reset between examinations.

(b) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. An x-ray tube used for fluoroscopy shall not produce x-rays unless the primary protective barrier is in position to intercept the entire useful beam.

(c) Means shall be provided for stepless adjustment of the field size. In addition, the following requirements must be met:

(1) The minimum field size at the greatest SID shall be no greater than five (5) cm by five (5) cm.

(2) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

Compliance with this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(d) For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID. In addition, the following requirements must be met:

(1) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than three hundred (300) square cm shall be provided with means for stepless adjustment of the x-ray field.

(2) All equipment with a fixed SID and a visible area of three hundred (300) square cm or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to one hundred twenty-five (125) square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five (5) cm by five (5) cm or less.

(3) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(4) Compliance with this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(e) Spot film devices which are certified components shall comply with the following additional requirements:

(1) Means shall be provided between the source and the patient for adjustment of the field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

(2) It shall be possible to adjust the field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be no greater than five (5) cm by five (5) cm.

(3) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent (2%) of the SID.

(4) For spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(f) X-ray production in the fluoroscopic mode shall be controlled by a dead-man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

(g) The exposure measured at the point where the center of the useful beam enters the patient and at a kVp typical of clinical use of the x-ray system shall not exceed ten (10) roentgens per minute, except during recording of fluoroscopic images or when provided with optional high-level control. Compliance shall be determined in accordance with subsection (j).

(h) When equipment is provided with a high-level control, it shall not be operable at any combination of tube voltage and current which will result in an exposure rate in excess of five (5) roentgens per minute at the point where the center of the useful beam enters the patient unless the high-level control is activated. The high-level control shall be operable only through a dead-man

switch. Additionally, a continuous signal audible to the fluoroscopist shall indicate when the high-level control is being employed. Compliance shall be determined in accordance with subsection (j).

(i) Certified systems which do not incorporate an automatic exposure control shall not be operable at any combination of tube voltage and current which will result in an exposure rate in excess of five (5) roentgens per minute, at the point where the center of beam enters the patient except during recording of fluoroscopic images or when the equipment is provided with an optional high-level control. Compliance shall be determined in accordance with subsection (j).

(j) Compliance with subsections (g) through (i) shall be determined as follows:

(1) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(2) If the source is below the table, the exposure rate shall be measured one (1) cm above the table top or cradle.

(3) If the source is above the table, the exposure rate shall be measured at thirty (30) cm above the table top with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(4) For C-arm type fluoroscopes, the exposure rate shall be measured thirty (30) cm from the input surface of the fluoroscopic imaging assembly.

(k) Periodic measurement of entrance exposure rate shall be performed in accordance with the following:

(1) Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

(2) Such measurements shall be made under conditions that satisfy the requirements of subsection (j).

(3) The kVp shall be the kVp typical of clinical use of the x-ray system.

(4) An x-ray system that incorporates automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system.

(5) An x-ray system that does not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the x-ray system.

(6) Results of such measurements shall be posted where any fluoroscopist has ready access to such results, and in the record required by section 118(aa)(5) of this rule. Such measurements shall be stated in roentgens per minute, and shall include the technique factors used in determining such results. The name of the person who performed the measurements and the date the measurements were performed shall be included with the results.

(l) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two (2) mR per hour at ten (10) cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate. The exposure rate shall be determined by measurements averaged over an area of one hundred (100) square cm with no linear dimension greater than twenty (20) cm. During such measurements, movable grids and compression devices shall be removed from the useful beam, and the attenuation block shall be positioned in the useful beam between the input surface of the fluoroscopic imaging assembly and a point ten (10) cm from the point of measurement of the entrance exposure rate. Exceptions to the measurement shall be as follows:

(1) If the source is below the table top, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) cm above the table top.

(2) If the source is above the table top and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the table top as possible, but no closer than thirty (30) cm.

(m) During fluoroscopy and cinefluorography, kV and mA shall be continuously indicated.

(n) The SSD shall be no less than:

(1) thirty-eight (38) cm on stationary fluoroscopes installed after June 25, 1978;

(2) thirty-five and five-tenths (35.5) cm on stationary fluoroscopes which were in operation prior to June 25, 1978;

(3) thirty (30) cm on all mobile fluoroscopes; or

(4) twenty (20) cm for image intensified fluoroscopes used in specific surgical applications.

(o) For image intensified fluoroscopes used in specific surgical applications, written safety procedures must be provided which state precautionary measures to be adhered to during use of such equipment.

(p) Means shall be provided to preset the cumulative ontime of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative ontime. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(q) Mobile fluoroscopes shall provide intensified imaging.

(r) Scattered radiation shall be controlled in accordance with the following:

(1) Fluoroscopic table designs, when combined with procedures utilized, shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be no less than twenty-five hundredths (0.25) mm lead equivalent.

(2) Equipment configuration, when combined with procedures, shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the table top, unless that individual:

(A) is at least one hundred twenty (120) cm from the center of the useful beam; or

(B) the radiation has passed through not less than twenty-five hundredths (0.25) mm lead equivalent material, including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in section 118(t)(2) of this rule.

(3) The commissioner may grant an exemption to subdivision (2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for protective barriers is practical, the commissioner shall not permit such exemption.

(Indiana State Department of Health; 410 IAC 5-6.1-120; filed Oct 29, 1993, 5:00 p.m.: 17 IR 372; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-121 General purpose radiographic systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 121. (a) All general purpose radiographic systems, except extraoral dental x-ray systems, shall be evaluated at least each twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. Extraoral dental x-ray systems must be evaluated at intervals not to exceed thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department. General purpose radiographic systems shall comply with all applicable portions of this section.

(b) The useful beam shall be limited to the area of clinical interest.

(c) General purpose stationary x-ray systems and mobile x-ray systems shall comply with the following requirements:

(1) There shall be a means for stepless adjustment of the field size.

(2) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(3) The commissioner may grant an exemption to subdivisions (1) and (2) for noncertified x-ray systems, provided the registrant applies for such an exemption in writing. An application for such exemption shall demonstrate that it is impractical to comply with subdivisions (1) and (2) and that the protection afforded through compliance with subdivisions (1) and (2) will be assured through alternate methods.

(4) Any light localizer used to define the x-ray field shall provide an average illumination of not less than ten (10) foot-candles at one hundred (100) cm or at the maximum SID, whichever is less.

(d) Stationary general purpose x-ray systems shall also comply with the following requirements:

(1) A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor:

(A) to align the center of the x-ray field with respect to the center of the image receptor to within two percent (2%) of the SID;

(B) to indicate the SID to within two percent (2%).

(2) The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

(3) The field size dimension and SID shall be indicated, in inches or cm, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

(e) Radiographic equipment having only one (1) image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor. Additionally, such equipment shall be provided with a means to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image

receptor does not extend beyond any edge of the image receptor.

(f) A timer shall be provided to terminate the exposure at:

(1) a preset time interval;

(2) a preset product of current and time;

(3) a preset number of pulses; or

(4) a preset radiation exposure to the image receptor.

It shall not be possible to make an exposure when the timer is set to the zero (0) or off position, if either is provided.

(g) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half (1/2) second duration or less, or during serial radiography when means are provided or permit completion of any single exposure of a series in process. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. X-ray controls shall be located as follows:

(1) Stationary x-ray systems shall have the x-ray control permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.

(2) Mobile and portable x-ray systems which are used for greater than one (1) week in the same location, such as a room or a suite, shall comply with subdivision (1).

(3) Mobile and portable x-ray systems which are used for greater than one (1) hour and less than one (1) week at the same location, such as a room or a suite, shall comply with subdivision (1) or be provided with a protective barrier six and five-tenths (6.5) feet high placed at least six (6) feet from the tube housing assembly and at least six (6) feet from the patient.

(4) Mobile and portable x-ray systems which are used to make an exposure of a patient at the use location shall comply with subdivision (3) or be provided with a method of x-ray control which will permit the operator to be at least twelve (12) feet from the tube housing assembly during an exposure.

(h) The following apply when an automatic exposure control is provided:

(1) Indication shall be made on the x-ray control panel when the mode of operation is selected.

(2) If the x-ray tube voltage is fifty (50) kVp or greater, the exposure time for field emission equipment rated for pulsed operation shall be no greater than the time interval equal to two (2) pulses.

(3) The exposure time for all equipment other than that specified in subdivision (2) shall be no greater than one-sixtieth (1/60) second or the time interval required to deliver five (5) mAs, whichever is greater.

(4) Either the product of peak x-ray tube voltage, current, and exposure time shall be no more than sixty (60) kWs per exposure or the product of x-ray tube current and exposure time shall be no more than six hundred (600) mAs per exposure, except when the x-ray tube voltage is less than fifty (50) kVp, in which case the product of x-ray tube current and exposure time shall be no more than two thousand (2,000) mAs per exposure.

(5) A visible signal shall indicate when an exposure has been terminated as required by subdivision (4). Manual resetting shall be required before further automatically timed exposures can be made.

(i) With a timer setting of five-tenths (0.5) second or less, the average exposure time (T_{avg}) shall be no less than five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}). A minimum of four (4) timer tests must be performed to determine T_{avg}, T_{max}, and T_{min}. This requirement is expressed mathematically as:

$$T_{avg} \geq 5 (T_{max} - T_{min})$$

(j) All mobile or portable radiographic systems shall be provided with means to limit the SSD to no less than thirty (30) cm.

(k) The coefficient of variation of exposure shall not exceed ten-hundredths (0.10) when all technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure (E_{avg}) is no less than five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}). This requirement is expressed mathematically as:

$$E_{avg} \geq 5 (E_{max} - E_{min})$$

(l) For capacitor energy storage equipment in standby status, radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed two (2) mR per hour at five (5) cm from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.

(m) General purpose x-ray systems incorporating one (1) or more certified components shall be required to comply with the following additional requirements which relate to those certified components:

(1) When such equipment is operated on an adequate power supply as specified by the manufacturer in accordance with applicable federal standards, the estimated coefficient of variation shall be no greater than five-hundredths (0.05) for any

specific combination of selected technique factors.

(2) When such equipment allows a choice of x-ray tube current settings and is operated on a power supply specified by the manufacturer in accordance with applicable federal standards, for any tube potential (kVp) within forty percent (40%) to one hundred percent (100%) of the maximum kVp rating, the absolute value of the difference between the ratio of average exposure in mR to the indicated mAs obtained at any two (2) consecutive tube current settings, shall not differ by more than ten-hundredths (0.10) of the absolute value of their sum. A minimum of four (4) measurements per tube current setting are required to determine each average exposure. This requirement is expressed mathematically as:

$$|X_1 - X_2| \leq 0.10 |X_1 + X_2|$$

Where: X_1 and X_2 = The ratios of average exposure to mAs obtained at each of two (2) consecutive tube current settings

(3) Deviation of technique factors from indicated values shall not exceed ten percent (10%) or the limits specified for that system by its manufacturer, whichever is greater.

(4) The following apply for general purpose stationary and mobile x-ray systems:

(A) There shall be means for stepless adjustment of the field size. The minimum field size at an SID of one hundred (100) cm shall be no greater than five (5) cm by five (5) cm.

(B) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than one hundred sixty (160) lux or fifteen (15) foot-candles at one hundred (100) cm or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from compliance with this clause.

(C) The edge of the light field at one hundred (100) cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of at least four (4) for beam-limiting devices used on stationary equipment and a contrast ratio of at least three (3) for beam-limiting devices used on mobile x-ray equipment. Compliance shall be determined utilizing a measuring instrument aperture of one (1) mm diameter.

(5) Beam limitation for portable x-ray systems shall comply with subsection (d) and subdivision (4).

(6) Stationary general purpose x-ray systems equipped with a tube housing assembly, an x-ray control, and, if so equipped, a table, all of which are certified in accordance with 21 CFR 1020.30(C), shall comply with the following:

(A) Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five (5) seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five (5) seconds or is manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.

(B) The field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than three percent (3%) of the SID. The sum of the absolute values for the field size length and width differences shall be no more than four percent (4%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

(C) The radiographic system shall be capable of operation, at the discretion of the operator, so that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of one hundred (100) cm shall be no greater than five (5) cm by five (5) cm. Return to positive beam limitation as specified in clauses (A) and (B) shall occur upon a change in image receptor.

(D) Positive beam limitation may be bypassed:

(i) when radiography is conducted without use of the cassette tray or permanently mounted vertical cassette holder;

(ii) or when either the beam axis or table angulation is not within ten (10) degrees of horizontal or vertical during any part of the exposure; or

(iii) during stereoscopic radiography.

If a bypass mode is provided, return to positive beam limitation shall be automatic.

(E) Capability may be provided to override positive beam limitation in the event of system failure or when it is necessary to perform special procedures which cannot be performed in the positive mode. However, if such capability is provided, it shall be necessary to use a key to override the positive mode and it shall be impossible to remove the key while the positive mode is overridden.

(n) Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the timer to its initial setting or to the zero (0) position. *(Indiana State Department of Health; 410 IAC 5-6.1-121; filed Oct 29, 1993, 5:00 p.m.: 17 IR 374; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-122 Special purpose x-ray systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 122. (a) In addition to compliance with sections 118, 119, and 121 of this rule, special purpose x-ray systems and associated facilities shall comply with this section. Special purpose x-ray facilities must be evaluated at intervals not to exceed twelve (12) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

(b) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(c) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. This subsection may be met if the system complies with section 121(c) of this rule. This subsection may also be met if means for alignment are provided, with either of the following:

(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the system is designed, with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed.

(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the system is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(Indiana State Department of Health; 410 IAC 5-6.1-122; filed Oct 29, 1993, 5:00 p.m.: 17 IR 377; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-123 Intraoral dental radiographic systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 123. (a) In addition to compliance with sections 118 and 119 of this rule, intraoral dental x-ray equipment and associated facilities shall comply with this section. Extraoral dental radiographic systems are exempt from this section, but must comply with section 121 of this rule. Intraoral dental x-ray facilities must be evaluated at intervals not to exceed thirty-six (36) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the SSD to no less than eighteen (18) cm if the system is capable of operation above fifty (50) kVp or no less than ten (10) cm, if the system is not capable of operation above fifty (50) kVp.

(c) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(1) if the minimum SSD is eighteen (18) cm or more, the x-ray field, at the minimum SSD, shall be containable in a circle of diameter seven (7) cm or less; or

(2) if the minimum SSD is less than eighteen (18) cm, the x-ray field, at the minimum SSD, shall be containable in a circle of diameter six (6) cm or less.

(d) Means shall be provided to terminate exposure at:

(1) a preset time interval;

(2) a preset product of current and time;

(3) a preset number of pulses; or

(4) a preset radiation exposure to the image receptor.

It shall not be possible to make an exposure when the timer is set to the zero (0) or off position if either is provided. With a timer setting of five-tenths (0.5) seconds or less, the average exposure period (T_{avg}) shall be no less than five (5) times the maximum

exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four (4) timer tests are performed. This requirement is expressed mathematically as:

$$T_{avg} \geq 5 (T_{max} - T_{min})$$

(e) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. X-ray controls shall be located as follows:

(1) Stationary x-ray systems installed after June 25, 1978, shall have the x-ray control permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.

(2) Mobile and portable x-ray systems which are used for greater than one (1) week in the same location, such as a room or suite, shall comply with subdivision (1).

(3) Mobile and portable x-ray systems which are used for greater than one (1) hour and less than one (1) week at the same location, such as a room or a suite, shall comply with subdivision (1) or be provided with a protective barrier six and five-tenths (6.5) feet high placed at least six (6) feet from the tube housing assembly and at least six (6) feet from the patient.

(4) Mobile and portable x-ray systems which are used to make an exposure of a patient at the use location shall comply with subdivision (3) or be provided with a method of x-ray control which will permit the operator to be at least twelve (12) feet from the tube housing assembly during an exposure.

(f) The coefficient of variation of exposure shall not exceed ten-hundredths (0.10) when all technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure (E_{avg}) is no less than five (5) times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}). This requirement is expressed mathematically as:

$$E_{avg} \geq 5 (E_{max} - E_{min})$$

(g) Patient and film holding devices shall be used when the techniques permit.

(h) The tube housing and the position indicating device shall not be hand held during an exposure.

(i) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin complies with subsection (c).

(j) Dental fluoroscopy shall be conducted only with image intensification.

(k) Diagnostic x-ray systems incorporating one (1) or more certified components shall be required to comply with the following additional requirements which relate to those certified components:

(1) When such equipment is operated on an adequate power supply as specified by the manufacturer in accordance with applicable federal standards, the coefficient of variation of exposure shall be no greater than five-hundredths (0.05) for any specific combination of selected technique factors.

(2) When such equipment allows a choice of x-ray tube current settings and is operated on a power supply specified by the manufacturer in accordance with applicable federal standards, for any tube potential (kVp) within forty percent (40%) to one hundred percent (100%) of the maximum kVp rating, the absolute value of the difference between the ratio of average exposure in mR to the indicated mAs obtained at any two (2) consecutive tube current settings, shall not differ by more than ten-hundredths (0.10) of the absolute value of their sum. A minimum of four (4) measurements per tube current setting are required to determine each average exposure. This requirement is expressed mathematically as:

$$|X_1 - X_2| \leq 0.10 |X_1 + X_2|$$

Where: X_1 and X_2 = The ratios of average exposure to mAs obtained at each of two (2) consecutive tube current settings

(3) Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to the zero (0) position.

(5) All dental x-ray systems manufactured on or after December 1, 1980, shall have a half-value layer of not less than one and five-tenths (1.5) mm aluminum equivalent. Systems operating above seventy (70) kVp are subject to the filtration requirements of section 119(f) of this rule.

(Indiana State Department of Health; 410 IAC 5-6.1-123; filed Oct 29, 1993, 5:00 p.m.: 17 IR 377; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-124 Therapeutic x-ray systems operating at less than one MeV

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 124. (a) This section and 410 IAC 5-9, excluding 410 IAC 5-9-8(a), 410 IAC 5-9-10(a), 410 IAC 5-9-10(c), and 410 IAC 5-9-10(d), shall apply to medical facilities using therapeutic x-ray systems capable of operating at less than one (1) MeV.

(b) When the tube is operated at its leakage technique factors, leakage radiation shall not exceed the following:

(1) For contact therapy systems, one hundred (100) mR per hour at five (5) cm from the surface of the tube housing assembly.

(2) For systems capable of operating from zero (0) to one hundred fifty (150) kVp which are manufactured prior to June 25, 1978, one (1) roentgen per hour at one (1) meter from the source.

(3) For systems capable of operating from zero (0) to one hundred fifty (150) kVp which were manufactured on or after June 25, 1978, one hundred (100) mR per hour at one (1) meter from the source.

(4) For systems capable of operating from greater than one hundred fifty (150) to five hundred (500) kVp, one (1) roentgen per hour at one (1) meter from the source.

(5) For systems capable of operating in excess of five hundred (500) kVp, no more than one-tenth of one percent (0.1%) of the useful beam at one (1) meter from the source.

(c) Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

(d) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent (1%) of the original x-ray beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the patient.

(e) Adjustable beam-limiting devices installed after June 25, 1978, shall comply with subsection (d). Adjustable beam-limiting devices installed before June 25, 1978, shall, for the portion of the x-ray beam to be blocked by such devices, transmit no more than five percent (5%) of the useful beam at the maximum kilovoltage and maximum treatment filter.

(f) The filter system shall be such that filters cannot be accidentally displaced from the useful beam at any possible tube orientation. Each filter shall be marked to identify its thickness and material of which it is constructed. For wedge filters, the wedge angle shall appear on the wedge or wedge tray. The radiation at five (5) cm from the filter insertion slot opening shall not exceed thirty (30) roentgens per hour at any operating condition.

(g) The tube housing assembly shall be capable of immobilization for stationary treatment. It shall be marked so that it is possible to determine the location of the focal spot to within five (5) mm. The marking shall be readily accessible for use during calibration procedures.

(h) Contact therapy system tube housing assemblies shall have a removable shield of at least five-tenths (0.5) mm lead equivalency at one hundred (100) kVp which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(i) Therapeutic x-ray systems capable of operating at greater than one hundred fifty (150) kVp, which were manufactured after June 25, 1978, shall be provided with a beam monitor system having the following capabilities:

(1) The system shall have the radiation detector of the monitoring system interlocked to prevent incorrect positioning.

(2) The system shall not allow irradiation until a value for exposure has been selected at the x-ray control panel.

(3) The system shall independently terminate irradiation when the selected exposure has been reached.

(4) The system shall be so designed that the dose administered to a patient prior to any system malfunction or power failure can be accurately determined.

(5) The system shall have a display at the x-ray control panel from which the dose at a reference point in the soft tissue can be calculated. This display must be intentionally reset to the zero (0) position.

(6) The system shall have a display at the x-ray control panel which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

(j) A timer shall be provided with a display at the x-ray control panel. The timer shall have a preset time selector and an elapsed time indicator. The timer shall be a cumulative timer which activates with the production of radiation and retains its readings after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to the zero (0) position. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation. The timer shall permit accurate presetting and determination of exposure times as short as one (1) second. The timer shall not permit an exposure if set at the zero

(0) position. When irradiation is controlled by a shutter mechanism, the timer shall not activate until the shutter is opened.

(k) The x-ray control panel shall be fitted with a device to terminate exposure at any time. In addition to displays required by other provisions of this section, the x-ray control panel shall indicate the following:

(1) When electrical power is available at the x-ray control panel.

(2) If activation of the x-ray tube is possible.

(3) When x-rays are being produced.

(4) kV and x-ray tube current.

For x-ray equipment manufactured after June 25, 1978, the x-ray control panel shall display specific filters in the beam.

(l) When an x-ray control panel may energize more than one (1) x-ray tube, it shall be possible to activate only one (1) x-ray tube at a time. The x-ray control panel shall identify which x-ray tube is energized, and the tube housing assembly shall also indicate when that tube is energized.

(m) There shall be means of determining the SSD to within one (1) cm.

(n) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds, the beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. After the system is at operating parameters, the shutter shall be controlled electrically by the operator from the x-ray control panel. The x-ray control panel shall indicate the shutter position.

(o) Each x-ray system equipped with a beryllium or other low filtration window shall be clearly labeled as such upon the tube housing assembly and at the x-ray control panel.

(p) Facilities which will house therapeutic x-ray systems capable of operating at fifty (50) kVp or more shall comply with the following:

(1) Provision shall be made for verbal communication between the patient and the operator at the x-ray control panel. However, where treatment requirements or excessive noise levels make verbal communication impractical, other effective methods of communication shall be utilized.

(2) Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the x-ray control panel.

(3) When the primary viewing system is electronic, an alternate viewing system shall be available for use in the event of failure of the primary viewing system. The alternate viewing system may also be electronic. In the event of failure of both viewing systems, the therapeutic x-ray system shall not be used to irradiate patients until one (1) of the viewing systems is again fully operational.

(q) Facilities which will house therapeutic x-ray systems capable of operating at one hundred fifty (150) kVp or more shall comply with subsection (o) and the following:

(1) All protective barriers shall be fixed, except for entrance doors or beam interceptors.

(2) The x-ray control panel shall be located outside the treatment room.

(3) Interlocks shall be provided such that all treatment room entrances must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to continue irradiation without closing all entrance doors and manually reinitiating irradiation at the x-ray control panel.

(4) When any door referred to in subdivision (3) is opened while the x-ray tube is activated, the exposure one (1) meter from the source shall be reduced to less than one hundred (100) mR per hour.

(r) Registrants shall have all new therapeutic x-ray facilities, and existing facilities not previously surveyed, surveyed by a radiation oncology physicist approved by the department. Such surveys shall also be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard. The survey shall be done before the therapeutic x-ray system is used for therapeutic purposes, and an evaluation report, including all violations of this rule on a form acceptable to the commissioner, must be completed by the radiation oncology physicist and a copy forwarded to the registrant and to the commissioner within thirty (30) days of receipt of the completion of the survey. The survey and report shall indicate all locations where the dose equivalent rate exceeds the limits specified in this rule.

(s) The registrant shall establish procedures to check all timer calculations by an independent method or by a second individual before administering thirty percent (30%) of the prescribed total dose, to assure that the given dose agrees with the manual or computer generated dose calculation, and with the written order of a practitioner of the healing arts. Additionally, the registrant shall verify that the correct beam filtration and cone factors are used and documented.

(t) Calibration of therapeutic x-ray systems subject to this section shall be performed before the system is first used for irradiation of an individual and thereafter at time intervals not to exceed twelve (12) months. Calibrations shall be also be performed

after any change which might significantly alter the beam energy, spatial distribution, or other output characteristics of the therapy beam. Calibration shall be performed by a radiation oncology physicist approved by the department, who is physically present at the facility. Radiation measurements conducted during calibrations required by this subsection shall be performed using a dosimetry system which complies with the following:

(1) The dosimetry system shall have an air-kerma or exposure calibration factor traceable to the National Institute for Standards and Technology.

(2) The dosimetry system shall have been calibrated within the previous two (2) years and after any servicing that may have affected its calibration. The system shall have been calibrated in such a fashion that an uncertainty can be stated for the radiation output measured by the system. The dosimetry system shall have had constancy checks performed on the system as specified by a radiation oncology physicist. Calibration shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated with a maximum uncertainty of five percent (5%).

(3) Calibration of each therapy beam shall include, but not be limited to, the output, half-value layer, and cone factors. Records of calibration measurements and dosimetry system calibrations conducted in accordance with this subsection shall be maintained by the registrant for at least five (5) years after completion of such calibration.

(u) An independent check of the output of a therapeutic x-ray system shall be performed annually. The check shall be performed by either of the following:

(1) A radiation oncology physicist approved by the department, other than the one who performed the annual output calibration, using a dosimetry system other than the one that was used during said annual calibration. The dosimetry system must also comply with subsection (t).

(2) A thermoluminescence dosimetry service capable of measuring doses with an accuracy of five percent (5%) or less.

(v) Output spot checks shall be performed on therapeutic x-ray systems during spot checks conducted in accordance with subsection (t), and thereafter at intervals not to exceed one (1) month, by a radiation oncology physicist approved by the department. Output spot check procedures shall be in writing and shall have been developed by a radiation oncology physicist approved by the department. Output spot check procedures shall specify:

(1) which tests or measurements are to be performed;

(2) the frequency the tests or measurements are to be performed;

(3) the acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last calibration conducted in accordance with subsection (t); and

(4) the action to be taken if a tolerance has been exceeded for any test or measurement required by the written output spot check procedures.

If an output spot check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per timer unit compared to the value determined in the last spot check conducted under this subsection, the radiation oncology physicist shall calibrate the therapeutic x-ray system. Records of each output spot check measurement conducted in accordance with this subsection shall be maintained by the registrant for a minimum of five (5) years from the date the output calibration was performed.

(w) The registrant shall perform weekly output constancy checks on each of their therapeutic x-ray systems in accordance with written output constancy check procedures developed by a radiation oncology physicist approved by the department. The output constancy check procedures shall specify:

(1) the tests or measurements to be performed;

(2) the acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last calibration conducted in accordance with subsection (t); and

(3) the action to be taken if a tolerance has been exceeded for a test or measurement required by the written output constancy check procedures.

At least monthly, a radiation oncology physicist approved by the department shall review the results of all required output constancy checks performed since his or her last such review. If an output constancy check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per timer unit compared to the value determined in the last calibration conducted in accordance with subsection (t), the registrant shall repair the therapeutic x-ray system or undertake other corrective action before the equipment is again used to irradiate patients. The registrant shall also perform an output constancy check to determine whether or not the therapeutic x-ray system is again in compliance with this subsection prior to utilizing the equipment to irradiate patients. A record of each output constancy check performed in accordance with this subsection, and any repairs or corrective action undertaken in compliance with this subsection, shall be maintained by the registrant for a minimum of two (2) years

from the date the output constancy check, repair, or corrective action was performed.

(x) The registrant shall perform checks on treatment planning computers and dose calculation algorithms in accordance with written quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the written quality assurance procedures shall require that the registrant do the following:

(1) Ensure that any computer software changes, including beam data files, have been correctly implemented without corrupting beam data.

(2) Verify that all users of treatment planning computers have been trained in the use of the computers.

(y) The registrant shall establish and maintain a written quality management plan to assure that radiation from an x-ray therapy system is administered as ordered by a practitioner of the healing arts. At a minimum, a quality management plan must assure all of the following:

(1) Prior to administration, a written order for therapeutic radiation must be prepared by a practitioner of the healing arts. The order shall specify, at a minimum, the following:

(A) The patient's name.

(B) The anatomical treatment site or sites.

(C) For each treatment site, the following:

(i) Beam energy.

(ii) HVL.

(iii) The dose per fraction.

(iv) The number of fractions.

(v) The total dose.

If, in the opinion of a practitioner of the healing arts, any delay could jeopardize the health of a patient, the practitioner may verbally order therapeutic radiation, as long as the practitioner prepares a written order in accordance with this subdivision, to confirm his or her verbal orders, within seventy-two (72) hours of issuing the verbal order.

(2) Treatment plans and related calculations for radiation are in accordance with the written order of a practitioner of the healing arts.

(3) Each administration of therapeutic radiation is in accordance with a written order of a practitioner of the healing arts.

(4) Any deviation from the written order of a practitioner of the healing arts in excess of ten percent (10%) of the daily prescribed dose is identified, evaluated, and the findings communicated to the practitioner of the healing arts.

(z) The registrant shall review the radiation oncology chart of patients subjected to irradiation from a therapeutic x-ray system in accordance with written quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the written quality assurance procedures shall require the following:

(1) The documented timer settings used for each field is *[sic., are]* in conformance with the calculations.

(2) The therapeutic x-ray system operator initials the treatment documentation for each patient he or she treats, each day.

(3) The daily radiation dose and the cumulative radiation dose are recorded.

(4) Each written order for therapy treatment is being followed.

(5) The total prescribed dose for each treatment site is appropriately indicated.

(aa) The registrant shall submit a written report to the commissioner of any misadministration within fifteen (15) days of discovery of the misadministration. The report shall:

(1) state the name and address of the registrant;

(2) state the name of the practitioner of the healing arts who prescribed the x-ray therapy at issue;

(3) state the name of the individual who was improperly irradiated or the name of that individual's parent or guardian, if applicable;

(4) briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated;

(5) describe the actions taken by the registrant to prevent a recurrence of similar misadministrations; and

(6) state what information has been presented to the individual who was improperly irradiated, or to that individual's parent or guardian, if applicable.

A copy of the report shall be maintained by the registrant for at least five (5) years after the date of the misadministration.

(bb) If possible, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the individual who has been improperly irradiated, or that individual's parent or guardian, if applicable, about the misadministration, unless, in the opinion of a practitioner of the healing arts, such notification would be harmful to that individual. Also, within twenty-four (24)

hours of discovery of a misadministration, the registrant shall notify the referring practitioner of the healing arts about the misadministration. At a minimum, the notification shall briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated.

(cc) Therapeutic x-ray systems shall not be left unattended unless the system or the treatment room door is secured against unauthorized use.

(dd) When a patient must be held in position for radiation therapy, mechanical supports or restraining devices shall be used.

(ee) The tube housing assembly shall not be held by hand during operation unless the system is designed to require holding and the kVp of the system does not exceed fifty (50) kVp. In such cases, the holder shall wear protective gloves and an apron of not less than five-tenths (0.5) mm lead equivalency at one hundred (100) kVp.

(ff) No individual other than the patient shall be in the treatment room during exposures from therapeutic x-ray systems unless such individual is shielded by protective barriers sufficient to reduce their exposure to no more than that allowed by 410 IAC 5-4-2. No individual other than the patient shall be in the treatment room during exposures from therapeutic x-ray systems operating above one hundred fifty (150) kVp.

(gg) A therapeutic x-ray system shall not be used to administer radiation therapy unless it complies with subsections (t), (v), and (w). *(Indiana State Department of Health; 410 IAC 5-6.1-124; filed Oct 29, 1993, 5:00 p.m.: 17 IR 379; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-125 Therapeutic x-ray or electron systems operating at one MeV or more

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 125. (a) This section and 410 IAC 5-9, excluding 410 IAC 5-9-8(a), 410 IAC 5-9-10(a), 410 IAC 5-9-10(c), and 410 IAC 5-9-10(d), shall apply to medical facilities using therapeutic x-ray or electron systems capable of operating at one (1) MeV or more.

(b) Therapeutic x-ray or electron systems manufactured after January 1, 1985, shall comply with the following:

(1) The absorbed dose due to leakage radiation, when measured at any point in the patient plane, shall not exceed one-tenth of one percent (0.1%) for x-ray leakage or five-hundredths percent (0.05%) for neutron leakage of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the isocenter or normal treatment distance.

(2) For each therapeutic x-ray or electron system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subdivision (1) for operating conditions producing maximum leakage radiation. Radiation measurements excluding neutrons shall be averaged over an area of one hundred (100) square cm or less. Neutron measurements shall be averaged over an area of two hundred (200) square cm or less. Records on leakage radiation measurements shall be maintained for inspection by the commissioner.

(c) Therapeutic x-ray or electron systems manufactured on or before January 1, 1985, shall comply with the following:

(1) The absorbed dose due to leakage radiation at any point in the patient plane shall not exceed one-tenth of one percent (0.1%) of the maximum absorbed dose of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the isocenter or normal treatment distance for x-ray leakage.

(2) For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in subdivision (1) for operating conditions producing maximum leakage radiation. Radiation measurements shall be averaged over an area of one hundred (100) square cm or less. Records on leakage radiation measurements shall be maintained for inspection by the commissioner.

(d) Adjustable or interchangeable beam-limiting devices shall be provided. Such devices shall transmit no more than two percent (2%) of the useful beam, excluding its neutron component, at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam-limiting device.

(e) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation shall be available at the control panel describing each filter. For wedge filters, the wedge angle shall be indicated on the wedge or wedge tray. If the absorbed dose rate data required by subsection (t) relates exclusively to operation with a field-flattening or beam-scattering filter in place, such filter shall not be removable by hand.

(f) Those therapeutic x-ray or electron systems manufactured after January 1, 1985, which utilize a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering filters shall comply with the following:

(1) Irradiation shall not be possible until a selection of a filter or filter code has been made at the x-ray control panel.

(2) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

(3) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the x-ray control panel.

(g) The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following requirements are met:

(1) The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten (10) cm greater than the practical range of the electrons shall not exceed the values stated in the table in this subdivision. Linear interpolation shall be used for values not stated.

TABLE III

Maximum Energy of Electron Beam	X-Ray Absorbed Dose as a Fraction of Maximum Dose
1 MeV	0.03
15 MeV	0.05
35 MeV	0.10
50 MeV	0.20

Compliance shall be determined using the following:

(A) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam.

(B) A phantom having cross sectional dimensions which exceed the measurement radiation field by at least five (5) cm and of depth sufficient to perform the required measurement.

(2) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in the table in this subdivision. Linear interpolation shall be used for values not stated.

TABLE IV

Maximum Photon Energy	Absorbed Dose at the Surface as a Fraction of the Maximum Dose
1 MeV	0.80
2 MeV	0.70
5 MeV	0.60
15 MeV	0.50
35 MeV	0.40
50 MeV	0.20

Compliance shall be determined by measurements made as follows:

(A) Within a phantom using an instrument which will allow extrapolation to the surface absorbed dose.

(B) Using a phantom having size and placement which complies with subdivision (1).

(C) After removal of all beam-modifying devices which can be removed by hand, except for beam-scattering or beam-flattening filters.

(h) All therapeutic x-ray or electron systems shall be provided with one (1) or more dose monitoring chambers, in accordance with the following:

(1) Therapeutic x-ray or electron systems manufactured after January 1, 1985, shall be provided with at least two (2) dose monitoring chambers. The dose monitoring chambers shall be incorporated into two (2) separate dose monitoring systems.

(2) Therapeutic x-ray or electron systems manufactured on or before January 1, 1985, shall be provided with at least one (1) dose monitoring chamber. The dose monitoring chamber shall be incorporated into the primary dose monitoring system.

(i) Each dose monitoring chamber shall be removable only by use of tools and shall be interlocked to prevent incorrect positioning. Each dose monitoring chamber shall form part of a dose monitoring system from which readings of the absorbed dose

at a reference point in the treatment volume can be calculated in dose monitor units. Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation. Each dose monitoring system shall have a legible display located at the control panel.

(j) Therapeutic x-ray or electron systems manufactured after January 1, 1985, shall comply with this subsection. The design of each dose monitoring system shall assure that malfunctioning of one (1) system shall not cause incorrect functioning of the second system. The failure of any element common to both monitoring systems which could affect the correct function of both systems shall terminate irradiation. Each dose monitoring system display shall:

(1) maintain a reading until intentionally reset to the zero (0) position;

(2) have only one (1) scale and no scale multiplying factors;

(3) utilize a design such that increasing dose is displayed by increasing numbers; and

(4) be such that, in the event a dose monitoring system fails, the dose monitor units delivered may be accurately determined. In the event of a power failure, the dose monitoring information displayed at the control panel at the time of the power failure shall be retrievable from at least one (1) dose monitoring system.

(k) For therapeutic x-ray or electron systems manufactured after January 1, 1985, which are inherently capable of producing useful beams with asymmetry exceeding five percent (5%), the asymmetry of the radiation beam in two (2) orthogonal directions shall be monitored before the beam passes through the beam-limiting device. Monitoring devices, indicators, and controls shall be provided so that if the difference in dose rate between one (1) region and another region symmetrically displaced from the central axis of the beam exceeds five percent (5%) of the central axis dose rate, this condition is indicated at the control panel. If the difference exceeds ten percent (10%), the controls shall automatically terminate irradiation.

(l) Irradiation shall not be possible until selection of the number of dose monitor units to be delivered has been made at the control panel. The preselected number of dose monitor units shall be displayed at the control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the dosimeter display to the zero (0) position before subsequent treatment can be initiated.

(m) During stationary beam therapy, the primary dose monitoring system shall terminate irradiation when the preselected number of dose monitor units have been detected by that system. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when the system detects that the preselected number of dose monitoring units set at the control panel indicate either fifteen percent (15%), or greater, or forty (40) dose monitor units, or greater, above the preselected number of dose monitor units set at the control panel. For therapeutic x-ray or electron systems manufactured after January 1, 1985, which are used for stationary beam therapy:

(1) a second dose monitoring system shall be incorporated which can terminate irradiation when fifteen percent (15%), or greater, or forty (40) dose monitor units, or greater, above the number selected at the x-ray control panel has been detected by the second dose monitoring system; and

(2) the control panel shall indicate which dose monitoring system has terminated irradiation.

(n) It shall be possible to interrupt irradiation and gantry rotation at any time at the control panel. Following an interruption, it shall be possible for the operator to commence irradiation without reselecting operating conditions. If any change is made of a preselected value during an interruption, irradiation and gantry rotation shall be automatically terminated.

(o) A timer that has a display shall be provided at the control panel. The timer shall have a preset time selector and an elapsed time indicator. The timer shall be a cumulative timer that activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated, it shall be necessary to reset the elapsed time indicator to the zero (0) position before irradiation can be initiated. The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

(p) Equipment capable of both x-ray therapy and electron therapy shall comply with the following additional requirements:

(1) Irradiation shall not be possible until the type of radiation to be utilized has been selected at the control panel. The type of radiation selected shall be displayed at the control panel before and during irradiation.

(2) An interlock system shall be provided to ensure that the equipment can emit only that type of radiation which has been selected.

(3) An interlock system shall be provided to prevent irradiation if operating conditions selected in the treatment room do not agree with the operating conditions selected at the control panel.

(4) When electron applicators are fitted, an interlock system shall prevent irradiation with x-rays except to obtain a port film.

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

(q) Equipment capable of generating radiation beams of different energies shall comply with the following:

(1) Irradiation shall not be possible until an energy value has been selected at the control panel. The energy value selected shall be displayed at the control panel before and during irradiation.

(2) An interlock system shall be provided to prevent irradiation if operating conditions selected in the treatment room do not agree with the operating conditions selected at the control panel.

(3) For therapy systems manufactured after January 1, 1985, except systems that employ a straight through waveguide design, an interlock system shall be provided to terminate irradiation if the bending magnet current for the energy selected varies by more than ten percent (10%) of its normal value.

(r) Equipment capable of both stationary beam therapy and moving beam therapy shall comply with the following:

(1) Irradiation shall not be possible until either stationary beam therapy or moving beam therapy has been selected at the control panel. The mode of treatment selected shall be displayed at the x-ray control panel.

(2) An interlock system shall be provided to ensure that the equipment can operate only in the mode selected.

(3) An interlock system shall be provided to prevent irradiation if any operation selected to be carried out in the treatment room does not agree with the operation selected at the control panel.

(4) For therapy systems manufactured after January 1, 1985, an interlock system shall be provided to terminate irradiation if the gantry moves during stationary beam therapy, or if the gantry ceases rotation before the preselected arc is swept, unless the stoppage is preplanned.

(5) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(6) Therapy systems manufactured after January 1, 1985, shall also comply with the following:

(A) An interlock system shall be provided to terminate irradiation if the gantry speed, dose rate, or dose rate per degree varies by more than twenty percent (20%) of the preselected value.

(B) For moving beam therapy wherein irradiation is terminated based on the arc swept, the dose monitor units shall differ by less than five percent (5%) from the value calculated for the absorbed dose per unit angle.

(C) For moving beam therapy wherein the dose monitor system terminates irradiation, the termination shall be in accordance with subsection (m).

(s) For therapy systems manufactured after January 1, 1985, a system shall be provided from which readings of the absorbed dose rate at a reference point in the treatment volume can be calculated. The dose monitoring chambers specified in subsection (h) may form part of this system. The dose monitor unit rate shall be displayed at the control panel.

(t) The registrant shall determine, or shall obtain from the manufacturer, the location of the target or the virtual source of x-rays with reference to an accessible point on the radiation head. If the equipment is capable of electron therapy, the registrant shall also determine, or shall obtain from the manufacturer, the location of the electron window with reference to an accessible point on the radiation head.

(u) Capability shall be provided for radiation safety interlocks to be checked for proper operation.

(v) Facilities which will house therapeutic x-ray or electron systems capable of operating at more than one (1) MeV shall comply with 410 IAC 5-4 and the following:

(1) All protective barriers shall be fixed except for entrance doors or beam interceptors.

(2) The control panel shall be located outside the treatment room.

(3) Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be located so the operator can observe the patient from the control panel.

(4) When the primary viewing system is electronic, either an alternate viewing system shall be available for use in the event of failure of the primary viewing system, or the therapeutic x-ray or electron system shall not be used when the primary viewing system is not fully functional. Alternate viewing systems may also be electronic. In the event of failure of both viewing systems, the therapeutic x-ray or electron system shall not be used to irradiate patients until one (1) of the viewing systems is again fully operational.

(5) Provision shall be made for verbal communication between the patient and the operator at the control panel. However, where treatment requirements or excessive noise levels make verbal communication impractical, other effective methods of communication shall be utilized.

(6) Each treatment room entrance shall be provided with a readily observable warning light near the outside of the entrance. The warning light shall indicate when irradiation is in progress in the treatment room.

(7) Interlocks shall be provided such that all treatment room entrances must be closed before treatment can be initiated or

continued. If the radiation beam is interrupted by any door opening, it shall not be possible to continue irradiation without closing all entrance doors and manually reinitiating irradiation at the control panel.

(w) Registrants shall have all new therapeutic x-ray or electron facilities, and existing facilities not previously surveyed, surveyed by a radiation oncology physicist approved by the department. Such surveys shall also be performed after any change in the facility or equipment which might cause a significant increase in radiation hazard. The registrant shall obtain a written report of the survey from the radiation oncology physicist, and a copy of the report shall be transmitted by the registrant to the commissioner within thirty (30) days of receipt of the report of the survey. The survey and report shall indicate all locations where the dose equivalent rate exceeds the limits specified in this rule.

(x) The registrant shall establish procedures to check all monitor unit calculations by an independent method or by a second individual before administering thirty percent (30%) of the prescribed total dose to assure that the dose to a single point on the central axis, or to a point of special interest, agrees with the manual or computer generated dose calculation and with the written order of a practitioner of the healing arts. Additionally, the registrant shall verify that the correct central axis depth-dose values, field size factors, off-axis ratios, and beam modifying factors are used and documented.

(y) Calibration of therapeutic x-ray or electron systems subject to this section shall be performed in accordance with an established calibration protocol acceptable to the commissioner, such as the protocol established by the American Association of Physicists in Medicine. The calibrations shall be performed before the system is first used for irradiation of an individual, and thereafter at time intervals not to exceed twelve (12) months. Calibrations shall also be performed after any change which might significantly alter the dose monitor unit, beam energy, spatial distribution, or other characteristics of the therapy beam. Calibration shall be performed by a radiation oncology physicist approved by the department, who is physically present at the facility. Radiation measurements conducted during calibrations required by this subsection shall be performed using a dosimetry system which complies with the following:

(1) The dosimetry system shall have an air-kerma calibration factor for cobalt 60 gamma rays traceable to the National Institute for Standards and Technology.

(2) The dosimetry system shall have been calibrated within the previous two (2) years and after any servicing that may have affected its calibration. The system shall have been calibrated in such a fashion that an uncertainty can be stated for the radiation output measured by the system. The dosimetry system shall have had constancy checks performed on the system as specified by a radiation oncology physicist approved by the department. Calibration shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated with a maximum uncertainty of five percent (5%).

(3) Calibration of each therapy beam shall include, but not be limited to, the following determinations:

(A) Verification that the equipment is operating in compliance with the design specifications concerning the radiographic isocenter, light-radiation field congruency, laser alignment, optical distance indicator, field size indicators, variation in the axis of rotation for the table, collimator, gantry, and beam flatness and symmetry at specified depths for various gantry angles.

(B) Verification of beam energy, output factors, off-axis ratios, dose-depth values, and isodose data for each beam.

(C) Verification of transmission data for all beam modification devices such as wedges, blocking trays, compensators, and custom blocks.

(D) Verification that existing depth-dose data and isodose charts applicable to the equipment continues to be valid or are updated to existing machine conditions.

Records of calibration measurements and dosimetry system calibrations conducted in accordance with this subsection shall be maintained by the registrant for at least five (5) years after completion of such calibration.

(z) An independent check of the output of each therapeutic beam shall be performed annually. The check shall be performed by either of the following:

(1) A radiation oncology physicist approved by the department, other than the one who performed the annual output calibration, using a dosimetry system other than the one that was used during the annual calibration. The dosimetry system must also comply with subsection (y).

(2) A thermoluminescence dosimetry service capable of measuring doses with an accuracy of five percent (5%) or less.

(aa) Output spot checks shall be performed on therapeutic x-ray or electron systems during spot checks conducted in accordance with subsection (y), and thereafter at intervals not to exceed one (1) month by a radiation oncology physicist approved by the department. Output spot check procedures shall be in writing and shall have been developed by a radiation oncology physicist approved by the department. Output spot check procedures shall specify which tests or measurements to be performed, the frequency the tests or measurements are to be performed, the acceptable tolerance for each parameter measured compared to the value for that

parameter as determined in the last calibration conducted in accordance with subsection (y), and the action to be taken if a tolerance has been exceeded for any test or measurement required by the written output spot check procedures. Written output spot check procedures are required for at least the following parameters:

(1) Output per monitor unit.

(2) Light-radiation field congruency.

(3) Laser alignment.

(4) Optical distance indicators.

(5) Field size indicators.

If an output spot check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per monitor unit compared to the value determined in the last spot check conducted in this subsection, the radiation oncology physicist shall calibrate the therapeutic x-ray system. Records of each output calibration measurement conducted in accordance with this subsection shall be maintained by the registrant for a minimum of five (5) years from the date the output calibration was performed.

(bb) The registrant shall perform weekly output constancy checks on each of their therapeutic x-ray or electron systems in accordance with written output constancy check procedures developed by a radiation oncology physicist approved by the department. The output constancy check procedures shall specify the following:

(1) The tests or measurements to be performed.

(2) The acceptable tolerance for each parameter measured compared to the value for that parameter as determined in the last calibration conducted in accordance with subsection (y).

(3) The action to be taken if a tolerance has been exceeded for a test or measurement required by the written output constancy check procedures.

At least monthly, a radiation oncology physicist approved by the department shall review the results of all required output constancy checks performed since his or her last such review. If an output constancy check conducted in accordance with this subsection indicates a variance of more than five percent (5%) in output per monitor unit compared to the value determined in the last calibration conducted in accordance with subsection (y), the registrant shall repair the therapeutic x-ray or electron system or undertake other corrective action before the equipment is again used to irradiate patients. The registrant shall also perform an output constancy check to determine whether or not the therapeutic x-ray or electron system is again in compliance with this subsection prior to utilizing the equipment to irradiate patients. A record of each output constancy check performed in accordance with this subsection, and any repairs or corrective action undertaken in compliance with this subsection, shall be maintained by the registrant for a minimum of two (2) years from the date the output constancy check, repair, or corrective action was performed.

(cc) The registrant shall perform checks on treatment planning computers and dose calculation algorithms in accordance with quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the quality assurance procedures shall require that the registrant do the following:

(1) Verify that the output for external beam programs, including irregular fields, agree with measured beam data for test cases.

(2) Ensure that any computer hardware changes have been correctly installed.

(3) Ensure that any computer software changes, including beam data files, have been correctly implemented without corrupting beam data.

(4) Verify that all users of treatment planning computers have been trained in the use of the computers.

(dd) The registrant shall establish and maintain a written quality management plan to assure that radiation from an x-ray or electron therapy system is administered as ordered by a practitioner of the healing arts. At a minimum, the quality management plan must assure the following:

(1) Prior to administration, a written order for therapeutic radiation must be prepared by a practitioner of the healing arts. Said order shall specify, at a minimum, the following:

(A) The patient's name.

(B) The anatomical treatment site or sites.

(C) For each treatment site, treatment mode, and beam energy, the following:

(i) The dose per fraction.

(ii) The number of fractions.

(iii) The total dose.

If, in the opinion of a practitioner of the healing arts, any delay could jeopardize the health of a patient, said practitioner may verbally order therapeutic radiation, as long as the practitioner prepares a written order in accordance with this subdivision,

to confirm his or her verbal orders within seventy-two (72) hours of issuing the verbal order.

(2) Treatment plans and related calculations for radiation are in accordance with the written order of a practitioner of the healing arts.

(3) That each administration of therapeutic radiation is in accordance with a written order of a practitioner of the healing arts.

(4) That deviations from the written order of a licensed practitioner of the healing arts in excess of ten percent (10%) of the daily prescribed dose is identified, evaluated, and the findings communicated to the practitioner of the healing arts.

(ee) The registrant shall review the radiation oncology chart of patients subjected to irradiation from a therapeutic x-ray or electron system in accordance with written quality assurance procedures developed by a radiation oncology physicist approved by the department. At a minimum, the written quality assurance procedures must require the following:

(1) That the documented monitor units used for each field is *[sic., are]* in conformance with calculations.

(2) That the therapeutic x-ray or electron system operator initials the treatment documentation for each patient he or she treats, each day.

(3) The daily radiation dose and the cumulative radiation dose is *[sic., are]* recorded.

(4) Each written order for therapy treatment is being followed.

(5) The total prescribed dose for each treatment site is appropriately indicated.

(ff) The registrant shall submit a written report to the commissioner of any misadministration within fifteen (15) days of discovery of the misadministration. The report shall contain the following:

(1) State the name and address of the registrant.

(2) State the name of the practitioner of the healing arts who prescribed the x-ray or electron therapy at issue.

(3) State the name of the individual who was improperly irradiated, or the name of that individual's parent or guardian, if applicable.

(4) Briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated.

(5) Describe the actions taken by the registrant to prevent a recurrence of similar misadministrations.

(6) State what information has been presented to the individual who was improperly irradiated, or to that individual's parent or guardian, if applicable.

A copy of the report shall be maintained by the registrant for at least five (5) years after the date of the misadministration.

(gg) If possible, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the individual who has been improperly irradiated, or that individual's parent or guardian, if applicable, about the misadministration, unless, in the opinion of a practitioner of the healing arts, such notification would be harmful to that individual. Also, within twenty-four (24) hours of discovery of a misadministration, the registrant shall notify the referring practitioner of the healing arts about the misadministration. At a minimum, the notifications shall briefly describe the nature of the misadministration and any resultant effect on the individual who was improperly irradiated.

(hh) A therapeutic x-ray system shall not be used to administer radiation therapy unless it complies with subsections (u), (y), (z), and (aa) through (cc). *(Indiana State Department of Health; 410 IAC 5-6.1-125; filed Oct 29, 1993, 5:00 p.m.: 17 IR 383; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-126 Veterinary medicine radiographic systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 126. (a) No person other than a veterinarian shall direct or order the application of radiation to any animal, nor shall any person other than a veterinarian, or a person working under the direct supervision of a veterinarian, apply radiation to animals. Such direction or order to apply radiation shall be in the course of the veterinarian's professional practice or in the interest of science and shall comply with all applicable sections of this rule.

(b) Veterinary x-ray facilities shall comply with applicable provisions of sections 118, 120, and 123 of this rule and this section. All veterinary x-ray facilities must be evaluated at intervals not to exceed twenty-four (24) months by a diagnostic imaging physicist or x-ray machine inspector approved by the department.

(c) The protective tube housing shall be of diagnostic type.

(d) Light beam diaphragms shall be provided for collimating the useful beam to the area of clinical interest. Cones may be used only if it can be demonstrated that the x-ray tube and cassette can be fixed such that the primary beam is limited to the cassette.

Diaphragms and cones shall provide the same degree of protection as is required of the housing.

(e) The total filtration permanently in the useful beam shall not be less than five-tenths (0.5) mm aluminum equivalent for machines operating up to fifty (50) kVp, one and five-tenths (1.5) mm aluminum equivalent for machines operating from fifty (50) to seventy (70) kVp, and two and five-tenths (2.5) mm aluminum equivalent for machines operating above seventy (70) kVp.

(f) A device shall be provided to terminate the exposure after a preset time or exposure. It shall not be possible to make an exposure when the timer is set to the zero (0) or off position if either is provided.

(g) A dead-man switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six (6) feet from the animal during x-ray exposures.

(h) All radiographic areas shall be provided with sufficient protective barriers that the radiation limits specified in 410 IAC 5-4-2, 410 IAC 5-4-5(a), and 410 IAC 5-4-6 are not exceeded.

(i) The operator shall stand away from the useful beam and the animal as far as reasonably possible during the radiographic exposures.

(j) No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required to ensure a successful radiographic procedure.

(k) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and a protective apron, and the individual shall be so positioned that no part of his or her body will be struck by the useful beam. The exposure of any individual who must hold an animal during radiography shall be monitored via a personnel dosimetry program. *(Indiana State Department of Health; 410 IAC 5-6.1-126; filed Oct 29, 1993, 5:00 p.m.: 17 IR 389; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-6.1-127 Mammographic x-ray equipment

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 127. (a) Mammographic x-ray facilities shall comply with applicable provisions of sections 118 and 119 of this rule and this section. All mammographic x-ray facilities must be evaluated at least once every twelve (12) months by a diagnostic imaging physicist approved by the department.

(b) The registrant shall assure that the results of all mammography procedures are interpreted by a physician certified by the ABR, the American Osteopathic Board of Radiology, or by a physician accredited by the ACR through their mammography accreditation program.

(c) The registrant shall assure that the physician does the following:

(1) Has successfully completed or taught a minimum of forty (40) hours of postgraduate instruction in mammography interpretation.

(2) Has successfully completed or taught a minimum of fifteen (15) hours of postgraduate work in mammography interpretation every thirty-six (36) months.

(3) Reads the results of ten (10) or more screening or diagnostic mammographic exams per week.

(4) Prepares and signs a written report on his or her interpretation of the results of each mammography procedure.

(5) Provides a copy of the written report and the original images or films to the registrant for inclusion in the patient's medical record.

(6) Provides a written statement to the patient, either through the referring physician or his or her designee, or, if a referring physician is not available, directly to the patient. The statement shall be written in terms easily understood by a lay person and must describe the test results and the importance of the mammogram to ongoing health, as well as that person's responsibility to share with any new physician or supplier of their next mammogram the date and place of their previous mammography procedure. If the results of the mammogram are positive, the statement must describe the next step that should be taken by the patient. The statement must also record the following:

(A) The date of the mammography procedure.

(B) The name of the facility providing the mammography procedure.

(C) The physician to whom the person wants a copy of the statement to be sent, if any.

The statement must further indicate that the original images or films are being provided to the mammography facility for inclusion in the individual's medical record.

(d) The registrant shall assure that a physician qualified in accordance with subsection (c)(1) through (c)(3) documents at least annually that he or she:

(1) has checked the procedure manual and has observed at least monthly the performance of the operator of the mammographic x-ray equipment and has determined that both are adequate; and

(2) has verified that safe operating procedures are used and that all applicable requirements of this rule are being met.

(e) The registrant shall assure that all operators of mammographic x-ray equipment:

(1) have a general diagnostic x-ray machine operator's certificate in accordance with 410 IAC 5-11;

(2) have passed the advanced examination in mammography administered by the ARRT or have successfully completed ten (10) hours of specialized training in mammographic positioning, compression, and technique factor setting prior to performing mammograms; and

(3) successfully complete ten (10) hours of specialized training in mammographic positioning, compression, and technique factor setting at least every twenty-four (24) months thereafter.

(f) The registrant must have an orientation program for operators of mammographic x-ray equipment based on a procedure manual that is available to all members of the staff.

(g) All x-ray equipment used to perform mammography shall be specifically designed for mammography.

(h) Target-filter combinations shall comply with the following:

(1) For film/screen mammography, the target shall be constructed of molybdenum, with molybdenum filtration and a beryllium window. Tungsten targets with special filters such as palladium or rhodium are also acceptable, but only if the x-ray equipment has been accredited by the ACR.

(2) For xeroradiography, the target shall be constructed of tungsten with aluminum filtration.

(i) The x-ray equipment shall be capable of use with antiscatter grids.

(j) An x-ray control shall be incorporated such that an exposure can be terminated at any time except for exposures of one-half (1/2) second or less. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated. The x-ray control panel shall have labeled control settings or meters to show all physical factors used for exposure, such as focal spot, kVp, mA, mAs, time, and automatic exposure control. The x-ray equipment must be operable only from a shielded position.

(k) A mark on the visible exterior surface of the source assembly shall indicate the location of the focal spot. The SID shall be no less than fifty (50) cm.

(l) For film/screen equipment, the half-value layer shall be no less than three-tenths (0.3) mm aluminum equivalent at a measured tube voltage of thirty (30) kVp with the compression device in the useful x-ray beam. Otherwise, the half-value layer shall be no less than that specified in section 119(f), Table I of this rule.

(m) For xeroradiography equipment, the half-value layer shall be no less than one (1.0) mm aluminum equivalent at the clinically employed kVp.

(n) A compression device shall be provided. For film/screen systems, the compression device shall be of the flat plate type, parallel to the image receptor.

(o) Mammographic x-ray equipment shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID, except the edge of the image receptor designed to be adjacent to the chest wall, in which case the x-ray field may not extend beyond this edge by more than two percent (2%) of the SID.

(p) For mammographic x-ray equipment equipped with a beam-limiting device and a light localizer, the light field shall be aligned with the radiation field within two percent (2%) of the SID.

(q) For all mammographic x-ray equipment:

(1) the kVp shall be accurate within two (2) kV, plus or minus; and

(2) the coefficient of variation shall be no greater than five-hundredths (0.05) for each kVp tested.

Compliance shall be based on determination of the coefficient of variation and the average of at least four (4) consecutive measurements for the kVp at which the x-ray equipment is normally used. Compliance may be based on single measurements for other kVps over the range of use. However, if any single measurement is out of compliance, an average and coefficient of variation shall be determined at that kVp for comparison to subdivisions (1) and (2).

(r) Mammographic x-ray equipment shall have automatic exposure control, including the following:

(1) The coefficient of variation for automatic exposure control reproducibility shall be no greater than five-hundredths (0.05). Determination of compliance shall be based on at least four (4) consecutive measurements of exposure or optical density

obtained at a fixed kVp and attenuator thickness.

(2) Mammographic x-ray equipment shall:

(A) be capable of maintaining constant film density to within plus or minus three-tenths (0.3) of the average optical density over the kVp range used for thicknesses of approximately two (2) cm, four (4) cm, and six (6) cm of acrylic or BR-12; or

(B) have kVp/thickness density control correction charts.

(s) The coefficient of variation for exposure timer reproducibility shall be no greater than five-hundredths (0.05). Compliance shall be based on at least four (4) consecutive measurements.

(t) The coefficient of variation for exposure shall be no greater than five-hundredths (0.05) when all technique factors are held constant. Determination of compliance shall be based on at least four (4) consecutive measurements.

(u) When mammographic x-ray equipment allows a choice of tube current settings and is operated on a power supply specified by the manufacturer in accordance with applicable federal standards, for any tube potential (kVp) within forty percent (40%) to one hundred percent (100%) of the maximum kVp rating, the absolute value of the difference between the ratio of average exposure in mR to the indicated mAs obtained at any two (2) consecutive tube current settings shall not differ by more than ten-hundredths (0.10) of the absolute value of their sum. A minimum of four (4) measurements per tube current setting are required to determine each average exposure. This requirement is expressed mathematically as:

$$|X_1 - X_2| \leq 0.10 |X_1 + X_2|$$

Where: X_1 and X_2 = The ratios of average exposure to mAs obtained at each of two (2) consecutive tube current settings

(v) For a cranio-caudal view of a four and five-tenths (4.5) cm compressed breast with fifty percent (50%) glandular tissue, the average glandular dose shall not exceed the following:

(1) For a film/screen without grid, one-tenth (0.1) centigray (0.1 rad) per projection.

(2) For a film/screen with grid, three-tenths (0.3) centigray (0.3 rad) per projection.

(3) For xeroradiography, four-tenths (0.4) centigray (0.4 rad) per projection.

(w) There shall be a quality assurance program specific to mammography, covering all components of the x-ray equipment, from the x-ray generator to the image developer, to ensure consistently high quality images with minimum patient exposure. The quality assurance program shall be reviewed at least annually. Establishment and conduct of the quality assurance program shall be the responsibility of the registrant under the direction of a physician and a diagnostic imaging physicist approved by the department. The diagnostic imaging physicist must do the following:

(1) Conduct, or train others to conduct, equipment performance monitoring.

(2) Analyze the monitoring results to determine if there are any problems requiring correction.

(3) Serve as the liaison between the facility and service engineer.

(x) All quality assurance records shall be maintained for at least three (3) years and shall be readily available for inspection by the commissioner.

(y) The registrant shall assure that monitoring is conducted at least once each twelve (12) months at each mammographic x-ray facility as part of a quality assurance program. The monitoring shall be conducted by a diagnostic imaging physicist approved by the department in accordance with Table V and the following:

TABLE V

Parameter	Frequency	Individual Responsible
Darkroom cleanliness	daily	mammographer
Processor performance	daily	mammographer
Screen cleanliness	weekly	mammographer
View boxes and viewing conditions	weekly	mammographer
Image quality (phantom images)	monthly	mammographer
Repeat analysis	quarterly	mammographer
Analysis of fixer retention in film	quarterly	mammographer
Darkroom fog	semiannually	mammographer

Screen-film contact	semiannually	mammographer
Compression	semiannually	mammographer
AEC density control function	annually	diagnostic imaging physicist
Star pattern focal spot size test	annually	diagnostic imaging physicist
Uniformity of screen speed	annually	diagnostic imaging physicist
Assembly physical evaluation	annually	diagnostic imaging physicist

(1) Processor performance shall be monitored daily before the first patient examination.

(2) Image quality shall be evaluated utilizing the RMI Model 156 ACR mammography accreditation phantom (or other image quality phantom approved in advance by the commissioner) each time mammographic x-ray equipment is moved, altered in any major way (such as replacement of parts), and at least monthly between movements or alterations. Image quality shall be evaluated by obtaining a test image at the settings normally used for a four and five-tenths (4.5) cm compressed breast with fifty percent (50%) glandular tissue. A file of such images shall be maintained for review by the physician and the diagnostic imaging physicist for comparison with earlier images. Image quality of the RMI Model 156 phantom shall comply with the following:

(A) Fibrils of seventy-five hundredths (0.75) mm, eighty-nine hundredths (0.89) mm, one and twelve-hundredths (1.12) mm, and one and fifty-six hundredths (1.56) mm shall be visualized.

(B) Masses of seventy-five hundredths (0.75) mm, one (1) mm, and two (2) mm shall be visualized.

(C) Speck groups of thirty-two hundredths (0.32) mm, forty-hundredths (0.40) mm, and fifty-hundredths (0.50) mm shall be fully visualized.

If the results fall outside the acceptable range, the test must be repeated. If the results continue to be unacceptable, the cause of the problem must be identified and corrected before further examinations are conducted.

(Indiana State Department of Health; 410 IAC 5-6.1-127; filed Oct 29, 1993, 5:00 p.m.: 17 IR 389; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-6.1-128 Mammography inspection for calendar year 1993

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 128. Notwithstanding section 122(a) of this rule, all x-ray facilities providing mammographic x-ray services shall be inspected in accordance with this rule, on or after the effective date of this rule and before January 1, 1994. However, any x-ray facility providing mammographic x-ray services, which was inspected on or after January 1, 1993, and before the effective date of this rule by a person qualified in accordance with section 118(h) of this rule, shall be considered in compliance with this section. *(Indiana State Department of Health; 410 IAC 5-6.1-128; filed Oct 29, 1993, 5:00 p.m.: 17 IR 392; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 7. Sealed Radioactive Sources in the Healing Arts

410 IAC 5-7-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. The provisions of 410 IAC 5-7 apply to all licensees or registrants who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2, PT G, Sec G.1; filed May 26, 1978, 3:30 pm: 1 IR 221; filed Feb 29, 1984, 10:10 am: 7 IR 966; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-7-1.1 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1.1. As used in 410 IAC 5-7, the following definitions apply:

"Brachytherapy" means a method of radiation therapy in which an encapsulated source or group of sources is utilized to deliver beta or gamma radiation at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body. *(Indiana State Department of Health; 410 IAC 5-7-1.1; filed Feb 29, 1984, 10:10 am: 7 IR 966; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-7-2 Interstitial, intracavitary, and superficial applications

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) Accountability, Storage and Transit.

(1) Except as otherwise specifically authorized by the board, each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources to their place of storage.

(2) Each licensee or registrant shall conduct a physical inventory at intervals not to exceed 6 months to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the board and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.[1/]

[1/] The U.S. Nuclear Regulatory Commission requires these inventories to be done on a quarterly basis.

(3) Each licensee shall follow the radiation safety and handling instructions approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state and furnished by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.

(4) Each licensee or registrant shall assure that needles or standard medical applicator cells containing cobalt-60 as wire, radium-226, or cesium-137 are not opened while in the licensee's or registrant's possession unless specifically authorized by a license or permit issued by the board.

(b) Testing Sealed Sources for Leakage and Contamination.

(1) All sealed sources, containing more than 100 microcuries of radioactive material with a half-life greater than 30 days, or 10 microcuries of radium-226, shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state and described by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within 6 months prior to the transfer.

(2) Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Any test conducted pursuant to 410 IAC 5-7-2(b)(1) which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of 410 IAC 5-4. A report shall be filed with the board within 5 days of the source withdrawal describing the equipment involved, the test results, and the corrective action taken.

(3) Leak test results shall be recorded in units of microcuries and maintained for inspection by the board.

(c) Radiation Surveys.

(1) The maximum radiation level at a distance of one meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be entered on the patient's chart and other signs as required under 410 IAC 5-7-2(d).

(2) The radiation levels in the patient's room and the surrounding area shall be determined, recorded, and maintained for inspection by the board.

(3) The licensee or registrant shall assure that patients treated with the cobalt-60, cesium-137, iridium-192 or radium-226 implants remain hospitalized until a source count and radiation survey of the patient confirm that all implants have been removed.

(d) Signs and Records.

(1) In addition to the requirements of 410 IAC 5-4-11, the bed, cubicle, or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions. The sign is not required provided the exception in 410 IAC 5-4-12(b) is met.

(2) The following information shall be included in the patient's chart:

(i) The radionuclide administered, number of sources, activity in millicuries and time and date of administration;

(ii) The exposure rate at 1 meter, the time the determination was made, and the name of the individual who made the determination;

(iii) The radiation symbol; and

(iv) The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under 410 IAC 5-4-2.

(Indiana State Department of Health; Rule HRH-2, PT G, Sec G.2; filed May 26, 1978, 3:30 pm: 1 IR 221; filed Feb 29, 1984, 10:10 am: 7 IR 966; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-7-3 Teletherapy

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) Equipment.

(1) The housing shall be so constructed that, at 1 meter from the source, the maximum exposure rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each 1 meter from the source, shall not exceed 2 milliroentgens per hour.

(2) For teletherapy equipment installed after the effective date of 410 IAC 5, the leakage radiation measured at 1 meter from the source when the beam control mechanism is in the "on" position shall not exceed 0.1 percent of the useful beam exposure rate.

(3) Adjustable or removable beam-defining diaphragms shall allow transmission of not more than 5 percent of the useful beam.

(4) The beam control mechanism shall be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.

(5) The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.

(6) When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.

(7) There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is "on" or "off."

(8) The equipment shall be provided with a locking device to prevent unauthorized use.

(9) The control panel shall be provided with a timer that automatically terminates the exposure after a preset time.

(10) Provision shall be made to permit continuous observation of patients during irradiation.

(b) Operation. No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.

(c) Testing for Leakage and Contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in 410 IAC 5-7-2(b). Tests of leakage may be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.

(d) Calibration and Physical Decay Determinations.

(1) Calibration measurements shall be performed by a qualified radiation therapy physicist on each teletherapy unit:

(i) Prior to the first use of the unit for treating humans;

(ii) Prior to treating humans;

(A) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last calibration corrected mathematically for physical decay;

(B) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location; and

(C) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(iii) At intervals not exceeding 1 year.

(2) Calibration measurement shall include determination of:

(i) The exposure rate or dose rate to an accuracy within 3 percent for the range of field sizes and for the range of distances or for the axis distance, used in radiation therapy;

(ii) The congruence between the radiation field and the field indicated by the light beam localizing device;

(iii) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;

(iv) Timer accuracy; and

(v) The accuracy of all distance measuring devices used for treating humans.

(3) The exposure rate or dose rate values shall be corrected mathematically for physical decay at intervals not exceeding 1 month.

(4) Calibration measurements and physical decay corrections shall be performed by a qualified radiation therapy physicist in accordance with 410 IAC 5-7-3(g).

(e) Spot-Check Measurements

(1) Spot-check measurements shall be performed on each teletherapy unit at intervals not exceeding 1 month.

(2) Spot-check measurements shall include determination of:

(i) Timer accuracy;

(ii) The congruence between the radiation field and the field indicated by the light beam localizing device;

(iii) The accuracy of all distance measuring devices used for treating humans;

(iv) The exposure rate, dose rate or a quantity related in a known manner to these rates for one typical set of operating conditions; and

(v) The difference between the measurements made in 410 IAC 5-7-3(e)(2)(iv) and the anticipated output expressed as a percentage of the anticipated output. The anticipated output is the value obtained at the last calibration corrected mathematically for physical decay.

(3) Spot-check measurements shall be performed in accordance with procedures established by a qualified radiation therapy physicist in accordance with 410 IAC 5-7-3(g)(1). A qualified radiation therapy physicist need not actually perform the spot-check measurements. If a qualified radiation therapy physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified radiation therapy physicist within 15 days.

(f) Dosimetry System Calibration

(1) Calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists of Medicine. The dosimetry system shall have been calibrated within the previous 2 years and after any servicing that may have affected system calibration.

(2) Spot-check measurements shall be performed using a dosimetry system that has been calibrated in accordance with 410 IAC 5-7-3(f)(1). Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with 410 IAC 5-7-3(f)(1). This alternative calibration method shall have been performed within the previous 1 year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by the alternative method shall not be used for teletherapy calibration measurements.

(g) Records. The licensee or registrant shall maintain, for inspection by the board, records of the measurements, tests, corrective actions, and instrument calibrations.

(1) Records of teletherapy calibration measurements and calibration of the instruments used to make these measurements shall be preserved for 5 years after completion of the teletherapy calibration.

(2) Records of spot-check measurements and corrective actions and calibration of instruments used to make spot-check measurements shall be preserved for 2 years after completion of the spot-check measurements and corrective actions.

(Indiana State Department of Health; Rule HRH-2, PT G, Sec G.3; filed May 26, 1978, 3:30 pm: 1 IR 222; filed Feb 29, 1984, 10:10 am: 7 IR 968; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 8. Radiation Safety Requirements for Analytical X-Ray Equipment

410 IAC 5-8-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. 410 IAC 5-8 provides special requirements for analytical x-ray equipment. The requirements of 410 IAC 5-8 are in addition to, and not in substitution for, applicable requirements in other parts of 410 IAC 5. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.1; filed May 26, 1978, 3:30 pm: 1 IR 222; filed Feb 29, 1984, 10:10 am: 7 IR 969; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-8-2 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. As used in 410 IAC 5-8, the following definitions apply:

"Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

"Fail-safe characteristics" mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Local components" mean part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data-recording procedures which are related to radiation safety.

"Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.2; filed May 26, 1978, 3:30 pm: 1 IR 223; filed Feb 29, 1984, 10:10 am: 7 IR 970; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-8-3 Equipment requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant (or licensee) may apply to the board for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used; and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Warning Devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of:

(i) X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(ii) Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after June 25, 1978, warning devices shall have fail-safe characteristics.

(c) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent

casual opening.

(d) Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) "CAUTION–HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray source housing; and

(2) "CAUTION RADIATION–THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or

(3) "CAUTION–RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing in accordance with 410 IAC 5-4-11 if the radiation source is a radionuclide.

(e) Shutters. On open-beam configurations installed after June 25, 1978, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) Warning Lights. An easily visible warning light labeled with the words "X-RAY, ON," or words having a similar intent, shall be located:

(1) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

(2) In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.

(3) On equipment installed after June 25, 1978, warning lights shall have fail-safe characteristics.

(g) Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

(1) Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

(2) Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 millirems in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.

(3) If radioactive sources are used, corresponding dose limits shall not exceed 2 mrem per hour.

(h) Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.3; filed May 26, 1978, 3:30 pm: 1 IR 223; filed Feb 29, 1984, 10:10 am: 7 IR 970; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-8-4 Area requirements; surveys; posting

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. (a) Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 410 IAC 5-4-6. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(b) Surveys

(1) Radiation surveys, as required by 410 IAC 5-4-9, of all analytical x-ray systems sufficient to show compliance with paragraph 410 IAC 5-8-4(a) shall be performed:

(i) Upon installation of the equipment, and at least once every 12 months thereafter;

(ii) Following any change in the initial arrangement, number or type of local components in the system;

(iii) Following any maintenance requiring the disassembly or removal of a local component in the system;

(iv) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

(v) Any time a visual inspection of the local components in the system reveals an abnormal condition; and

(vi) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 410 IAC 5-4-2.

(2) Radiation survey measurements shall not be required if a registrant (or licensee) can demonstrate compliance to the satisfaction of the board with 410 IAC 5-8-4 in some other manner.

(c) Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION–X-RAY EQUIPMENT," or words having a similar intent in accordance

with 410 IAC 5-4-11. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.4; filed May 26, 1978, 3:30 pm: 1 IR 224; filed Feb 29, 1984, 10:10 am: 7 IR 971; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-8-5 Operation requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.

(b) Bypassing. No person shall bypass a safety device unless such person has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(c) Repair or Modification of X-Ray Tube Systems. Except as specified in 410 IAC 5-8-5(b), no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(d) Radioactive Source Replacement, Testing or Repair. Radioactive source housings shall be opened for source replacement, leak testing or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. *(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.5; filed May 26, 1978, 3:30 pm: 1 IR 224; filed Feb 29, 1984, 10:10 am: 7 IR 971; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-8-6 Personnel requirements; instruction; monitoring

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Instruction. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment;

(2) Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) Proper operating procedures for the equipment;

(4) Recognition of symptoms of an acute localized exposure; and

(5) Proper procedures for reporting an actual or suspected exposure.

(b) Personnel Monitoring.

(1) Finger or wrist dosimetric devices shall be provided to and shall be used by:

(i) Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

(ii) Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 410 IAC 5-4-2 unless evaluated by a qualified radiation health physicist.

(Indiana State Department of Health; Rule HRH-2, PT H, Sec H.6; filed May 26, 1978, 3:30 pm: 1 IR 224; filed Feb 29, 1984, 10:10 am: 7 IR 972; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 9. Radiation Safety Requirements for Particle Accelerators

410 IAC 5-9-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. (a) 410 IAC 5-9 establishes procedures for the registration and the use of particle accelerators. Particle accelerations utilized only for medical applications are subject to all provisions of 410 IAC 5-9 with the exception of 410 IAC 5-9-8(a), 410 IAC 5-9-10(a), (c), and (d).

(b) In addition to the requirements of 410 IAC 5-9, all registrants (or licensees) are subject to the requirements of 410 IAC 5-1, 410 IAC 5-2, 410 IAC 5-4, and 410 IAC 5-10. Registrants engaged in industrial radiographic operations are subject to the requirements of 410 IAC 5-5 and registrants engaged in the healing arts are subject to the requirements of 410 IAC 5-6 *[410 IAC 5-6 was repealed filed Oct 29, 1993, 5:00 p.m.: 17 IR 392. See 410 IAC 5-6.1.]* and/or 410 IAC 5-7. Registrants engaged in the production of radioactive material are subject to the requirements of 410 IAC 5-3. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.1; filed May 26, 1978, 3:30 pm: 1 IR 224; filed Feb 29, 1984, 10:10 am: 7 IR 972; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-2 Registration required

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. No person shall receive, use, transfer, own or acquire a particle accelerator except as authorized in a registration issued pursuant to 410 IAC 5-2. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.2; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 973; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-2.5 Issuance of registration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2.5. In addition to 410 IAC 5-2, a registration application for use of a particle accelerator will be approved only if the board determines that:

(a) The registrant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with 410 IAC 5-9 and 410 IAC 5-4 and 410 IAC 5-10 in such a manner as to minimize danger to public health and safety or property.

(b) The registrant's proposed or existing equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property.

(c) The issuance of the registration will not be inimical to the health and safety of the public, and the registrant satisfies any applicable special requirement in 410 IAC 5-9-3.

(d) The registrant has appointed a radiation safety officer;

(e) The registrant and/or the applicant's staff has substantial experience in the use of particle accelerators and training sufficient for application to its intended uses.

(f) The registrant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the board.

(g) The registrant has an adequate training program for operators of particle accelerators. *(Indiana State Department of Health; 410 IAC 5-9-2.5; filed Feb 29, 1984, 10:10 am: 7 IR 973; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-3 Human uses; special provisions for registration

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. In addition to the requirements set forth in 410 IAC 5-2, a registration for use of a particle accelerator in the healing arts will be issued only if:

(a) Whenever deemed necessary by the board, the registrant has appointed a medical committee of at least three members to

evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth-dose calculations and protection against radiation;

(b) The individuals designated by the registrant as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

(c) The individual designated by the registrant as the user is a physician. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.3; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 973; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-4 General radiation safety requirements (Repealed)

Sec. 4. *(Repealed by Indiana State Department of Health; filed Feb 29, 1984, 10:10 am: 7 IR 829)*

410 IAC 5-9-5 Limitations on operation; termination

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

(1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) Has received copies of and instructions in 410 IAC 5-9 and, the applicable requirements of 410 IAC 5-4 and 410 IAC 5-10, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

(b) The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.5; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 974; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-6 Installation consultant and survey; shielding

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) A qualified radiation or health physicist shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

(b) Each particle accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to assure compliance with 410 IAC 5-4-2 and 410 IAC 5-4-6. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.6; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 974; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-7 Controls and interlock devices

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

(b) All entrances into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

(c) Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

(d) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

(e) When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped, and lastly at the main control console.

(f) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control without resetting the cutoff switch. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.7; filed May 26, 1978, 3:30 pm: 1 IR 225; filed Feb 29, 1984, 10:10 am: 7 IR 974; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-8 Warning devices

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) Each location designated as a high radiation area, and each entrance to such location shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(b) Except in facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and adjacent radiation areas.

(c) Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with 410 IAC 5-4-11. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.8; filed May 26, 1978, 3:30 pm: 1 IR 226; filed Feb 29, 1984, 10:10 am: 7 IR 975; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-9 Operating and emergency procedures

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

(b) The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

(c) All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Results of such tests shall be maintained at the accelerator for inspection by the board.

(d) Electrical circuit diagrams of the accelerator and the associated safety interlock systems shall be kept current and maintained for inspection by the board and shall be available to the operator at each accelerator facility.

(e) If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) Authorized by the radiation safety committee and/or radiation safety officer;

(2) Recorded in a permanent log and a notice posted at the accelerator control console; and

(3) Terminated as soon as possible.

(f) A copy of the current operating and the emergency procedures shall be maintained at the accelerator control panel. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.9; filed May 26, 1978, 3:30 pm: 1 IR 226; filed Feb 29, 1984, 10:10 am: 7 IR 975; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-10 Monitoring systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. (a) There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been appropriately calibrated for the radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year and after each servicing and repair.

(b) A radiation protection survey shall be performed and documented by, a qualified radiation or health physicist when changes have been made in shielding operation, equipment or occupancy of adjacent areas.

(c) Radiation levels in all high radiation areas shall be continuously monitored. The monitoring system shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

(d) All area monitors shall be calibrated at intervals not to exceed 1 year and after each servicing and repair.

(e) Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present.

(f) Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination.

(g) All area surveys shall be made in accordance with the written procedures established by a qualified radiation or health

physicist or the radiation safety officer.

(h) Records of all radiation protection surveys, calibrations and instrumentation tests shall be maintained at the accelerator facility for inspection by the board. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.10; filed May 26, 1978, 3:30 pm: 1 IR 226; filed Feb 29, 1984, 10:10 am: 7 IR 975; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-9-11 Ventilation systems

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. (a) Ventilation systems shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in 410 IAC 5-4-27, Table I.

(b) A registrant, as required by 410 IAC 5-4-7, shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits specified in 410 IAC 5-4-27, Table II, except as authorized pursuant to 410 IAC 5-4-17 or 410 IAC 5-4-7(b). For purposes of 410 IAC 5-9-11, concentrations may be averaged over a period not greater than one year. Every effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as is reasonably achievable. *(Indiana State Department of Health; Rule HRH-2, PT I, Sec I.11; filed May 26, 1978, 3:30 pm: 1 IR 226; filed Feb 29, 1984, 10:10 am: 7 IR 976; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 10. Notices, Instructions and Reports to Workers; Inspections

410 IAC 5-10-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. 410 IAC 5-10 establishes requirements for notices, instructions and reports by licensees or registrants to individuals engaged in activities under a license or registration and options available to such individuals in connection with board inspections of licensees or registrants to ascertain compliance with the provisions of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and 410 IAC 5, orders and licenses issued thereunder regarding radiological working conditions. 410 IAC 5-10 apply *[sic.]* to all persons who receive, possess, use, own or transfer sources of radiation licensed by or registered with the board pursuant to 410 IAC 5-2 and 410 IAC 5-3. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.1; filed May 26, 1978, 3:30 pm: 1 IR 227; filed Feb 29, 1984, 10:10 am: 7 IR 976; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-10-2 Posting of documents for workers' examination

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. (a) Each licensee or registrant shall post current copies of the following documents:

(1) 410 IAC 5-10 and 410 IAC 5-4;

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

(3) The operating procedures applicable to work under the license or registration;

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 410 IAC 5-1, and any response from the licensee or registrant.

(b) If posting of a document specified in 410 IAC 5-10-2(a)(1), (2), or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Board form X "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

(d) Documents, notices or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(e) Board documents posted pursuant to 410 IAC 5-10-2(a)(4) shall be posted within 5 working days after receipt of the

documents from the board; the licensee's or registrant's response, if any, shall be posted within 5 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.11; filed May 26, 1978, 3:30 pm: 1 IR 227; filed Feb 29, 1984, 10:10 am: 7 IR 976; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-10-3 Instructions to workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. (a) All individuals working in or frequenting any portion of a restricted area:

(1) Shall be kept informed of the storage, transfer, or use of sources of radiation in such portions of the restricted area;

(2) Shall be instructed in the health protection problems associated with exposure to such radiation or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of board rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;

(4) Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to or cause a violation of board rules and licenses or unnecessary exposure to sources of radiation;

(5) Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to sources of radiation; and

(6) Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 410 IAC 5-10-4.

(b) The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.12; filed May 26, 1978, 3:30 pm: 1 IR 227; filed Feb 29, 1984, 10:10 am: 7 IR 977; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-10-4 Reports furnished to individual workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. (a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in 410 IAC 5-10-4. The information reported shall include data and results obtained pursuant to board rules, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to 410 IAC 5-4-21. Each notification and report shall:

(1) Be in writing;

(2) Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number;

(3) Include the individual's exposure information; and

(4) Contain the following statement:

> "This report is furnished to you under the provisions of 410 IAC 5-10. You should preserve this report for further reference."

(b) Each licensee or registrant shall advise each worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to 410 IAC 5-4-21(a) and (c).

(c) Each licensee or registrant shall furnish to each worker a report of the worker's exposure to radiation or radioactive material upon termination of employment. Such report shall be furnished within 30 days from the termination of employment or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar quarter in which the worker's activities involved exposure to sources of radiation licensed by or radiation machines registered with the board and shall include the dates and locations of work under the license or registration in which the worker participated.

(d) When a licensee or registrant is required pursuant to 410 IAC 5-4-24 to report to the board any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the board.

(e) At the request of a worker who is terminating employment in a given calendar quarter with the licensee or registrant in work involving radiation dose or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility in that calendar quarter, each licensee or registrant shall provide to each such worker or to the worker's designee at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.13; filed May 26, 1978, 3:30 pm: 1 IR 227; filed Feb 29, 1984, 10:10 am: 7 IR 977; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-10-5 Inspections by board; representatives of licensee, registrant, or workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. (a) Each licensee or registrant shall afford to the board at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to 410 IAC 5.

(b) During an inspection, board inspectors may consult privately with workers as specified in 410 IAC 5-10-6. The licensee or registrant may accompany board inspectors during other phases of an inspection.

(c) If at the time of inspection an individual has been authorized by the workers to represent them during board inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 410 IAC 5-10-3.

(e) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany board inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, board inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.14; filed May 26, 1978, 3:30 pm: 1 IR 228; filed Feb 29, 1984, 10:10 am: 7 IR 978; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-10-6 Inspectors consulting with workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Board inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of board rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, 410 IAC 5, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 410 IAC 5-10-7(a).

(c) The provisions of 410 IAC 5-10-6(b) shall not be interpreted as authorization to disregard instructions pursuant to 410 IAC 5-10-3. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.15; filed May 26, 1978, 3:30 pm: 1 IR 228; filed Feb*

29, 1984, 10:10 am: 7 IR 978; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-10-7 Request for inspection by workers

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) Any worker or representative of workers who believes that a violation of IC 13-1-2 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, 410 IAC 5 or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the division of industrial hygiene and radiological health. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the division of industrial hygiene and radiological health no later than at the time of inspection.

(b) If upon receipt of such notice the director, division of industrial hygiene and radiological health, determines that the complaint meets the requirements set forth in 410 IAC 5-10-7(a), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

(c) No licensee or registrant or contractor or subcontractor of the licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under 410 IAC 5 or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by 410 IAC 5-10. *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.16; filed May 26, 1978, 3:30 pm: 1 IR 228; filed Feb 29, 1984, 10:10 am: 7 IR 979; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-10-8 Inspection not warranted; informal review; notice

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) If the division of industrial hygiene and radiological health determines, with respect to a complaint under 410 IAC 5-10-7, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the division of industrial hygiene and radiological health shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the board who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the board who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the board may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the board shall affirm, modify or reverse the determination of the division of industrial hygiene and radiological health and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefore.

(b) If the division of industrial hygiene and radiological health determines that an inspection is not warranted because the requirements of 410 IAC 5-10-7(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 410 IAC 5-10-7(a). *(Indiana State Department of Health; Rule HRH-2, PT J, Sec J.17; filed May 26, 1978, 3:30 pm: 1 IR 229; filed Feb 29, 1984, 10:10 am: 7 IR 979; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 10.1. Wireline Service Operations and Subsurface Tracer Studies; Safety Standards

410 IAC 5-10.1-1 Scope of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 1. 410 IAC 5-10.1 establishs *[sic.]* radiation safety requirements for persons using sources of radiation for wireline service operations including mineral logging, radioactive markers, and subsurface tracer studies. The requirements of this section are in addition to, and not in substitution for, the requirements of 410 IAC 5-1, 410 IAC 5-2, 410 IAC 5-3, 410 IAC 5-4, and 410 IAC 5-10. *(Indiana State Department of Health; 410 IAC 5-10.1-1; filed Feb 29, 1984, 10:10 am: 7 IR 980; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-2 Applicability of rule

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. 410 IAC 5 applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral logging, radioactive markers or subsurface tracer studies. *(Indiana State Department of Health; 410 IAC 5-10.1-2; filed Feb 29, 1984, 10:10 am: 7 IR 980; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-3 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. As used in 410 IAC 5-10.1 the following definitions apply:

"Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary jobsites.

"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

"Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

"Logging tool" means a device used subsurface to perform well-logging.

"Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

"Temporary jobsite" means a location to which radioactive materials have been dispatched to perform wireline service operations or subsurface tracer studies.

"Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

"Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well and/or adjacent formations.

"Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

"Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline. *(Indiana State Department of Health; 410 IAC 5-10.1-3; filed Feb 29, 1984, 10:10 am: 7 IR 980; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-4 Prohibition

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor or land owner that:

(a) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

(b) In the event a decision is made to abandon the sealed source downhole, the requirements of 410 IAC 5-10.1-25(c) shall be met. *(Indiana State Department of Health; 410 IAC 5-10.1-4; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-5 Transportation and dose limit requirements

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of 410 IAC 5-3 and the dose limitation requirements of 410 IAC 5-4 are met. *(Indiana State Department of Health; 410 IAC 5-10.1-5; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-6 Storage precautions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Each source of radiation, except accelerators, shall be provided with a storage and/or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

(b) Sources of radiation shall be stored in a manner which will minimize danger from explosion and/or fire. *(Indiana State Department of Health; 410 IAC 5-10.1-6; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-7 Transport precautions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. Transport Precautions. Transport containers shall be physically secured to the transporting vehicle to prevent accidential *[sic.]* loss, tampering or unauthorized removal. *(Indiana State Department of Health; 410 IAC 5-10.1-7; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-8 Survey instruments

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. (a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this part and by 410 IAC 5-4-9. Instrumentation shall be capable of measuring 0.1 milliroentgen per hour through at least 20 milliroentgens per hour.

(b) Each radiation survey instrument shall be calibrated:

(1) At intervals not to exceed 6 months and after each instrument servicing;

(2) At energies and radiation levels appropriate for use; and

(3) So that accuracy within plus or minus 20 percent of the true radiation level can be demonstrated on each scale.

(c) Calibration records shall be maintained for a period of 2 years for inspection by the board. *(Indiana State Department of Health; 410 IAC 5-10.1-8; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-9 Leak testing of sealed sources

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. (a) Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage.

Records of leak test results shall be kept in units of microcuries and maintained for inspection by the board for 6 months after the next required leak test is performed or until transfer or disposal of the sealed source.

(b) Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. The test sample shall be taken from the surface of the source, source holder or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample.

(c) Interval of Testing. Each sealed source of radioactive material shall be tested at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(d) Leaking or Contaminated Sources. If the test reveals the presence of 0.005 microcurie or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired or disposed of in accordance with 410 IAC 5. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the board.

(e) Exemptions. The following sources are exempted from the periodic leak test requirements of 410 IAC 5-10.1-9(a) through (d):

(1) Hydrogen-3 sources;

(2) Sources of radioactive material with a half-life of 30 days or less;

(3) Sealed sources of radioactive material in gaseous form;

(4) Sources of beta- and/or gamma-emitting radioactive material with an activity of 100 microcuries or less; and

(5) Sources of alpha-emitting radioactive material with an activity of 10 microcuries or less.

(Indiana State Department of Health; 410 IAC 5-10.1-9; filed Feb 29, 1984, 10:10 am: 7 IR 981; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)

410 IAC 5-10.1-10 Quarterly inventory

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for 2 years from the date of the inventory for inspection by the board and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory. *(Indiana State Department of Health; 410 IAC 5-10.1-10; filed Feb 29, 1984, 10:10 am: 7 IR 982; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-11 Utilization records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 11. Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the board for 2 years from the date of the recorded event, showing the following information for each source of radiation:

(a) Make, model number, and a serial number or a description of each source of radiation used;

(b) The identity of the well-logging supervisor or field unit to whom assigned;

(c) Locations where used and dates of use; and

(d) In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well. *(Indiana State Department of Health; 410 IAC 5-10.1-11; filed Feb 29, 1984, 10:10 am: 7 IR 982; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-12 Sealed sources used in downhole operations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 12. Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.

(a) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured one year after the effective date of 410 IAC 5 shall be certified by the manufacturer or other testing organization acceptable to the board to meet the following minimum criteria:

(1) Be of doubly encapsulated construction;

(2) Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and

(3) Has been individually pressure tested to at least 24,656 pounds per square inch absolute (170 MN/m^2) without failure.

(b) For sealed sources, except those containing radioactive material in gaseous form, acquired one year after the effective date of 410 IAC 5, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of 410 IAC 5-10.1-12(a), the sealed source shall not be put into use until such determinations and testing have been performed.

(c) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations two years after the effective date of 410 IAC 5 shall be certified by the manufacturer, or other testing organization acceptable to the board, as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N542, "Sealed Radioactive Sources, Classification" in effect on the effective date of 410 IAC 5.

(d) Certification documents shall be maintained for inspection by the board for a period of 2 years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the board authorizes disposition. *(Indiana State Department of Health; 410 IAC 5-10.1-12; filed Feb 29, 1984, 10:10 am: 7 IR 982; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-13 Labels

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 13. (a) Each source, source holder or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER[1/]
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

(b) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER[1/]
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES
(OR NAME OF COMPANY)

[1/] or CAUTION

(Indiana State Department of Health; 410 IAC 5-10.1-13; filed Feb 29, 1984, 10:10 am: 7 IR 982; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)

410 IAC 5-10.1-14 Inspection and maintenance

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 14. (a) Each licensee or registrant shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of 2 years for inspection by the board.

(b) If any inspection conducted pursuant to 410 IAC 5-10.1-14(a) reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

(c) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. *(Indiana State Department*

of Health; 410 IAC 5-10.1-14; filed Feb 29, 1984, 10:10 am: 7 IR 983; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)

410 IAC 5-10.1-15 Training and testing of personnel

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 15. (a) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this part until such individual has:

(1) Received, in a course recognized by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state instruction in the subjects outlined in 410 IAC 5-10.1-26 and demonstrated an understanding thereof;

(2) Read and received instruction in the requirements contained in 410 IAC 5-10.1 and the applicable sections of 410 IAC 5-1, 410 IAC 5-4, and 410 IAC 5-10 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

(3) Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(b) No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(1) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and

(2) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(c) The licensee or registrant shall maintain employee training records for inspection by the board for 2 years following termination of employment. *(Indiana State Department of Health; 410 IAC 5-10.1-15; filed Feb 29, 1984, 10:10 am: 7 IR 983; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-16 Operating and emergency procedures

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 16. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in 410 IAC 5-4;

(b) Methods and occasions for conducting radiation surveys;

(c) Methods and occasions for locking and securing sources of radiation;

(d) Personnel monitoring and the use of personnel monitoring equipment;

(e) Transportation to temporary jobsites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

(f) Minimizing exposure of individuals in the event of an accident;

(g) Procedure for notifying proper personnel in the event of an accident;

(h) Maintenance of records;

(i) Inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

(j) Procedure to be followed in the event a sealed source is lodged downhole; and

(k) Procedures to be used for picking up, receiving, and opening packages containing radioactive material. *(Indiana State Department of Health; 410 IAC 5-10.1-16; filed Feb 29, 1984, 10:10 am: 7 IR 983; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-17 Personnel monitoring

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 17. (a) No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual.

(b) Personnel monitoring records shall be maintained for inspection until the board authorizes disposition. *(Indiana State Department of Health; 410 IAC 5-10.1-17; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-18 Security during operations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 18. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized and/or unnecessary entry into a restricted area, as defined in 410 IAC 5-1. *(Indiana State Department of Health; 410 IAC 5-10.1-18; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-19 Handling tools

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 19. The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources. *(Indiana State Department of Health; 410 IAC 5-10.1-19; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-20 Subsurface tracer studies

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 20. (a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

(b) No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the board. *(Indiana State Department of Health; 410 IAC 5-10.1-20; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-21 Particle accelerators

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 21. No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of 410 IAC 5-4-2 and 410 IAC 5-4-6 as applicable, are met. *(Indiana State Department of Health; 410 IAC 5-10.1-21; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-22 Surveys; records

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 22. (a) Radiation surveys and/or calculations shall be made and recorded for each area where radioactive materials are stored.

(b) Radiation surveys and/or calculations shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and/or calculations shall include each source of radiation

or combination of sources to be transported in the vehicle.

(c) After removal of the sealed source from the logging tool and before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(d) Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.

(e) Records required pursuant to 410 IAC 5-10.1-22(a) through (d) shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the board for 2 years after completion of the survey. *(Indiana State Department of Health; 410 IAC 5-10.1-22; filed Feb 29, 1984, 10:10 am: 7 IR 984; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-23 Recordkeeping at field stations

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 23. Each licensee or registrant shall maintain, for inspection by the board, the following documents and records for the specific devices and sources used at the field station:

(a) Appropriate license, certificate of registration or equivalent document;

(b) Operating and emergency procedures;

(c) Applicable regulations;

(d) Records of the latest survey instrument calibrations pursuant to 410 IAC 5-10.1-22;

(e) Records of the latest leak test results pursuant to 410 IAC 5-10.1-9;

(f) Quarterly inventories required pursuant to 410 IAC 5-10.1-10;

(g) Utilization records required pursuant to 410 IAC 5-10.1-11;

(h) Records of inspection and maintenance required pursuant to 410 IAC 5-10.1-14; and

(i) Survey records required pursuant to 410 IAC 5-10.1-22. *(Indiana State Department of Health; 410 IAC 5-10.1-23; filed Feb 29, 1984, 10:10 am: 7 IR 985; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-24 Recordkeeping at temporary jobsites

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 24. Each licensee or registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the board:

(a) Operating and emergency procedures;

(b) Survey records required pursuant to 410 IAC 5-10.1-22 for the period of operation at the site;

(c) Evidence of current calibration for the radiation survey instruments in use at the site; and

(d) When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration or equivalent document(s). *(Indiana State Department of Health; 410 IAC 5-10.1-24; filed Feb 29, 1984, 10:10 am: 7 IR 985; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-25 Notification of incidents, abandonment, and lost sources

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 25. (a) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of 410 IAC 5-4.

(b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

(1) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

(2) Notify the board immediately by telephone if radioactive contamination is detected at the surface or if the source appears

to be damaged.

(c) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

(1) Advise the well-operator of 410 IAC 5 and an appropriate method of abandonment, which shall include:

(i) The immobilization and sealing in place of the radioactive source with a cement plug;

(ii) The setting of a whipstock or other deflection device; and

(iii) The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by 410 IAC 5-10.1-25(d).

(2) Notify the board by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and

(3) File a written report with the board within 30 days of the abandonment, setting forth the following information:

(i) Date of occurrence and a brief description of attempts to recover the source;

(ii) A description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form;

(iii) Surface location and identification of well;

(iv) Results of efforts to immobilize and set the source in place;

(v) Depth of the radioactive source;

(vi) Depth of the top of the cement plug;

(vii) Depth of the well; and

(viii) Information contained on the permanent identification plaque.

(d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque[2/] for posting the well or well-bore. This plaque shall:

(1) Be constructed of long-lasting material, such as stainless steel or monel; and

(2) Contain the following information engraved on its face:

(i) The word "CAUTION";

(ii) The radiation symbol without the conventional color requirement;

(iii) The date of abandonment;

(iv) The name of the well-operator or well owner;

(v) The well name and well identification number(s) or other designation;

(vi) The sealed source(s) by radionuclide and quantity of activity;

(vii) The source depth and the depth to the top of the plug; and

(viii) An appropriate warning, depending on the specific circumstances of each abandonment.[3/]

[2/] An example of a suggested plaque is shown in 410 IAC 5-10.1-27.

[3/] Appropriate warnings may include: (a) "Do not drill below plug back depth"; (b) "Do not enlarge casing"; or (c) "Do not re-enter the hole", followed by the words, "before contacting the Indiana state board of health."

(e) The licensee shall immediately notify the board by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences. *(Indiana State Department of Health; 410 IAC 5-10.1-25; filed Feb 29, 1984, 10:10 am: 7 IR 985; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-26 Training courses for logging supervisors; scope

Authority: IC 16-41-35-26; IC 16-41-35-29

Affected: IC 16-41-35

Sec. 26.

SUBJECTS TO BE INCLUDED
IN TRAINING COURSES
FOR LOGGING SUPERVISORS

I. Fundamentals of Radiation Safety

A. Characteristics of radiation

B. Units of radiation dose and quantity of radioactivity

C. Significance of radiation dose

1. Radiation protection standards
2. Biological effects of radiation dose

D. Levels of radiation from sources of radiation
E. Methods of minimizing radiation dose
1. Working time
2. Working distances
3. Shielding

II. Radiation Detection Instrumentation to be Used
A. Use of radiation survey instruments
1. Operation
2. Calibration
3. Limitations

B. Survey techniques
C. Use of personnel monitoring equipment
III. Equipment to be Used
A. Handling equipment
B. Sources of radiation
C. Storage and control of equipment
D. Operation and control of equipment
IV. The Requirements of Pertinent Federal and State Rules
V. The Licensee's or Registrant's Written Operating and Emergency Procedures
VI. The Licensee's or Registrant's Record Keeping Procedures *(Indiana State Department of Health; 410 IAC 5-10.1-26; filed Feb 29, 1984, 10:10 am: 7 IR 986; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

410 IAC 5-10.1-27 Plaque on wells containing abandoned sealed sources

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 27. Example of Plaque for Identifying Wells Containing Sealed Sources Containing Radioactive Material Abandoned Downhole

[COMPANY NAME]
[WELL IDENTIFICATION]

CAUTION

ONE 2 CURIE CS-137 RADIOACTIVE SOURCE ABANDONED
3-3-75 AT 8400 FT. PLUG BACK DEPTH 8200 FT.
DO NOT RE-ENTER THIS WELL BEFORE CONTACTING
INDIANA STATE BOARD OF HEALTH

The size of the plaque should be convenient for use on active or inactive wells; e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information; e.g., 1/2-inch and 1/4-inch letter size, respectively. *(Indiana State Department of Health; 410 IAC 5-10.1-27; filed Feb 29, 1984, 10:10 am: 7 IR 986; readopted filed Nov 15, 2001, 1:30 p.m.: 25 IR 1270)*

Rule 11. Diagnostic Radiation Machine Operators; Certification

410 IAC 5-11-1 Definitions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35; IC 25-10-1; IC 25-13-1; IC 25-14-1; IC 25-22.5; IC 25-29-1

Sec. 1. As used in 410 IAC 5-11:

"Board" means the Indiana state board of health.

"Board-approved" means that a matter has been presented to the board for consideration and has received the board's approval.

"CAHEA" means Committee on Allied Health Education and Accreditation.

"Certificate" means a license and the term is used synonymously with license pursuant to IC 13-1-2-11(c) *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

"Certification" means an authorization to operate a radiation machine in some capacity. This term is used synonymously with licensure pursuant to IC 13-1-2-11 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

"Committee" means the radiologic technology certification committee.

"Dental hygienist" means a person licensed under IC 25-13-1.

"General certification" means an authorization to perform all diagnostic radiographic procedures.

"JRCERT" means Joint Review Committee on Education in Radiologic Technology.

"Limited certification" means an authorization to perform diagnostic radiographic procedures limited to specific areas of the human body and done with direct on-site practitioner supervision.

"On-the-job training program (OJT)" means a board-approved course of study which is coordinated by the sponsoring practitioner of the healing arts.

"Operator" means that person, under the direction of a healing arts practitioner, who physically positions the patient, the X-ray film, sets the exposure factors and actuates or directs the actuation of the X-ray tube for diagnostic purposes.

"Practitioner of the healing arts" means a person licensed to practice medicine or osteopathic medicine, pursuant to IC 25-22.5; to practice dentistry, pursuant to IC 25-14-1; to practice chiropractic medicine, pursuant to IC 25-10-1; and to practice podiatric medicine, pursuant to IC 25-29-1.

"Radiation machine" means a diagnostic X-ray machine.

"Radiologic technologist" means an individual, other than a licensed practitioner, who (a) performs, may be called upon to perform, or who is certified to perform a comprehensive scope of diagnostic radiologic procedures employing equipment which emits ionizing radiation and (b) is delegated or exercised *[sic.]* responsibility for the operation of radiation generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs or other procedures which contribute to any significant extent to the site or dosage of ionizing radiation to which a patient is exposed. Radiologic technologists are distinguished from personnel whose use of diagnostic procedures is limited to a few specific body sites and/or standard procedures, from those personnel in other clinical specialties who may occasionally be called upon to assist in diagnostic radiology, and from those technicians or assistants whose activities do not, to any significant degree, determine the site or dosage of radiation to which a patient is exposed.

"Radiologic technology" means the application of X-rays to human beings for diagnostic or therapeutic purposes.

"Student" means a person attending a board-approved course in radiologic technology or a person who has satisfactorily completed a board-approved course in radiologic technology and has not yet received his results from the first certification test after his completing of the course.

"Temporary status" means an authorization to operate a radiation machine on human beings for a period of time not to exceed the notification of the results of the third consecutive test after completion of a board-approved training course. *(Indiana State Department of Health; 410 IAC 5-11-1; filed Jun 16, 1981, 2:50 pm: 4 IR 1448; filed Feb 20, 1984, 11:31 am: 7 IR 987; filed Aug 12, 1987, 4:30 pm: 11 IR 79; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-11-2 Display of certificate

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 2. Any operator must prominently display a current certificate at his place of employment authorizing all utilized procedures. *(Indiana State Department of Health; 410 IAC 5-11-2; filed Jun 16, 1981, 2:50 pm: 4 IR 1448; filed Feb 20, 1984, 11:31 am: 7 IR 988; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-11-3 Exemptions

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 3. Exception to 410 IAC 5-11:

(a) practitioners of the healing arts are exempt;

(b) dental hygienists licensed with the state of Indiana are exempt;

(c) students in board-approved programs of general radiologic technology under the direction of a certified radiologic technologist are exempt;

(d) students in board-approved programs of limited radiologic technology under the direction of a healing arts practitioner are exempt;

(e) students in healing arts practitioner schools where the student is under the direction of a practitioner of the healing arts are exempt;

(f) students participating in board-approved OJT programs under direct on-site supervision of a practitioner of the healing arts are exempt;

(g) operators of radiation equipment on other than living human beings are exempt;

(h) radiologic technologists who were certificated by the American Registry of Radiologic Technologists (ARRT) or any other similar professional organization recognized and approved by the board are exempt from the requirements found in 410 IAC 5-11-4 or 410 IAC 5-11-5 and will be granted a certificate upon proof of certification by the professional organization and the satisfactory completion of an application form approved by the board;

(i) an individual who provides written proof to the board that he/she was actively employed as a radiation machine operator for at least forty-eight (48) months between January 1, 1978, and December 31, 1984, will be granted a certificate upon the satisfactory completion of an application form approved by the board and will be exempt from further requirements found in 410 IAC 5-11-4(a) and (b) and 410 IAC 5-11-5(b), (c) and (d);

(j) an individual from another state seeking reciprocity with Indiana in the area of limited dental radiography will be granted a limited certificate upon the satisfactory completion of an application form approved by the board and providing proof of passing the Dental Assisting National Board (DANB) exam for general chairside assisting;

(k) the board may grant such exemptions or exceptions from the requirements of 410 IAC 5-11 as it determines are necessary and will not result in an undue hazard to public health and safety.

(Indiana State Department of Health; 410 IAC 5-11-3; filed Jun 16, 1981, 2:50 pm: 4 IR 1448; filed Feb 20, 1984, 11:31 am: 7 IR 989; filed Aug 12, 1987, 4:30 pm: 11 IR 80; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-11-4 General certification

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 4. The requirements for the general certification of diagnostic X-ray machine operators for use on human beings are as follows:

(a) An applicant for general certification as an operator of a radiation machine who is not elsewhere exempted in 410 IAC 5-11 shall:

(1) have graduated from a CAHEA/JRCERT approved program;

(2) have satisfactorily completed the board approved American registry of radiologic technologists examination and be certified by the American registry of radiologic technologist in diagnostic radiology designated as ARRT(R);

(3) have satisfactorily completed an application form approved by the board.

(b) An applicant may challenge the board-approved examination three (3) consecutive times with a valid temporary status letter. After the third unsuccessful attempt at the board-approved examination, the temporary status is no longer valid and the applicant must refrain from taking radiographs in Indiana until he/she is successful in passing the examination.

(c) All certificates are valid for two (2) years.

(Indiana State Department of Health; 410 IAC 5-11-4; filed Jun 16, 1981, 2:50 pm: 4 IR 1449; filed Feb 20, 1984, 11:31 am: 7 IR 989; filed Aug 12, 1987, 4:30 pm: 11 IR 80; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5-11-5 Limited certification

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 5. Limited certification may be granted to operators in five (5) areas:

(a) Areas of practice are limited as follows:

(1) chest X-ray procedures are limited to radiography of the chest only;

(2) chiropractic X-ray procedures are limited to spine and extremities;

(3) dental X-ray procedures are limited to dental radiography;

(4) limited general X-ray procedures are limited to radiography of the human body without the use of contrast media;

(5) podiatry X-ray procedures are limited to radiography of the foot, ankle, and lower leg below the knee.

(b) Applicants for limited certification as operators of diagnostic X-ray equipment not elsewhere exempted in 410 IAC 5-11 must comply with the following requirements:

(1) dental radiography applicants shall have satisfactorily completed either a formal educational program from a school whose radiographic program is approved by the commission on dental accreditation or a formal educational program approved by the board or a board approved OJT program;

(2) limited general, chest, chiropractic and podiatric radiology applicants shall have first satisfactorily completed a board approved OJT program.

(c) Applicant shall have satisfactorily completed an examination approved by the board after fulfilling requirements of subdivision (b)(1) or (b)(2) of this section;

(1) the board-approved examinations for limited certification follows:

(A) In the area of dental radiography either the Dental Assisting National Board (DANB) examination in general chairside assisting or the DANB Dental Radiation Health and Safety examination.

(B) In the area of chiropractic radiography either the American Chiropractic Registry of Radiologic Technologists (ACRRT) examination or the Indiana state board of health board approved examination.

(C) The Indiana state board of health examination is the board-approved exam for the following limited areas; chest radiography, limited general radiography and podiatric radiography.

(2) applicant may challenge the board-approved examination three (3) consecutive times with a valid temporary status letter;

(3) after the third unsuccessful attempt at the board-approved examination, the temporary status is no longer valid and the applicant must refrain from taking radiographs in Indiana until he/she has had further board-approved education and passed the board-approved examination.

(d) Applicant must have satisfactorily completed an application form approved by the board indicating the appropriate limited category.

(e) Limited certificates are valid for two (2) years.

(f) Operators who have been granted a limited certification shall at all times have on-site practitioner supervision. The practitioner shall be responsible for assessment of the diagnostic quality and pathology of the radiograph exposed by the operator with limited certification. *(Indiana State Department of Health; 410 IAC 5-11-5; filed Jun 16, 1981, 2:50 pm: 4 IR 1449; filed Feb 20, 1984, 11:31 am: 7 IR 990; filed Aug 12, 1987, 4:30 pm: 11 IR 81; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-11-6 Renewal of certification

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 6. (a) Thirty (30) days prior to the expiration of a person's certification, a renewal application for certification for a term of two (2) years shall be submitted to the board on a form approved by the board.

(b) An individual whose certificate has been expired for longer than four (4) months will be required to resubmit all board required documentation to receive certification.

(c) An individual with an expired certificate shall not take radiographs in Indiana until recertified. *(Indiana State Department of Health; 410 IAC 5-11-6; filed Jun 16, 1981, 2:50 pm: 4 IR 1449; filed Feb 20, 1984, 11:31 am: 7 IR 990; filed Aug 12, 1987, 4:30 pm: 11 IR 81; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-11-7 Denial, revocation and suspension of certificates

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 7. (a) The certificate of any operator may be denied, revoked, or suspended by the board if after due hearing the board determines that the operator:

(1) has engaged in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public;

(2) becomes a drug abuser as defined in IC 16-13-6.1-2 *[IC 16-13 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*;

(3) becomes an alcohol abuser as defined in IC 16-13-6.1-2 *[IC 16-13 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*;

(4) develops such physical or mental disability or other condition that continued practice or performance of his duties may be dangerous to patients or the public;

(5) fails to comply with any rule of the board relating to the certification of operators or sources of radiation; or

(6) has operated an X-ray machine that does not meet all applicable requirements set forth in 410 IAC 5-6 *[410 IAC 5-6 was repealed filed Oct 29, 1993, 5:00 p.m.: 17 IR 392. See 410 IAC 5-6.1.]* (Radiological Health X-rays in the Healing Arts) or any rule of the board.

(b) When the certificate of any person has been revoked or suspended as herein provided, the board may, after the expiration of two (2) years, entertain an application for restoration of such certificate. *(Indiana State Department of Health; 410 IAC 5-11-7; filed Jun 16, 1981, 2:50 pm: 4 IR 1450; filed Feb 20, 1984, 11:31 am: 7 IR 990; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-11-8 Charges against operators; hearings

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 8. The board shall furnish the certificate holder with written notice setting out the substance of each offense charged with sufficient detail to reasonably apprise such person of the nature, time, and place thereof. The certificate holder shall have the right to be present in person or be represented by counsel, to present evidence, and to be heard in opposition to the charges which may be instituted. The hearing may be conducted by a hearing officer appointed by the board and shall be in accordance with IC 4-22-1 *[Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.]. (Indiana State Department of Health; 410 IAC 5-11-8; filed Jun 16, 1981, 2:50 pm: 4 IR 1450; filed Feb 20, 1984, 11:31 am: 7 IR 991; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-11-9 Radiologic technology certification committee; duties

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 9. To assist the board in administering 410 IAC 5-11, a radiologic technology certification committee described below shall be appointed by the board and should consist of two (2) licensed physicians who limit their practice to radiology, one (1) family practitioner, one (1) chiropractor, one (1) podiatrist, one (1) dentist, and three (3) radiologic technologists.

(a) The committee may evaluate the training and experience of applicants and make recommendations to the board.

(b) The committee may recommend amendments of 410 IAC 5-11 to the board.

(c) The committee will assist the board in any directed capacity.

(d) The committee may develop application forms for approval by the board. *(Indiana State Department of Health; 410 IAC 5-11-9; filed Jun 16, 1981, 2:50 pm: 4 IR 1450; filed Feb 20, 1984, 11:31 am: 7 IR 991; filed Aug 12, 1987, 4:30 pm: 11 IR 82; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5-11-10 Use of testing services and review committees

Authority: IC 16-41-35-26; IC 16-41-35-29
Affected: IC 16-41-35

Sec. 10. The board and the radiologic technology certification committee may utilize nationally accepted testing services and review committees to assist in it in the administration of 410 IAC 5-11. *(Indiana State Department of Health; 410 IAC 5-11-10; filed Jun 16, 1981, 2:50 pm: 4 IR 1450; filed Feb 20, 1984, 11:31 am: 7 IR 991; filed Aug 12, 1987, 4:30 pm: 11 IR 82; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 5.1. RADON

Rule 1. Radon

410 IAC 5.1-1-1 "Building" defined
Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 1. As used in this rule, "building" means a roofed and walled structure built or used for human habitation. *(Indiana State Department of Health; 410 IAC 5.1-1-1; filed Oct 27, 1993, 9:00 a.m.: 17 IR 349; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-2 "Commissioner" defined
Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 2. As used in this rule, "commissioner" means the state health commissioner or his or her authorized representative. *(Indiana State Department of Health; 410 IAC 5.1-1-2; filed Oct 27, 1993, 9:00 a.m.: 17 IR 349; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-3 "Contact hour" defined
Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 3. As used in this rule, "contact hour" means an instructional session about radon-222, radon-222 testing, radon-222 mitigation, or the health effects of exposure to radon-222 of at least sixty (60) minutes duration. *(Indiana State Department of Health; 410 IAC 5.1-1-3; filed Oct 27, 1993, 9:00 a.m.: 17 IR 349; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-4 "Department" defined
Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 4. As used in this rule, "department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 5.1-1-4; filed Oct 27, 1993, 9:00 a.m.: 17 IR 349; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-5 "Diagnostic testing" defined
Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 5. As used in this rule, "diagnostic testing" means a test conducted to determine the presence or absence of radon-222 or to determine the primary source or sources of radon-222 leakage into a living area. This term shall not be construed as authorization for a person to perform testing to determine radon-222 concentrations in a living area for the purposes of determining the need for radon-222 mitigation without complying with this rule. *(Indiana State Department of Health; 410 IAC 5.1-1-5; filed Oct 27, 1993, 9:00 a.m.: 17 IR 349; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-6 "EPA" defined
Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 6. As used in this rule, "EPA" means the United States Environmental Protection Agency. *(Indiana State Department*

of Health; 410 IAC 5.1-1-6; filed Oct 27, 1993, 9:00 a.m.: 17 IR 349; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5.1-1-7 "Instant readout device" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 7. As used in this rule, "instant readout device" means any hand-held instrument that immediately quantifies radon-222 concentrations or provides data necessary to perform calculations that will quantify radon-222 concentrations. *(Indiana State Department of Health; 410 IAC 5.1-1-7; filed Oct 27, 1993, 9:00 a.m.: 17 IR 349; errata filed Nov 9, 1993, 9:00 a.m.: 17 IR 410; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-8 "Interference with department agent" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 8. As used in this rule, "interference with department agent" means, but is not limited to, physical obstruction, attack, or threatened attack on a representative or agent of the department while that representative or agent is conducting inspection, certification, or enforcement activities pursuant to IC 16-41-38 or this rule. *(Indiana State Department of Health; 410 IAC 5.1-1-8; filed Oct 27, 1993, 9:00 a.m.: 17 IR 349; errata filed Nov 9, 1993, 9:00 a.m.: 17 IR 410; errata filed Jan 28, 2000, 7:48 a.m.: 23 IR 1401; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-9 "Laboratory" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 9. As used in this rule, "laboratory" means a place equipped for experimental study in a science. *(Indiana State Department of Health; 410 IAC 5.1-1-9; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-10 "Living area" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 10. As used in this rule, "living area" means the lowest area in a building that could be adapted for human habitation. For example, a basement would be a living area if it could be converted to a den, playroom, or bedroom without major structural changes. *(Indiana State Department of Health; 410 IAC 5.1-1-10; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-11 "Mitigate" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 11. As used in this rule, "mitigate" means to repair or alter a building or building design for the purpose in whole or in part of reducing the concentration of radon-222 in the indoor atmosphere. *(Indiana State Department of Health; 410 IAC 5.1-1-11; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-12 "Passive monitor" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 12. As used in this rule, "passive monitor" means those types of radon-222 detectors that do not require external power

or batteries to operate. Charcoal canisters and alpha track detectors are the principle *[sic.]* types of passive monitors. *(Indiana State Department of Health; 410 IAC 5.1-1-12; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-13 "Person" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 13. As used in this rule, "person" means an individual, partnership, copartnership, corporation, firm, company, association, society, holding company, trustee, school corporation, school city, school town, school district, any unit of government, or any other legal entity, its or their successors or assigns, or agents of the aforesaid. *(Indiana State Department of Health; 410 IAC 5.1-1-13; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-14 "Picocuries per liter" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 14. As used in this rule, "picocuries per liter" means two and twenty-two hundredths (2.22) radioactive disintegrations per minute per liter of air. *(Indiana State Department of Health; 410 IAC 5.1-1-14; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-15 "Primary radon tester" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 15. As used in this rule, "primary radon tester" means an individual who measures radon-222 concentrations utilizing detection instruments other than passive monitors. A primary radon tester may also place passive monitors in buildings for radon-222 testing but may not analyze passive monitors. *(Indiana State Department of Health; 410 IAC 5.1-1-15; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-16 "Quality assurance program" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 16. As used in this rule, "quality assurance program" means a program which includes procedures that assure data are scientifically valid and of known precision and accuracy and a system for recording and monitoring these procedures. *(Indiana State Department of Health; 410 IAC 5.1-1-16; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-17 "Radon-222" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 17. As used in this rule, "radon-222" means the radioactive noble gas radon-222 and related decay products produced by the disintegration of radon-222. *(Indiana State Department of Health; 410 IAC 5.1-1-17; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-18 "Radon laboratory tester" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 18. As used in this rule, "radon laboratory tester" means an individual who manufactures passive monitors or analyzes passive monitors for radon-222 after they have been exposed to the atmosphere. A radon laboratory tester may also place passive monitors in buildings for radon-222 testing and measure radon-222 concentrations utilizing detection instruments other than passive monitors. *(Indiana State Department of Health; 410 IAC 5.1-1-18; filed Oct 27, 1993, 9:00 a.m.: 17 IR 350; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-19 "Research" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 19. As used in this rule, "research" means scientific investigation by testing or mitigating, or both, for radon-222. *(Indiana State Department of Health; 410 IAC 5.1-1-19; filed Oct 27, 1993, 9:00 a.m.: 17 IR 351; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-20 "Secondary radon tester" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 20. As used in this rule, "secondary radon tester" means an individual who places passive monitors in, and/or retrieves passive monitors from, buildings for radon-222 testing. *(Indiana State Department of Health; 410 IAC 5.1-1-20; filed Oct 27, 1993, 9:00 a.m.: 17 IR 351; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-21 "Test" defined

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 21. As used in this rule, "test" means the act of examining a building for the presence of radon-222 which may include analysis of the detector utilized. *(Indiana State Department of Health; 410 IAC 5.1-1-21; filed Oct 27, 1993, 9:00 a.m.: 17 IR 351; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-22 Certificate required; exclusion

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-35; IC 16-41-38

Sec. 22. (a) No person may test, analyze, or mitigate for radon-222 in a building unless they are, or have in their employ, an individual certified to perform such services in accordance with this rule. However, a person who is testing or mitigating for radon-222 is exempt from the provisions of this rule if the person is:

(1) performing the testing or mitigation on a building or area of land which the person owns; or

(2) conducting research on radon-222 testing or mitigation with consent of the owner or occupant, and the owner or occupant is not charged for the testing or mitigation.

(b) Individuals certified to perform radon-222 measurement or mitigation services under this rule shall conduct such activities in accordance with IC 16-41-35, IC 16-41-38, this rule, and the application for certification submitted by the individual.

(c) Certification shall expire on December 31 of the year following the year of issuance. *(Indiana State Department of Health; 410 IAC 5.1-1-22; filed Oct 27, 1993, 9:00 a.m.: 17 IR 351; errata filed Nov 9, 1993, 9:00 a.m.: 17 IR 410; errata filed Jan 28, 2000, 7:48 a.m.: 23 IR 1401; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-23 Certification of secondary radon testers

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38-3

Sec. 23. (a) A secondary radon tester must be certified in order to place and/or retrieve, or represent or advertise that he or

she can place and/or retrieve, passive monitors in a building for radon-222 testing.

(b) The requirements for all individuals seeking certification to test as a secondary radon tester are as follows:

(1) Submission of a sworn affidavit that the individual has read and agrees to adhere to EPA's "Indoor Radon and Radon Decay Product Measurement Device Protocols" (July 1992, EPA-402-R-92-004).

(2) Proof of successful completion, and current listing on, the EPA National Radon Measurement Proficiency Program, or an equivalent measurement proficiency program approved by the commissioner.

(3) Submission of a complete and accurate application form prescribed by the commissioner along with a fee of one hundred dollars ($100). An application will not be considered complete unless the required fee has been submitted.

(Indiana State Department of Health; 410 IAC 5.1-1-23; filed Oct 27, 1993, 9:00 a.m.: 17 IR 351; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2280; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5.1-1-24 Certification of primary radon testers

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 24. (a) A primary radon tester must be certified in order to test for radon-222, or represent or advertise that he or she can test for radon-222, in a building.

(b) The requirements for all individuals seeking certification to test as a primary radon tester are as follows:

(1) Submission of a sworn affidavit that the individual has read and agrees to adhere to EPA's "Indoor Radon and Radon Decay Product Measurement Device Protocols" (July 1992, EPA-402-R-92-004).

(2) Proof of successful completion, and current listing on, the EPA National Radon Measurement Proficiency Program, or an equivalent measurement proficiency program approved by the commissioner, for the radon-222 detection instruments utilized, excluding passive monitors.

(3) Submission of a complete and accurate application form prescribed by the commissioner along with a fee of one hundred dollars ($100). An application will not be considered complete unless the required fee has been submitted.

(c) If using an instant readout device for radon-222 detection, evidence that the calibration and accuracy tests recommended by the manufacturer are being met shall be provided to the commissioner yearly. If there are no manufacturer's recommended frequencies, calibration and accuracy tests shall be made in accordance with EPA's "Indoor Radon and Radon Decay Product Measurement Device Protocols" (July 1992, EPA-402-R-92-004). If frequencies for calibration and accuracy tests are not specified in the EPA's protocol for the type of equipment being utilized, calibration and accuracy tests shall be made at least once each year and in the same month each succeeding year. If repairs are indicated, such repairs must be made, and calibration tests must be conducted after the repairs are performed. *(Indiana State Department of Health; 410 IAC 5.1-1-24; filed Oct 27, 1993, 9:00 a.m.: 17 IR 351; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2280; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-25 Certification of radon laboratory testers

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 25. (a) A radon laboratory tester must be certified in order to analyze or test for radon-222, or represent or advertise that he or she can analyze or test for radon-222, in a building.

(b) If a person employs one (1) or more individuals to perform radon-222 laboratory testing, the employer shall either be certified in accordance with this section or shall employ at least one (1) individual certified in accordance with this section on a full-time basis who shall be responsible for all of the employer's radon-222 laboratory testing activities. If the employer is not a certified radon laboratory tester and the employer is no longer able to keep a certified radon laboratory tester in its employ, the employer shall do the following:

(1) Notify the commissioner of the termination of the certified radon laboratory tester by telephone within two (2) working days of the termination.

(2) Notify the commissioner of the termination of the certified radon laboratory tester in writing within ten (10) working days of the termination.

(3) Immediately cease offering services as a radon laboratory tester until such time as a new full-time individual is employed to be responsible for all the employer's radon-222 laboratory testing activities.

This section shall not relieve other employees from the requirement to become certified if they perform work as a primary or secondary tester.

(c) The requirements for all individuals seeking certification as a radon laboratory tester are as follows:

(1) The individual must have a bachelor's degree from an accredited university or college in the physical sciences or engineering, or in a related field approved by the commissioner, or a minimum of two (2) years full-time experience, or equivalent as determined by the commissioner, in radiation measurement.

(2) Submission of a sworn affidavit that the full-time individual referenced in subsection (b) has read and agrees to adhere to EPA's "Indoor Radon and Radon Decay Product Measurement Device Protocols" (July 1992, EPA-402-R-92-004).

(3) Proof of successful completion, and current listing on, the EPA National Radon Measurement Proficiency Program, or an equivalent measurement proficiency program approved by the commissioner, for the radon-222 detection instruments utilized, excluding passive monitors.

(4) Submission of a complete and accurate application form prescribed by the commissioner along with a fee of one hundred dollars ($100). An application will not be considered complete unless the required fee has been submitted.

(d) A radon laboratory tester's results of tests for radon-222 shall be submitted to the commissioner annually following the procedures outlined in section 28(f) of this rule. If using an instant readout device for radon-222 detection, evidence that the calibration and accuracy tests recommended by the manufacturer are being met shall be provided to the commissioner yearly. If there are no manufacturer's recommended frequencies, calibration and accuracy tests shall be made in accordance with EPA's "Indoor Radon and Radon Decay Product Measurement Device Protocols" (July 1992, EPA-402-R-92-004). If frequencies for calibration and accuracy tests are not specified in the EPA's protocol for the type of equipment being utilized, calibration and accuracy tests shall be made at least once each year and in the same month each succeeding year. If repairs are indicated, such repairs must be made, and calibration tests must be conducted after the repairs are performed. *(Indiana State Department of Health; 410 IAC 5.1-1-25; filed Oct 27, 1993, 9:00 a.m.: 17 IR 352; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2281; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-26 Certification of radon mitigators

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 26. (a) A radon mitigator must be certified before he or she can mitigate for radon-222, or represent or advertise that he or she can mitigate for radon-222, in a building.

(b) If a person employs one (1) or more individuals to perform radon-222 mitigation, the employer shall either be certified in accordance with this section or shall employ at least one (1) individual certified in accordance with this section on a full-time basis. The certified employer or the certified employee or employees shall be responsible for the employer's radon-222 mitigation activities. If the employer is not a certified radon mitigator and the employer is no longer able to keep a certified radon mitigator in its employ, the employer shall do the following:

(1) Notify the commissioner of the termination of the certified radon mitigator by telephone within two (2) working days of the termination.

(2) Notify the commissioner of the termination of the certified radon mitigator in writing within ten (10) working days of the termination.

(3) Immediately cease offering services as a radon mitigator until such time as a new individual is employed on a full-time basis to be responsible for all the employer's radon mitigation activities.

(c) It shall be the responsibility of the certified radon mitigator to report any diagnostic testing to the building owner or its representative prior to any mitigation performed.

(d) The requirements for all individuals seeking certification as a radon mitigator are as follows:

(1) Proof of successful completion, and current listing on, the most recent EPA National Radon Contractor Proficiency Program, or an equivalent proficiency program approved by the commissioner.

(2) Submission of a complete and accurate application form prescribed by the commissioner along with a fee of one hundred dollars ($100). An application will not be considered complete unless the required fee has been submitted.

(Indiana State Department of Health; 410 IAC 5.1-1-26; filed Oct 27, 1993, 9:00 a.m.: 17 IR 352; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2282; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5.1-1-27 Recertification of primary and secondary radon testers, radon laboratory testers, and radon mitigators

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 27. (a) Prior to recertification as a primary or secondary radon tester, radon laboratory tester, or radon mitigator, the following must occur:

(1) Continuing education shall be completed within the prior two (2) years and may be obtained as follows:

(A) Continuing education must be from a course approved by the commissioner and must be at least six (6) contact hours. Written confirmation of attendance, signed by the course instructor, or its designee, shall be submitted at the time of application for recertification.

(B) Full-time employment as a certified primary radon tester, secondary radon tester, radon laboratory tester, or radon mitigator, whichever is applicable, for the prior two (2) years, provided written confirmation of full-time employment, signed by the business owner or chief executive officer of the business which employed the individual, has been submitted along with the application for recertification.

(2) A complete and accurate application for recertification shall be submitted to the commissioner on a form prescribed by the commissioner and shall include the fee specified in section 23(b)(3), 24(b)(3), 25(c)(4), or 26(d)(2) of this rule, whichever is applicable. An application will not be considered complete unless the required fee has been submitted.

(b) Individuals shall satisfy the requirement for biennial reexamination of primary radon testers, secondary radon testers, radon laboratory testers, and radon mitigators established in IC 16-41-38-3 if they comply with section 23(b)(2), 24(b)(2), 25(c)(3), or 26(d)(1) of this rule, whichever is applicable. *(Indiana State Department of Health; 410 IAC 5.1-1-27; filed Oct 27, 1993, 9:00 a.m.: 17 IR 353; errata filed Nov 9, 1993, 9:00 a.m.: 17 IR 410; errata filed Jan 28, 2000, 7:48 a.m.: 23 IR 1401; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-28 Certification standards; passive monitors; records; reporting

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 28. (a) No individual required to be certified in accordance with this rule may advertise a service unless the individual has previously obtained a valid certificate from the commissioner to perform that service.

(b) Radon-222 mitigation activities shall be conducted in accordance with mitigation protocols set forth in the EPA National Radon Contractor Proficiency Program (Interim Radon Mitigation Standards, December 15, 1991), and the following:

(1) In the case of an existing building, the individual performing mitigation shall ensure that the building is tested for radon-222 concentrations before and after any mitigation is performed. However, diagnostic testing is not required to be performed by a certified primary radon tester, secondary tester, or laboratory tester.

(2) The test conducted before mitigation shall be conducted by a certified primary radon tester, a certified secondary radon tester, or a certified laboratory tester and shall be at least forty-eight (48) hours in duration.

(3) The postmitigation test shall be conducted by a certified primary radon tester, a certified secondary radon tester, or a certified laboratory tester and shall be conducted no sooner than twelve (12) hours after completion of the mitigation. If passive monitors are utilized, they may be left with the building owner or occupant to be opened, set out, collected, sealed, and forwarded to a certified laboratory tester or a certified primary radon tester, provided the owner or occupant is given written instructions on the proper procedure to follow to assure that representative radon-222 measurements are obtained.

(4) Results of radon-222 tests shall be reported to the commissioner on a form prescribed by the commissioner and shall meet the requirements of subsection (f).

(5) Prior to conducting any radon-222 mitigation work, the radon mitigator shall submit a written outline of the mitigation work to be performed to the building owner or its representative. Along with the outline the radon mitigator must submit a written statement about any diagnostic testing he or she has performed, including where in the building such tests were conducted and what the results were in picocuries per liter. If no diagnostic testing was performed, that must be specifically reported, in writing, to the building owner or its representative. Information on any approvals and permits which must be obtained in the locality in which the mitigation work is to be performed also must be provided to the building owner or its representative, if applicable.

(6) Any construction undertaken to mitigate for radon-222 shall be in accordance with all applicable state and local building codes. Such construction shall be conducted or supervised by a certified radon mitigator who, at a minimum, shall be present at the start of such construction and at the conclusion of such construction.

(7) Warranty information and information on the proper method of checking and servicing of mitigation equipment installed by the radon mitigator to maintain its function shall be provided in writing to the client.

(c) No person may test, analyze, or mitigate radon-222 without first providing evidence that the person is certified in accordance with this rule or that the person has in its employ an individual certified in accordance with this rule.

(d) Prior to conducting any radon-222 testing or mitigation, the certified individual shall give each client a copy of a notice about radon-222 testing and mitigation prepared by the department specifically for that purpose.

(e) A secondary radon tester, primary radon tester, or radon laboratory tester may only distribute those passive monitors which have been manufactured or prepared by a person who is certified in accordance with section 25 of this rule, or who employs at least one (1) individual on a full-time basis who is certified in accordance with section 25 of this rule.

(f) All certified primary radon testers and certified laboratory testers providing radon-222 services shall submit to the commissioner, on a form approved by the commissioner, the results of all radon-222 screening measurements, follow-up measurements, and postmitigation measurements, if known. All certified radon mitigators shall submit to the commissioner, on a form approved by the commissioner, any radon-222 mitigation conducted for each calendar year. Said reports must be submitted by January 31 for the previous calendar year. For radon-222 measurements and for any mitigation conducted, the information must, at a minimum, contain the following:

(1) The name of the certified individual providing the service.

(2) The complete mailing address of the building involved.

(3) The county in which the building is located.

(4) The type of radon-222 mitigation conducted, if any.

(5) The type of measurement conducted (screening, follow-up, or postmitigation) and the results in picocuries per liter.

(6) The date of last calibration of the detection instrument and the instrument serial number.

(g) Within thirty (30) days after providing mitigation or postmitigation testing, the individual providing the service shall report to the owner of the building or its representative the results of all radon-222 testing conducted in picocuries per liter.

(h) Records of radon-222 tests, quality assurance programs, calibration measurements, and equipment repairs conducted by a certified secondary radon tester, primary radon tester, or radon laboratory tester shall be retained by that individual for at least three (3) years. Records of mitigation conducted by a certified radon mitigator shall be retained by that individual for at least three (3) years. *(Indiana State Department of Health; 410 IAC 5.1-1-28; filed Oct 27, 1993, 9:00 a.m.: 17 IR 353; errata filed Nov 9, 1993, 9:00 a.m.: 17 IR 410; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-29 Remedies; right of entry; reciprocity

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 4-21.5; IC 16-41-38

Sec. 29. (a) The radon certification of any individual may be denied, revoked, or suspended in accordance with IC 4-21.5 if it is determined that the individual:

(1) has engaged in unethical or unprofessional conduct of a character likely to deceive, defraud, or harm the building owner or occupant or the public, including, but not limited to:

(A) intentional placement of testing devices in areas likely to bias results; or

(B) for radon-222 mitigation, performing mitigation activities in existing buildings without prior testing;

(2) does not meet the education, training, and testing requirements for certification;

(3) does not submit annual test data as required;

(4) does not provide the client with a copy of the notice prepared by the department as required by section 28(d) of this rule; or

(5) does not comply with other applicable sections of this rule.

(b) No individual may provide applicable radon-222 testing or radon-222 mitigation services after revocation, denial, suspension, or voluntary surrender of a secondary radon tester, primary radon tester, radon laboratory tester, or radon mitigator certificate.

(c) No individual whose certification for primary radon tester, secondary radon tester, radon mitigator, or radon laboratory

tester has been suspended or revoked shall be eligible for reinstatement unless that person establishes, to the satisfaction of the commissioner, the following:

(1) The term of suspension prescribed in the order for suspension has elapsed.

(2) The individual has complied fully with the terms, if any, of the order for suspension or revocation.

(3) The individual can be safely recommended to the public as an individual fit to be reinstated and is able to practice its radon-222 business with reasonable skill and safety.

(d) The commissioner, his or her agents, and his or her employees shall have the right to enter, at all reasonable times, in or upon any public or private property, upon presentation of appropriate credentials, to inspect any equipment or records pertaining to radon-222 testing or mitigation, to inspect radon-222 testing laboratories, or to inspect radon-222 mitigation facilities or equipment that have been, or are to be, installed.

(e) A person accredited in another state to perform testing for, or mitigation of, radon-222 may be certified under this rule without passing an examination if:

(1) the person pays the applicable fee;

(2) the state in which the person is accredited maintains an accreditation program substantially similar to the certification program under this rule, as determined by the department; and

(3) the person can document successful completion of EPA's National Radon Measurement Proficiency Program or EPA's National Radon Contractor Proficiency Program, whichever is applicable to the certification desired, or successful completion of an equivalent proficiency program applicable to the certification desired, which has been approved by the commissioner.

(Indiana State Department of Health; 410 IAC 5.1-1-29; filed Oct 27, 1993, 9:00 a.m.: 17 IR 354; errata filed Nov 9, 1993, 9:00 a.m.: 17 IR 410; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 5.1-1-30 Civil penalties

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 4-21.5; IC 16-41-38

Sec. 30. (a) The commissioner may commence an action under IC 16-41-38 to levy civil penalties against an individual who:

(1) fails to comply with IC 16-41-38 or this rule; or

(2) interferes with or obstructs the department or its designated agent in the performance of official duties pursuant to IC 16-41-38 or this rule.

(b) A civil penalty in an amount in the appropriate range specified in this section may be sought for each day of each violation documented by the commissioner.

(c) In determining the seriousness of the violation and the specific amount of the civil penalty to be sought for each violation, the commissioner will consider the following:

(1) The potential for harm or imminent threat to public health.

(2) The extent of deviation from statutory or regulatory requirements.

(3) Degree of willfulness or negligence.

(4) History of noncompliance.

The absence of direct harm will not result in assessment of a lower penalty for a violation.

(d) Unless adjusted as provided for in subsection (e), all penalties shall be in accordance with the following schedule:

Violation	Rule Citation	Range of Penalty
Interference with department agent	410 IAC 5.1-1-30	$ 0 to $1,000
General requirements; exclusion	410 IAC 5.1-1-22	$ 0 to $1,000
Certification of secondary radon testers	410 IAC 5.1-1-23	$ 0 to $1,000
Certification of primary radon testers	410 IAC 5.1-1-24	$ 0 to $1,000
Certification of radon laboratory testers	410 IAC 5.1-1-25	$ 0 to $1,000
Certification of radon mitigators	410 IAC 5.1-1-26	$ 0 to $1,000
Recertification of primary and secondary radon testers, radon laboratory testers, and radon mitigators	410 IAC 5.1-1-27	$ 0 to $1,000

Certification standards; passive monitors; records; reporting	410 IAC 5.1-1-28	$ 0 to $1,000
Remedies; right of entry; reciprocity	410 IAC 5.1-1-29	$ 0 to $1,000

(e) After determining the appropriate penalty based on the schedule in this section, the commissioner may adjust the penalty to reflect a good faith effort to comply by the individual engaged in radon-222 activities.

(f) Each individual penalty may be multiplied by the number of days the particular violation has been documented by the commissioner.

(g) Penalties for all violations documented in an inspection or series of inspections will be totaled and sought under one (1) cause of action.

(h) After filing an action pursuant to IC 4-21.5, and in an attempt to resolve violations of IC 16-41-38 and this rule without resorting to a hearing, the commissioner may negotiate and enter into agreed orders. An agreed order may suspend all or part of the civil penalty calculated under the requirements and deadlines established in the agreed order.

(i) As provided by IC 16-41-38, an individual who violates this rule commits a Class A misdemeanor. *(Indiana State Department of Health; 410 IAC 5.1-1-30; filed Oct 27, 1993, 9:00 a.m.: 17 IR 355; errata filed Nov 9, 1993, 9:00 a.m.: 17 IR 410; errata filed Jan 28, 2000, 7:48 a.m.: 23 IR 1401; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 5.1-1-31 Incorporation by reference

Authority: IC 16-19-3-4; IC 16-41-38-2
Affected: IC 16-41-38

Sec. 31. The following documents are incorporated by reference as part of this rule:

(1) EPA's "Indoor Radon and Radon Decay Product Measurement Device Protocols" (July 1992, EPA-402-R-92-004).

(2) EPA's "National Radon Contractor Proficiency Program Protocol" (Interim Radon Mitigation Standards, December 15, 1991).

Two (2) copies of these documents are located in the files of the commissioner at 1330 West Michigan Street, Indianapolis, Indiana 46206-1964. Copies may also be obtained by request, mailed to the U.S. Environmental Protection Agency, Office of Air and Radiation, Washington, D.C. 20460. *(Indiana State Department of Health; 410 IAC 5.1-1-31; filed Oct 27, 1993, 9:00 a.m.: 17 IR 356; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 6. SANITARY ENGINEERING

Rule 1. Sewer Use; Cities and Towns

410 IAC 6-1-1 Sewerage systems in incorporated cities and towns; orders for construction and use

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1. Requiring the Construction and Use of Sewers and Sewerage Facilities in Incorporated Cities and Incorporated Towns. (1) Whenever investigation by the State Board of Health shall show that the lack of proper and adequate sewers and sewerage facilities in an incorporated city or town results in insanitary conditions, which may cause nuisances or produce conditions causative of disease, and that the construction of a proper and adequate sewerage system will abate and is a practical method to abate such insanitary conditions, said incorporated city or town shall, upon the issuance of an official order by the State Board of Health, immediately proceed with the construction of such sewers, interceptors, sewage treatment works, and such other parts and appurtenances of a sewerage system, as may be necessary to abate the insanitary conditions causative of disease and to protect the public health.

(2) When an investigation made by the State Board of Health in any incorporated city or town shows the municipal sewerage facilities are available and that conditions causative of disease result from failure to make use of such facilities, the board of trustees or common council of said city or town, upon issuance of an official order by the State Board of Health, shall immediately require that connections be made to the sewerage system or that the use of privies, cesspools, septic tanks or other means of sewage disposal, other than the municipal sewerage system, be discontinued.

(3) Provided, that such official order shall not be issued by the State Board of Health until after an opportunity for a hearing

has been given to the proper officials of such incorporated city or town, at which hearing the facts as shown by the investigation made by the State Board of Health shall be presented to said proper officials. *(Indiana State Department of Health; Reg HSE 10; filed Oct 18, 1945, 10:30 am: Rules and Regs. 1947, p. 1294; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: HSE 1 through 9 transferred to Environmental Management Board by IC 13-7-6-1.*

Rule 2. Swimming and Wading Pool Operations

410 IAC 6-2-0.1 Applicability

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 0.1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 6-2-0.1; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1795; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-0.2 "Air gap" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 0.2. "Air gap" means an unobstructed vertical distance through atmosphere between the water supply inlet and the flood level rim of the receiving unit. *(Indiana State Department of Health; 410 IAC 6-2-0.2; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1795; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-0.3 "Competition pool" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 0.3. "Competition pool" means any pool intended for use for accredited competitive aquatic events. Such pools may also be used for recreation and instruction. *(Indiana State Department of Health; 410 IAC 6-2-0.3; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1796; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-0.4 "Department" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 0.4. "Department" means the Indiana state department of health or its duly authorized representative. *(Indiana State Department of Health; 410 IAC 6-2-0.4; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1796; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-0.5 "Diving pool" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 0.5. "Diving pool" means any pool that is designed and constructed primarily for diving and which does not have a shallow end. *(Indiana State Department of Health; 410 IAC 6-2-0.5; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1796; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-0.6 "mg/l" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 0.6. "mg/l" means milligrams per liter and is equivalent to parts per million. *(Indiana State Department of Health; 410*

IAC 6-2-0.6; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1796; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-2-0.7 "Pools with wading areas" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 0.7. "Pools with wading areas" means any pool which has a portion of the shallow end with a maximum depth of twenty-four (24) inches. *(Indiana State Department of Health; 410 IAC 6-2-0.7; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1796; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-1 "Public swimming pool" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1. "Public swimming pool" means any swimming pool which is intended to be used for swimming or bathing and is operated by a concessionaire, owner, lessee, operator, or licensee, irrespective of whether a fee is charged for use. Nothing in this article shall be construed as applying to any swimming or wading pool, constructed at a one (1) or two (2) family dwelling, and maintained by an individual for the sole use of the household and house guests. *(Indiana State Department of Health; Reg HSE 16R,Sec 1; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 238; filed Jan 18, 1985, 10:00 a.m.: 8 IR 605; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1796; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-1.1 "Public wading pool" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1.1. "Public wading pool" means a small pool for use by children for bathing which:
(1) is designed and constructed for a turnover rate of at least one (1) turnover per hour;
(2) has a maximum depth of two (2) feet;
(3) has operation functions similar to a swimming pool; and
(4) is operated by a concessionaire, owner, lessee, operator, or licensee irrespective of whether a fee is charged for use.
(Indiana State Department of Health; 410 IAC 6-2-1.1; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1796; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-2-1.2 "Turnover rate" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1.2. "Turnover rate" means the period of time, expressed in hours, required to circulate a volume of water equal to the maximum pool water capacity. *(Indiana State Department of Health; 410 IAC 6-2-1.2; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1796; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-1.3 "Wave pool" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1.3. "Wave pool" means any pool with a bottom which is sloped upward from the deep end to the surface at the shallow end and which has equipment installed at the deep end to create wave motions in the water. *(Indiana State Department of Health; 410 IAC 6-2-1.3; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1797; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-1.4 "Zero depth pool" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1.4. "Zero depth pool" means any pool with a bottom which is sloped upward from the deep end to surface level at the shallow end. *(Indiana State Department of Health; 410 IAC 6-2-1.4; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1797; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-1.5 Swimming pool construction

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1.5. Public swimming pools and wading pools shall be designed, constructed, and maintained in accordance with 675 IAC 20-1.1 and 675 IAC 20-2-2 through 675 IAC 20-2-27. *(Indiana State Department of Health; 410 IAC 6-2-1.5; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1797; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-2 Water supply; plumbing fixtures

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 2. (a) The water supply serving the swimming pool and all plumbing fixtures, including drinking fountains, lavatories, and showers, shall be obtained from a municipal water supply system if at all possible; otherwise, the water supply shall come from a source which meets the Indiana department of environmental management public water supply drinking water quality standards under 327 IAC 8-2.

(b) All portions of the water distribution system serving the swimming pool and auxiliary facilities shall be protected against backflow and backsiphonage. Water introduced into the pool, either directly or through the recirculation system, shall be supplied through an air gap or by other methods acceptable to the state building commissioner in accordance with 675 IAC 16, the Indiana Plumbing Code. *(Indiana State Department of Health; Reg HSE 16R,Sec 3; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 239; filed Jan 18, 1985, 10:00 a.m.: 8 IR 606; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1797; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-3 Sewer system; drains

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 3. (a) A sewer system shall be utilized which is adequate to serve the facility, including bathhouse, locker room, and related accommodations. The building drains and sewers shall have capacity to carry filter backwash flows without surcharging or flooding onto the equipment room floor. Pool water and filter washwater may not be discharged directly to a drain, ditch, stream, or lake if it is in violation of 327 IAC 2-1. If such discharge would be in violation of that rule, facilities, such as a detention basin to settle suspended solids and to dissipate disinfectants, must be constructed to remove sufficient contaminants to assure compliance with 327 IAC 2-1.

(b) There shall be no direct physical connection between the sewer system and any drain from the swimming pool, wading pool, or recirculation system. Any swimming pool, gutter drain, or overflow from the recirculation system when discharged to the sewer system, storm drain, or approved natural drainage course shall connect through a suitable air gap to preclude the possibility of a backup of sewage or waste into the swimming pool piping system. All sumps, deck drainage systems, and other drainage fixtures or systems connected with the pool facility which discharge to a sewer or storm drain shall be properly trapped and vented to prevent sewer gases and odors from reaching the pool area.

(c) Public swimming pools and wading pools and their ancillary facilities shall discharge to the public sewerage system if such is feasibly available in the local area. If a public sewerage system is not available within a reasonable distance, sewage may be disposed of in accordance with the following:

(1) 410 IAC 6-10, concerning commercial on-site wastewater disposal, in the case of sewage disposal systems which the rule

defines as “on-site”.

(2) Applicable rules of the water board, in the case of sewage disposal facilities other than on-site sewage disposal systems.

(d) All drains in public swimming pools and wading pools shall be designed and maintained to prevent flow velocities from exceeding two (2) feet per second. *(Indiana State Department of Health; Reg HSE 16R,Sec 4; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 239; filed Jan 18, 1985, 10:00 a.m.: 8 IR 606; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1797; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-4 Depth markings

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 4. Depth markings shall conform to 675 IAC 20-2-26(c), the Indiana Swimming Pool Code. *(Indiana State Department of Health; Reg HSE 16R,Sec. 7; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 240; filed Jan 18, 1985, 10:00 a.m.: 8 IR 606; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1798; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-5 Visitor and spectator areas; food and drink areas

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 5. (a) There shall be separation between the spaces used by visitors and spectators at a public swimming pool or wading pool and those spaces used by bathers. Visitors and spectators in street clothes may be allowed within the perimeter enclosure if in a separate area which is provided and which is segregated from the space used by the bathers by a barrier or wall at least twenty-nine (29) inches high.

(b) No food or drink shall be permitted in the immediate area of the swimming pool or on the decks surrounding the pool except that food and beverage will be allowed in the visitor and spectator area, or in a similarly separated snack area for bathers, if beverages are served in nonbreakable containers and refuse containers are provided to keep litter off the pool decks. *(Indiana State Department of Health; Reg HSE 16R,Sec 24; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 253; filed Jan 18, 1985, 10:00 a.m.: 8 IR 606; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1798; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-6 Safety requirements; supervision; lifesaving/lifeguarding equipment

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 6. (a) The swimming pool shall be under the supervision of a capable individual who shall assume responsibility for compliance with all parts of this rule and any local ordinance relating to the safety of bathers.

(b) Acoustical treatment, including materials and ceiling design, shall be given to enclosed pool rooms to control noise levels so that swimmers can hear signals and directions of routine supervision as well as emergency control.

(c) Any swimming pool operated primarily for unorganized use and having an area of more than two thousand (2,000) square feet of water surface area shall be provided with an elevated lifeguard platform or chair. Such lifeguard platforms or chairs shall be placed in locations which eliminate sun glare on the water and in positions which will allow complete visual coverage of the pool and the pool bottom within a field of view no greater than forty-five degrees (45°) on either side of a line of sight extending straight out from the chair. In pools with four thousand (4,000) square feet or more of water surface area, additional elevated lifeguard platforms or chairs shall be provided and located to provide a clear, unobstructed view of the pool bottom in the area under surveillance.

(d) Not less than one (1) unit of lifesaving equipment shall be provided at every public swimming pool. For each two thousand (2,000) square feet of water surface area or major fraction thereof, one (1) unit of equipment shall be provided. Each unit of lifesaving equipment shall have its function plainly marked, be kept in good repair and in ready condition, and shall consist of all the following:

(1) A ring or throwing buoy not more than twenty (20) inches in diameter with enough weight for accurate throwing fitted with a forty-five (45) foot length of at least a one-fourth (¼) inch diameter line.

(2) A life pole, or shepherd's crook type of pole, having blunted ends with minimum length of twelve (12) feet.

(3) A spine board with ties and rigid cervical collars.

(e) Every swimming pool shall be equipped with a standard first aid kit, recommended or approved for swimming pools by the American Red Cross. The first aid kit shall be kept filled and ready for use. Availability of a kit in the office of the resident manager for a motel, campground, apartment complex, or hotel shall satisfy this requirement for such pools.

(f) Lifesaving equipment shall be mounted in conspicuous places distributed around the swimming pool deck and at lifeguard chairs. It shall be readily accessible, within twenty (20) feet of the pool, its function plainly marked, and kept in good repair and ready condition. Bathers or others shall not be permitted to tamper with or remove such equipment from its established location for any purpose other than the intended emergency use.

(g) When the swimming pool is not open for use, access to the pool shall be prevented by a fixed barrier with a locked entrance and a sign stating "POOL CLOSED" in clearly legible letters at least four (4) inches high affixed to the entrance closure.

(h) Whenever the pool area is opened for use and no lifeguard service is provided, warning signs shall be placed in plain view at the entrances and inside the pool area which state, "Warning–No Lifeguard on Duty" with clearly legible letters, at least four (4) inches high. In addition, the signs shall also state in clearly legible letters at least two (2) inches high, "No Swimming Alone. Children Under 14 Years Of Age And Non-Swimmers Shall Not Use The Pool Unless Accompanied By A Responsible Adult.".

(i) Signs stating, "No Diving" in clearly legible letters at least four (4) inches high shall be displayed at nondiving areas and at portions which are five (5) feet deep or less. These signs must be clearly visible to bathers entering the pool in nondiving areas. Diving shall not be allowed in pools or areas of pools which are not designed and constructed for that purpose.

(j) Every swimming pool shall have a readily accessible room or area designated and equipped for emergency care.

(k) A properly connected, usable telephone shall be located at or within two hundred (200) feet of the public swimming pool or wading pool. The telephone must remain available for emergency use. Emergency telephone numbers must be posted within view of a person using said telephone. These telephone numbers shall include the name and telephone number of the nearest available physician, ambulance or rescue unit, hospital, police station, and fire department. A sign shall be posted in the immediate vicinity of the public swimming pool or wading pool stating the location of the telephone. The sign shall also state that emergency telephone numbers are posted at the telephone.

(l) Swimming pools having portions with water depths of more than five (5) feet shall have a removable buoyed transition line anchored at each end and extending across the width of the pool at a point one (1) foot upslope from the breakpoint between shallow (five (5) feet or less) and deep (over five (5) feet) areas whenever the pool is open for use except when the pool is being used for organized competitive activities.

(m) When on duty, lifeguards shall not perform any duties other than lifeguarding and shall not be in the water except in the line of duty.

(n) The operators of all public swimming pools and wading pools shall provide a lifeguard orientation and training program annually and when new guards are employed. *(Indiana State Department of Health; Reg HSE 16R,Sec 25; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 254; filed Jan 18, 1985, 10:00 a.m.: 8 IR 607; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1798; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-7 Disinfection; water quality

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 7. (a) Public swimming pools and wading pools, when open for use, shall be continuously and automatically disinfected with a chemical which imparts an easily measured, free residual. When chlorine is used in a public swimming pool or wading pool, a free chlorine residual of at least one (1.0) mg/l shall be maintained throughout the swimming pool or wading pool water. If other halogens are used, residuals of equivalent disinfecting strength shall be maintained. Whenever the residual disinfectant concentration falls below the minimum required concentration, the public swimming pool or wading pool shall be cleared and kept free of bathers until that minimum concentration has been restored.

(b) If chlorinated isocyanurate or cyanuric acid stabilizers are used in public swimming pools or wading pools, the cyanuric acid concentration shall not exceed one hundred (100) mg/l. The pool water shall be tested weekly for the concentration of such stabilizers and the results recorded.

(c) A self-contained positive pressure demand breathing apparatus, with air supply tank, designed for use in a chlorine atmosphere shall be provided at public swimming pools and wading pools when using gaseous chlorine. The self-contained breathing apparatus shall be kept in a closed cabinet, accessible without a key, located outside of the room in which the chlorinator

is located. All gaseous chlorine equipment shall be operated and maintained in accordance with standards and recommendations of The Chlorine Institute, Inc., fifth edition (1986). Pool equipment operating staff shall be trained in the use of the self-contained breathing apparatus and shall be prepared to show evidence of that training. A plan of action for an emergency arising from the use of gaseous chlorine shall be written, made known, posted, and practiced.

(d) A sign stating, "DANGER–HAZARDOUS CHEMICALS" in clearly legible letters at least four (4) inches high shall be posted on or adjacent to the entrance to the pool chemical feed or storage rooms.

(e) The department may accept other disinfecting materials or methods when such materials or methods have been adequately demonstrated to provide a satisfactory residual effect, either alone or in combination with other disinfectants, which is easily measured and otherwise equally effective, under conditions of use, as halogens in the concentrations required by subsection (a). Such materials and methods shall not be dangerous to public health, create objectionable physiological effects, or impart toxic properties to the water.

(f) A test kit for measuring the concentration of the disinfectant, accurate within five-tenths (0.5) mg/l, shall be used at each public swimming pool or wading pool, as follows:

(1) For each pool which uses chlorine as a disinfectant, the test kit shall cover a minimum range of five-tenths (0.5) mg/l to three (3) mg/l measured as free active chlorine and be capable of measuring total chlorine.

(2) For each pool which uses an alternate disinfectant, the test kit shall have the range and accuracy proportionate to the range covered in subdivision (1) and shall be adequate to measure the disinfectant levels needed to be comparative to the chlorine levels measured in subdivision (1).

(g) The water in a public swimming pool or wading pool shall be maintained in an alkaline condition as indicated by a pH of not less than seven and two-tenths (7.2) and not more than seven and eight-tenths (7.8). A pH test kit accurate to the nearest two-tenths (0.2) pH unit and covering a minimum range of seven (7.0) to eight (8.0) pH units shall be provided. The alkalinity of the water in public swimming pools and wading pools shall be at least eighty (80) mg/l as titrated to the methyl orange end point.

(h) The recirculation system shall be maintained in condition to recirculate the entire contents of the swimming pool or wading pool within the time listed in this subsection for turnover rate. A suitable means shall be provided to measure the flow of the water through the recirculation system. The recirculation system shall provide the following turnover rates:

(1) In all public swimming pools built before September 13, 1989, the turnover rate shall be the lesser of eight (8) hours or, based on maximum bather load, one and eight-tenths (1.8) gallons per minute per bather.

(2) In public swimming pools built after September 13, 1989:

POOL TYPE	TURNOVER RATE
Wading pools	1 hour
Wave pools	2 hours
Zero depth pools	2 hours
Pools with wading areas	2 hours
Competition pools	6 hours
Diving pools	12 hours
All other public pools	6 hours

(i) The water in a public swimming pool or wading pool shall have sufficient clarity at all times so that a black disc, six (6) inches in diameter, is readily visible when placed on a white field at the deepest point of the swimming pool. A public swimming pool or wading pool which does not meet the applicable clarity standards enumerated in this subsection is a health and safety hazard. Failure to meet this requirement shall constitute grounds for immediate closing of the pool.

(j) Operators of public swimming pools and wading pools shall arrange for the collection and bacteriological examination of at least one (1) sample of the water in the public swimming pool or wading pool per week whenever the public swimming pool or public wading pool is open for use. Such sampling shall start at least one (1) week prior to the opening of the public swimming pool or public wading pool. Results of such examination shall be reported to the department. Failure to meet these requirements shall constitute grounds for closure. No more than fifteen percent (15%) of the water samples collected from a public swimming pool or wading pool in any two (2) month period of time shall exhibit the following:

(1) Contain more than two hundred (200) bacteria colonies per milliliter, as determined by the heterotrophic thirty-five degree Centigrade (35°C) plate count.

(2) Show positive test (confirmed test) for coliform organisms in any of the five (5) ten (10) milliliter portions of a sample,

or more than one (1) coliform organism per fifty (50) milliliters when the membrane filter test is used or any presence of coliform when the one hundred (100) milliliter presence/absence test is used.

All swimming pool and wading pool water samples shall be collected, dechlorinated, and examined for total bacteria using the heterotrophic thirty-five degree Centigrade (35°C) plate count method and for total coliform using the multiple tube fermentation test, the membrane filter test, or the one hundred (100) milliliter presence/absence test. Such test shall be performed by a state approved bacteriological laboratory in accordance with the procedures outlined in the seventeenth edition of Standard Methods for the Examination of Water and Wastewater (APHA), PART 9000, Microbiological Examination of Water, published in 1989. Where samples are examined in laboratories other than those of the department, copies of the report of examination, or a weekly summary of such examinations, shall be sent by the laboratory, or by the public swimming pool or wading pool operator, to the department's division of sanitary engineering, using, for that purpose, forms to be provided upon request or on their own form if the results of both examinations are clearly shown.

(k) A public swimming pool or wading pool that does not meet the applicable bacteriological quality standards enumerated in this section is a health hazard. Failure to meet these standards shall constitute grounds for closure. The right is reserved to close any public swimming pool or wading pool in the event of any epidemic, or threatened epidemic, of disease which the department may have reason to believe may be transmitted through the use of public swimming pools or public wading pools, or because of continued failure to meet the facility water sampling requirements. The local health officer having jurisdiction has the same authority to close any public swimming pool or wading pool.

(l) Chemicals used in controlling the quality of water in public swimming pools and wading pools shall be demonstrated as imparting no toxic properties to the water. The addition of chemicals for algae control shall be approved by the department, and for chemicals which are classified as pesticides, by the Indiana state chemist. *(Indiana State Department of Health; Reg HSE 16R,Sec 26; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 255; filed Jan 18, 1985, 10:00 a.m.: 8 IR 608; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1799; errata filed Apr 12, 1993, 11:00 a.m.: 16 IR 2189; errata filed Jul 27, 1993, 9:00 a.m.: 16 IR 2859; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-8 Suits and towels; cleaning

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 8. (a) All multiuse suits and towels furnished to bathers by the public swimming pool and wading pool management shall be washed thoroughly with detergent and hot water of at least one hundred seventy-five degrees Fahrenheit (175°F), rinsed, and thoroughly dried after each use.

(b) Clean suits and towels must be kept strictly separated from those which have been used and are unlaundered. *(Indiana State Department of Health; Reg HSE 16R,Sec 27; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 256; filed Jan 18, 1985, 10:00 a.m.: 8 IR 608; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1801; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-9 Public swimming pools and wading pools; cleaning

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 9. (a) Visible dirt on the bottom and walls of the public swimming pool or wading pool shall be removed every twenty-four (24) hours or more frequently as required.

(b) Scum, oils, or floating matter on the public swimming pool or wading pool water surface shall be removed continuously by skimming, flushing, or other effective means when the public swimming pool or wading pool is open for use. *(Indiana State Department of Health; Reg HSE 16R,Sec 28; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 256; filed Jan 18, 1985, 10:00 a.m.: 8 IR 609; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1801; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-10 Records of operation; supervision; injuries; drownings

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 10. (a) The facilities and mechanical equipment of every public swimming pool and wading pool shall be operated under

the close supervision of a competent person, organization, agency, or manufacturer that is qualified and experienced in such operations or by an operator trained in accordance with standards of the National Swimming Pool Foundation (1986). The operator shall be on duty at all times the public swimming pool or wading pool is open.

(b) Proper operating records shall be kept daily showing the following:

(1) Total bather loads.

(2) Peak bather load.

(3) Volume of fresh water added.

(4) Operating periods of recirculation pumps and filters and corresponding rate-of-flow meter readings.

(5) Amounts of chemicals used.

(6) Disinfectant residuals.

(7) pH readings.

(8) Maintenance (and malfunctioning) of equipment.

Such records shall be kept for a minimum period of one (1) year, and shall be open to inspection by the department or local health departments at all times. Weekly summaries of these records shall be submitted to the department or to a local health department on request, using forms furnished by that department.

(c) Serious injuries and drownings which occur within the pool enclosure shall be reported within ten (10) days to the department's division of sanitary engineering using forms prescribed by the department and to the local health department. *(Indiana State Department of Health; Reg HSE 16R,Sec 29; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 256; filed Jan 18, 1985, 10:00 a.m.: 8 IR 609; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1801; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-2-11 Supervision; personal conduct

Authority: IC 16-19-3-4

Affected: IC 16-19-3

Sec. 11. (a) One (1) or more qualified lifeguards, trained by the American Red Cross, YMCA, or YWCA, and possessing as minimum qualifications, current basic lifeguarding, lifeguard training, adult cardiopulmonary resuscitation, and standard first aid course certificates, shall be on duty at pool side at all times when the swimming pool is open to use by bathers, except at pools with less than two thousand (2,000) square feet of water surface used exclusively by a motel, apartment complex, condominium, hotel, or similar occupancy which is complying with section 6(h) of this rule. Such lifeguard shall be in full charge of bathing and have authority to enforce all rules of safety and sanitation. Additional lifeguards sufficient to maintain a patron load of not more than seventy-five (75) persons per lifeguard shall be on duty when the pool is open for use. Lifeguards qualified as a lifesaver under this rule shall be allowed one (1) year from the effective date of this rule or until the expiration of their current certification, whichever is less, to meet the lifeguard requirements as defined in this subsection. At least one (1) individual trained in first aid and cardiopulmonary resuscitation shall be available at the public swimming pool or wading pool whenever the facility is open for use by bathers. The American Red Cross standard first aid course may be considered as a minimum.

(b) The following personal conduct requirements shall be enforced:

(1) All bathers shall be instructed to use the toilet, and particularly to urinate, before taking a cleansing bath and entering the pool.

(2) All persons using the swimming pool shall take a cleansing shower bath, using warm water and soap, and thoroughly rinsing off all soap suds, before entering the swimming pool rooms or enclosure. A bather leaving the pool to use the toilet shall take another cleansing bath before returning to the swimming pool room or enclosure.

(3) Spitting, spouting of water, blowing the nose, and other similar behavior in the swimming pool, shall be strictly prohibited.

(4) No running, boisterous or rough play, except supervised water sports, shall be permitted in the pool, on the runways, diving boards, floats, platforms, in dressing rooms, or showers.

(5) Suitable placards embodying the personal conduct requirements and instructions in this subsection, and those relating to suits and towels, where applicable, shall be conspicuously posted in the swimming pool room or enclosure and in the dressing rooms and offices at all swimming pools which are subject to this rule.

(6) Persons having any considerable area of exposed subepidermal tissue, open blisters, cuts, etc., shall be warned that those are likely to become infected and advised not to use the pool.

(7) All bathers must use the appropriate swim wear. Street clothes shall not be allowed in the pool.

(Indiana State Department of Health; Reg HSE 16R,Sec 30; filed Jul 3, 1968, 2:45 p.m.: Rules and Regs. 1969, p. 257; filed Jan

18, 1985, 10:00 a.m.: 8 IR 609; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1802; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-2-12 Severability (Repealed)

Sec. 12. *(Repealed by Indiana State Department of Health; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1803)*

410 IAC 6-2-13 Incorporation by reference

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 13. (a) Part 9000, Microbiological Examination of Water, Standard Methods for the Examination of Water and Wastewater, seventeenth edition, published by the American Public Health Association, Inc., in 1989, is hereby incorporated by reference as a part of this rule. Copies may be obtained from the American Public Health Association, Inc., 1015 15th Street NW, Washington, D.C. 20005.

(b) The standards of the Chlorine Institution, Inc., fifth edition, published in 1986, are hereby incorporated by reference as part of this rule. Two (2) copies of these standards are available for reference in the files of the department. Copies may be obtained from the Chlorine Institute, Inc., 2001 L Street NW, Washington, D.C. 20036.

(c) The Pool/Spa Operators Handbook of the National Swimming Pool Foundation, 1986 edition, is hereby incorporated by reference as part of this rule. Two (2) copies of these standards are available for reference in the files of the department. Copies may be obtained from the National Swimming Pool Foundation, 10803 Gulfdale, Suite 300, San Antonio, Texas 78216. *(Indiana State Department of Health; 410 IAC 6-2-13; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1803; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 3. Plumbing Regulations

410 IAC 6-3-1 Plumbing regulations; adoption

Authority: IC 16-19-3-4
Affected: IC 22-11-1-10

Sec. 1. Plumbing Regulations. The State Board of Health does hereby duly adopt Volume III of the Rules and Regulations of the Administrative Building Council of Indiana *[The current version of the Indiana Plumbing Code may be found at 675 IAC 16.]*, as amended and revised, commonly known as and customarily referred to as the Plumbing Rules and Regulations of the State Board of Health.

Information concerning said Rules and Regulations may be obtained from the Director, Administrative Building Council, State Board of Health Building, Indianapolis, Indiana. *(Indiana State Department of Health; Reg HSE 18; filed Oct 18, 1945, 10:30 am: Rules and Regs. 1947, p. 1309; filed Apr 19, 1955, 2:00 pm: Rules and Regs. 1956, p. 48; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Current address is the Department of Fire and Building Services, Indiana Government Center-South, 302 West Washington Street, Indianapolis, Indiana 46204.*

Rule 4. Heating, Ventilating and Air Conditioning Regulations

410 IAC 6-4-1 Heating, ventilating and air conditioning regulations; adoption

Authority: IC 16-19-3-4
Affected: IC 22-11-1-10

Sec. 1. Heating, Ventilating and Air Conditioning Regulations. The State Board of Health does hereby duly adopt Volume IV of the Rules and Regulations of the Administrative Building Council of Indiana *[The current version of the Indiana Mechanical Rules may be found at 675 IAC 18.]*, as amended and revised, commonly known as and customarily referred to as the Heating, Ventilating and Air Conditioning Regulations of the State Board of Health.

Information concerning said Rules and Regulations may be obtained from the Director, Administrative Building Council, State Board of Health Building, Indianapolis, Indiana. *(Indiana State Department of Health; Reg HSE 19; filed Oct 18, 1945, 10:30 am:*

Rules and Regs. 1947, p. 1309; filed Apr 19, 1955, 2:00 pm: Rules and Regs. 1956, p. 49; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Current address is the Department of Fire and Building Services, Indiana Government Center-South, 302 West Washington Street, Indianapolis, Indiana 46204.

Rule 5. School Construction Regulations (Repealed)

(Repealed by Indiana State Department of Health; filed Jan 18, 1985, 10:02 am: 8 IR 604)

Rule 5.1. School Buildings and School Sites; Health and Safety Requirements

410 IAC 6-5.1-1 Definitions

Authority: IC 16-19-3-4
Affected: IC 16-41-21; IC 20-8.1-3-17

Sec. 1. As used in 410 IAC 6-5.1:

"Approved" means approved by the state board in all instances where not otherwise specified.

"Classroom" is any place or area within a school in which students are instructed.

"Dormitory" is any place, area, room, or building occupied and provided by the school for student housing.

"Food service" is any place, area, or room within a school building or dormitory where food is routinely prepared and served.

"Grade or grade level" is the finished ground level at the face of the exterior walls.

"Local health officer" means the health officer of any county or local health department, or his duly authorized representatives.

"Person" means an individual, partnership, co-partnership, firm, company, association, society, holding company, trustee, school corporation, school city, school town, school district, any consolidated unit of government, or any other legal entity, its or their successors or assigns, or agent of any of the aforesaid.

"School" is any place, or structure in which systematic instruction of any kind or grade is carried on for more than 10 persons for five hours or more per week or two and one-half hours or more per day, including preschools, kindergartens; elementary and secondary schools providing instruction to meet the compulsory attendance law pursuant to IC 20-8.1-3-17; colleges, universities and other post-secondary educational institutions.

The following shall not be considered to be educational institutions subject to the provisions of 410 IAC 6-5.1:

(1) Sunday schools and Vacation Bible schools, and any other program of a religious entity except those that are accredited by the Indiana state department of education; or

(2) day care centers subject to the provisions of IC 12-3-2 *[IC 12-3 was repealed by P.L.2-1992, SECTION 897, effective July 1, 1992.]*; or

(3) private residences; or

(4) any educational institutional *[sic.]* or educational training that is:

(A) maintained or given by an employer or group of employers, without charge, for his or their employees or for persons they anticipate employing; or

(B) maintained or given by a labor organization, without charge, for its or their members or apprentices; or

(C) offers exclusively instruction which is clearly self-improvement, motivational or avocational in intent (including, but not limited to instruction in dance, religion, music, self defense or private tutoring).

(5) any private religious school except those that are accredited by the state department of education.

"School building or facility" is any structure used in connection with the operation of schools, including the site therefor, the equipment thereof, and all appurtenances thereto, such as heating, ventilation, water supply, sewage disposal, plumbing, drainage, lighting, walks, drives, playgrounds, athletic fields, and other necessary structures and improvements used in connection therewith.

"School site" is a plot of ground or property set apart for the use of a school.

"State board" means the state board of health.

"State health commissioner" means the commissioner of the Indiana state board of health or his duly authorized representatives.

"Swimming pool" is any structure, basin, chamber, or tank containing a body of water for swimming, diving, or recreational bathing, including its appurtenances. *(Indiana State Department of Health; 410 IAC 6-5.1-1; filed Jan 18, 1985, 10:02 am: 8 IR 596; filed May 20, 1986, 4:00 pm: 9 IR 2687; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-2 Administration of regulations

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 2. 410 IAC 6-5.1 shall be administered by the state board through the state health commissioner. *(Indiana State Department of Health; 410 IAC 6-5.1-2; filed Jan 18, 1985, 10:02 am: 8 IR 597; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-3 Notice of construction or modification

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 3. (a) 410 IAC 6-5.1 shall apply to every school building, including every existing building or portion of an existing building, devoted to school use.

(b) Any person or persons planning construction, addition to, or significant change in the construction of any school facility, shall prior to the initiation of any such construction, submit detailed plans and specifications, drawn to scale, to the state board for review and approval. These plans and specifications must be certified by a registered engineer or architect licensed to practice in the state of Indiana.

(c) Plans and specifications for construction or modification of sewage treatment and disposal facilities shall be submitted to the stream pollution control board for review and issuance of a construction permit prior to construction.

(d) If, after having been approved by the state board, the plans or specifications are changed in any respect covered by 410 IAC 6-5.1, such revised plans or specifications shall be submitted to the state board and approval obtained prior to implementation of the revisions in the project.

(e) Plans and specifications for school buildings and parts of buildings used for school purposes shall comply with all applicable requirements of the Indiana building rules pursuant to 675 IAC 1-1-1 through 3 *[675 IAC 1-1 was repealed, filed Apr 11, 1985, 12:11 pm: 8 IR 1010. See 675 IAC 12.]*.

(f) The owner or his authorized agent shall also comply with all local laws, ordinances, rules, and regulations. *(Indiana State Department of Health; 410 IAC 6-5.1-3; filed Jan 18, 1985, 10:02 am: 8 IR 597; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-4 Site

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 4. The school site shall be so located, constructed and maintained to protect the health and safety of the students, and shall provide accessibility for the physically handicapped.

(a) All school sites, including additions to existing school sites, and sites formerly utilized for school purposes shall be approved by the state board prior to use or reuse of a building constructed thereon for school purposes. Approval of the school site may be obtained prior to submittal of construction plans for the school building or prior to acquisition of the site.

(b) Sufficient level acreage shall be available to accommodate the building, any planned expansion, its approaches, and its play area. Where a private water supply or private sewage disposal system must be used, additional acreage may be required in order to provide minimum separation distances, and to accommodate planned expansion.

(c) School sites shall be free from any hazards or nuisances.

(1) No school site, school building, or addition to a school building shall be located nearer than 500 feet to any unhealthful condition. Nor shall any unhealthful condition be located or erected within 500 feet of any school site, school building, or school building addition.

(2) The site or finished grade shall permit drainage of the entire area, and shall prevent ponding and excessive inflow from surrounding areas. Provisions for disposal of storm water shall be made to prevent ponding, hazards, or nuisances.

(3) Suitable all-weather surfaced walks and driveways shall be provided from the street or highway for access to school entrances, school bus loading areas and parking areas; for delivery of fuel and supplies; and for the removal of ashes, refuse, grease, sludge, septage, etc.

(4) Loading and unloading areas for school buses and private vehicles shall be located off highways or streets and separate from playgrounds to assure maximum safety for the students.

(5) Ample space for parking shall be provided and so arranged that it will not interfere with regular traffic on the driveways or walkways.

(6) A safe sight distance shall be maintained at all vehicle exits and entrances to and from the school site onto public roads, streets, highways, or thoroughfares.

(7) Where a public water supply system is not available and adequate groundwater for potable use is not assured without detailed subsurface investigation, such investigation must be made to determine the availability of adequate groundwater, prior to site acquisition.

(8) Where an approved public sewer system is not available, an acceptable alternative means for sewage disposal must be determined prior to site acquisition.

(Indiana State Department of Health; 410 IAC 6-5.1-4; filed Jan 18, 1985, 10:02 am: 8 IR 597; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-5.1-5 Physical facilities

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 5. (a) All school buildings or parts thereof used for school purposes shall be located, constructed, and maintained to protect the health and safety of the students, and shall include provisions for the physically handicapped.

(b) All school buildings or parts thereof used for school purposes shall at all times be maintained in a clean, safe and sanitary condition and be in a good state of repair.

(c) Classrooms for preschool, kindergarten, and first or second grade students shall be part of the first story above grade, except where the building is fully sprinklered.

(d) In all classrooms, each student shall be provided with no less than 30 square feet of classroom area. The ceiling height for classrooms shall not be less than 7½ feet.

(e) All interior surfaces in school buildings shall be well maintained, easily cleanable and of non-toxic, durable construction. Each floor of a school building shall have adequate space provided for storage of cleaning equipment.

(f) All portions of school buildings or parts therof used for school purposes shall be provided with natural light by means of exterior glazed openings with an area not less than one-tenth of the total floor area, or shall be provided with artificial light. Windows shall be provided on only one side of each classroom.

(1) In all school buildings utilizing electrical light fixtures, the following average minimum levels of illumination (with variation in uniformity not to exceed two to one) shall apply:

Classrooms, laboratories, study halls, lecture rooms, art rooms, offices, libraries, and shops . . . . . 50 foot candles
Drafting rooms, typing rooms, sewing rooms, and those portions of rooms where detail work is to be done . . . . . 70 foot candles
Reception rooms, gymnasiums, cafeterias, food service areas*, and indoor swimming pools . . . . . 20 foot candles
*(410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]* requires that certain portions of food service areas be lighted in excess of 20 foot candles.)
Auditoriums**, shower/locker rooms, inside restrooms, corridors, store rooms, service areas and stairways . . . . . 10 foot candles
**(If used as a classroom, study hall or lecture room, auditoriums shall be provided with a minimum of 50 foot candles of light.)

(2) For the purposes of item (1) above, all light intensity measurements shall be at the level of work, or in rooms where no work is done, at a height of 30 inches above the floor.

(3) All classroom lighting shall be constructed to minimize direct glare.

(g) All light fixtures located in student areas shall be shielded to protect the students from injury due to bulb breakage.

(h) The exterior windows in classrooms shall be equipped with blinds, window shades of translucent material, or other approved means to control natural light.

(i) In student areas, windows having sills 30 inches or less from the floor shall be provided with approved safety glass or with protective devices installed on the interior of the room.

(j) All portions of school buildings or parts thereof used for school purposes shall be provided with natural ventilation by means of operable exterior windows with an area of not less than one-twentieth of the total floor area or shall be provided with a

mechanically operated ventilating system. The mechanically operated ventilating system shall supply a minimum of five cubic feet per minute of outside air, with a total circulation of not less than 15 cubic feet per minute per occupant in all portions of the building. Each such ventilating system shall be kept continuously in operation whenever a room it serves is occupied.

(1) Ventilation shall be sufficient to provide adequate oxygen, a character of freshness in the air and to remove exhaled air and undesirable odors during periods of student occupancy.

(2) Assembly rooms, auditoriums, gymnasiums, dressing rooms, interior restrooms, laboratories, shops, and other areas where toxic or otherwise objectionable odors are produced, shall be mechanically exhausted to the outside.

(k) All school buildings or parts therof used for school purposes shall be equipped with heating facilities with capacity sufficient to maintain a uniform temperature in all student areas under severest weather conditions. Portable space heaters are prohibited.

(1) Heating facilities shall be capable of, and shall be operated to maintain a temperature during periods of student occupancy, not less than 68° F. in all instructional rooms, offices, locker rooms, and cafeterias, not less than 65° F. in activity rooms and shops, and not less than 60° F. in interior toilet rooms.

(2) Heating facilities shall be constructed in such a manner that drafts and uneven heating are minimized.

(3) Pipes, ducts, and radiators containing steam, or hot water and located in student areas shall be shielded to protect occupants from injury.

(4) Heating facilities shall be constructed, operated and maintained for the efficient consumption and utilization of energy.

(l) Where provided, air-conditioning systems shall be capable of and shall be operated to maintain a temperature not to exceed 78° F. and 65 percent relative humidity during periods of student occupancy.

(m) The building electrical systems shall comply with the applicable requirements of the Indiana electrical rules (675 IAC 6-1-1 through 2 *[675 IAC 6 was repealed, filed Apr 9, 1985, 2:42 pm: 8 IR 1012. See 675 IAC 17.]*).

(1) The building electrical systems shall be sufficient to meet peak electrical demands and shall be maintained for the efficient consumption and utilization of energy.

(2) Classrooms shall be provided with electrical receptacles, located as required for connection of semi-permanent or often used equipment.

(3) All electrical receptacles and switches accessible to the students shall be shielded to prevent accidental shock. All electrical wiring accessible to the students shall be protected to prevent electric shock.

(4) In all restrooms and shower/locker rooms constructed after the effective date of 410 IAC 6-5.1, electrical receptacles provided for connection of personal grooming equipment shall be provided with ground fault circuit interrupters to prevent electric shock.

(n) All furniture and equipment used in any school building or a part of a building used for school purposes shall be durable and easily cleanable, with rounded corners and edges, and otherwise protected to ensure safety. Heights of furniture and equipment shall be based on the size of students using them.

(o) All primary and secondary school buildings or parts thereof used for school purposes shall provide storage for the clothing and belongings of each student. Lockers, hanger bars, or hooks shall be provided at the ratio of one for each student. Heights of lockers, hanger bars, hooks, and shelves shall be based on the size of students using them. Where provided, lockers shall set *[sic.]* upon closed front bases.

(p) Drinking water facilities shall be provided in all school buildings or parts thereof used for school purposes.

(1) The temperature of the water supplied for drinking purposes shall not be lower than 40° F. nor higher than 75° F.

(2) Drinking water facilities shall be provided at the ratio of one for each 75 students or fraction thereof.

(3) Drinking water facilities shall be constructed of impervious, easily cleanable materials, and shall be kept clean and in a good state of repair. Heights of drinking water facilities shall be based on the size of students using them.

(4) Drinking water facilities shall not be located in toilet rooms.

(5) Drinking fountains, where provided, shall be convenient to primary rooms, gymnasiums, playgrounds, and shops, but may be located to serve the greatest number of students; at least one conveniently located drinking fountain shall be provided on each floor having classrooms.

(6) Drinking fountains, where provided, shall have a sanitary type guarded angle-stream jet head and an adjustable flow regulator. The outlet shall not be below the flood rim of the fixture.

(q) Service sinks or similar facilities shall be provided in all school buildings or parts thereof used for school purposes.

(1) There shall be provided a minimum of one service sink or similar facility on each floor of the building, located near the storage space for cleaning equipment.

(2) Both hot and cold running water under pressure shall be available at each service sink.

(3) All service sinks or similar facilities shall be protected against back-siphonage.

(r) Provisions shall be made in all schools so that health examinations, screening tests, and first-aid service can be conducted to protect the health and safety of the students.

(1) Space shall be provided for one cot for each 300 students in the school. Cots shall be constructed of cleanable material and shall be disinfected after each use. Linens, pillows, and blankets, where provided, shall be washed after each use and stored in a manner to prevent contamination.

(2) As a minimum, a first-aid kit consisting of 48 one-inch by three-inch plastic adhesive bandages, 10 ammonia inhalants, 20 PVP swabs, four two-inch offset bandages, one 40-inch triangular bandage, six one-eighth ounce burn ointments, one four-inch offset bandage, one one ounce eye wash, ten stingkill swabs, one cold pak, and eight knucklebands, shall be provided in a readily accessible location.

(3) Restroom and handwashing facilities shall be located convenient to the cot space.

(s) Each school building or parts thereof used for school purposes shall be provided with restroom and sanitary facilities. Restrooms and sanitary facilities shall be kept in a clean condition, in good repair, well lighted and adequately ventilated. In cases where privies are provided, they shall be of the sanitary vault-type, constructed and operated in compliance with the standards of the state board.

(1) There shall be separate, readily accessible general-student-use restrooms for each sex. Restrooms shall not be more than 200 feet travel distance from any classroom for which they are provided. In all school buildings constructed or first utilized after the effective date of 410 IAC 6-5.1, interior restrooms, where provided for primary and secondary students, shall be located on each floor having classrooms. Restrooms adjoining and opening into preschool through second grade classrooms may be used by both sexes.

(2) Separate shower/locker rooms shall be provided for each sex using a gymnasium.

(3) Separate restrooms shall be provided for school staff or a locked compartment in both boys' and girls' restrooms shall be provided for the staff. Exception: Separate restroom facilities are not required for staff in post-secondary school buildings.

(4) Restrooms shall be equipped with lavatories or other satisfactory handwashing facilities, or such equipment shall be installed in an adjacent room through which the users must pass upon egress from the restroom. In cases where privies are provided, handwashing facilities shall be provided at a location through which the users must pass upon re-entering the school building.

(5) Restroom and shower/locker room entrances shall be screened to make the interior of the room hidden from the exterior.

(6) All restroom and shower/locker room floors shall be of smooth, non-porous materials. Walls and ceilings shall be of materials presenting a smooth, non-absorbent, easily cleaned surface.

(7) All shower/locker rooms and interior restrooms shall be provided with mechanical exhaust ventilation.

(8) All exterior door openings and operable windows of restrooms and shower/locker rooms shall be fly-proof and tight-fitting.

(9) Toilet fixtures, lavatories and shower heads shall be provided for each sex in accordance with the applicable requirements of the Indiana plumbing rules (675 IAC 5-1-1 through 3 *[675 IAC 5 was repealed, filed Mar 6, 1986, 3:00 pm: 9 IR 1657. See 675 IAC 16.]*). The number of fixtures provided shall be based on the maximum occupancy of the school. The heights of fixtures shall be based on the size of students using them.

(10) Interior toilet fixtures shall be of the water-flushed type. Multiple seat toilets or makeshift trough arrangements shall not be provided even though they may be equipped for water flushing. All toilet fixtures shall be protected against back-siphonage.

(11) Every water closet shall have an elongated bowl with open-front seat and shall be made of impervious material. All water closets shall be partitioned as necessary to provide individual stalls. Stall partitions shall extend to a height of not less than 5 1/2 feet from the floor and the bottom shall not be more than one foot above the floor. Partitions shall be of smooth surface, impervious, easily cleanable material; wood surfaces are not acceptable. An adequate supply of toilet paper shall be provided in a dispenser at each water closet or privy.

(12) Covered disposal facilities shall be provided in the restrooms for junior high school age girls and above, and in the restrooms for female staff.

(13) An adequate supply of soap and individual sanitary towels in dispensers, or other approved hand-drying devices, shall be provided convenient to all handwashing facilities. Common towels are not acceptable. If individual sanitary towels are provided, a suitable container for used towels shall also be provided.

(14) Where showers are provided, the nozzles shall be of the slanting spray-type.

(15) Body washing facilities shall be supplied with hot and cold water, under pressure. Hot water provided for body washing and handwashing facilities shall be maintained between 105° F. and 120° F. An anti-scald device shall be provided to automatically control the hot water temperature so that it cannot exceed 120° F. Either mixing-type faucets or automatic mixing devices shall be provided at each body washing facility.

(16) As a minimum, an adequate supply of cold water, under pressure, shall be provided at all handwashing facilities. Each handwashing facility provided with hot water shall have either a mixing-type faucet or an automatic mixing device.

(t) All student housing and dormitories, where provided by the school, shall be kept in good repair and shall be maintained in a clean, safe and sanitary condition.

(1) Sleeping rooms shall be sized to provide an area of not less than 50 square feet per student. Separate sleeping areas shall be provided for each sex.

(2) Separate restroom and sanitary facilities shall be provided for each sex. Restroom and sanitary facilities shall comply with applicable sections of 410 IAC 6-5.1.

(3) Food services and related facilities shall comply with applicable sections of 410 IAC 6-5.1.

(Indiana State Department of Health; 410 IAC 6-5.1-5; filed Jan 18, 1985, 10:02 am: 8 IR 598; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-5.1-6 Food services

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 6. (a) Any room or area in a school building used for the storage, preparation and serving of food, or the washing of food utensils, shall be constructed and operated in compliance with the applicable requirements of the food service rules of the state board (410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*).

(b) All food service equipment and utensils shall be in compliance with the applicable requirements of the food service rules of the state board (410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*).

(c) An adequate supply of hot and cold water, under pressure, shall be provided in all food service and related areas where food is prepared, or equipment, utensils, or containers are washed.

(d) In food services and related areas, handwashing facilities, including hot and cold water under pressure, shall be provided at locations convenient to the food preparation and utensil washing areas. Food preparation and utensil washing sinks are not acceptable as handwashing facilities for personnel. Each handwashing facility shall have either a mixing-type faucet or an automatic mixing device. Hot water must be available within a reasonable time after opening the faucets. An adequate supply of soap and individual sanitary towels in dispensers, or other approved hand-drying devices, shall be provided convenient to all handwashing facilities. Common towels are not acceptable. If individual sanitary towels are provided a suitable container for used towels shall also be provided.

(e) After the effective date of 410 IAC 6-5.1, grease traps or interceptors shall be constructed to provide access for maintenance and cleaning only from outside the building. *(Indiana State Department of Health; 410 IAC 6-5.1-6; filed Jan 18, 1985, 10:02 am: 8 IR 601; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-7 Swimming pools

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 7. (a) All swimming pools and related facilities operated as part of a school building shall be constructed in compliance with the applicable requirements of the Indiana swimming pool rules (675 IAC 9 *[675 IAC 9 was repealed, filed Jan 8, 1986, 12:04 pm: 9 IR 1028. See 675 IAC 20.]*).

(b) Swimming pools and related facilities shall be operated in compliance with the applicable requirements of the swimming and wading pool operation rules of the state board (410 IAC 6-2). *(Indiana State Department of Health; 410 IAC 6-5.1-7; filed Jan 18, 1985, 10:02 am: 8 IR 601; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-8 Water supply (Repealed)

Sec. 8. *(Repealed by Water Pollution Control Board; filed Sep 24, 1987, 3:00 pm: 11 IR 737)*

410 IAC 6-5.1-9 Sewage disposal

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 9. (a) All sewage treatment facilities for school buildings and related facilities shall be designed, constructed and maintained in accordance with the standards of the Indiana stream pollution control board.

(b) Where any governmental district, agency, community-type, or other public sewerage systems are available or become available within a reasonable distance from the school facility, a connection shall be made thereto and the public sewers shall be used exclusively. If a public sewerage system is not available, sewage shall be disposed of through an approved on-site sewage treatment facility.

(c) All parts of the sewer and sewage disposal or treatment system shall be located to prevent the possibility of contamination of the school water supply or the water supply of surrounding property owners. All components of the sewerage system shall be located at least 100 feet from any water supply well or buried pump suction line; however, sewers constructed of water works grade cast or ductile iron pipe having mechanical joints may be located within the 100-foot distance but not closer than 30 feet to a water supply well or buried pump suction line, with prior written approval of the state board. Exception: The separations enumerated herein shall not necessarily be considered adequate in areas where fissured stone or very permeable soils are encountered.

(d) All parts of the sewer and sewage disposal or treatment system shall be designed, constructed, and maintained to adequately transmit and dispose of daily sewage flows and peak sewage flows.

(e) Storm water or surface drainage shall not be discharged into any public or school sanitary sewer system. Water softener and filter backwash water, boiler blowdown water, and swimming pool water shall not be discharged into any sanitary sewer which drains to an on-site sewage treatment facility, without prior written approval of the state board.

(f) In all school buildings and additions to school buildings constructed after the effective date of 410 IAC 6-5.1, the following shall apply:

(1) Unless it can be documented to the satisfaction of the Indiana stream pollution control board that wastewater is generated at lesser rates, school sewage disposal systems shall be designed and constructed to treat a minimum of 15 gallons per day per elementary student and below, 25 gallons per day per secondary student and above, and 100 gallons per day per dormitory bed, based on maximum building occupancy.

(2) Sewers shall have manholes constructed at intervals of not more than 400 feet along the sewer. Manholes shall be installed at every change in size, alignment or grade of the sewer. Cleanouts the same size as the sewer, and extending to grade, may be substituted for manholes on sewer runs of less than 100 feet; such cleanouts may also be installed at the terminus of a sewer if a manhole is located within 300 feet of the terminus.

(3) The liquid capacity of septic tanks serving schools shall be sufficient to allow for at least 48 hours detention at design flow. One or two tanks may be utilized as long as the design provides two compartments in series. Tank lengths shall be a minimum of three times the tank width, and the compartments in combination shall have a surface settling rate no greater than 30 gallons per day per square foot. A gas deflection baffle shall be provided as part of the final tank outlet.

(Indiana State Department of Health; 410 IAC 6-5.1-9; filed Jan 18, 1985, 10:02 am: 8 IR 602; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-5.1-10 Refuse disposal

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 10. (a) The township trustee, board of school commissioners, or similar school governing board shall be responsible for the satisfactory storage, collection and disposal of refuse generated in school buildings and related facilities.

(b) Refuse shall be stored in conveniently located, fly-tight, water-tight containers. Where service permits, approved hopper-type containers should be substituted for refuse cans.

(c) Refuse cans and containers shall be stored on racks with at least eight inches clearance off the ground, or on a concrete base, or by other approved construction. All refuse containers must be kept in a sanitary condition, and closed when not in use.

(d) The area around the refuse storage cans and containers shall be kept clean and free of litter.

(e) Refuse shall be disposed of at a permitted solid waste facility or in accordance with Rule 320 IAC 5 *[Pursuant to a style standard adopted by the code revision commission on August 25, 1983, the revisor has renumbered 320 IAC 5 concerning the refuse disposal act as 330 IAC 4.]*.

(f) All incinerators for combustible refuse shall be designed, constructed and maintained in accordance with the applicable rules of the Indiana air pollution control board.

(g) Garbage and empty food containers shall not be placed in any incinerator constructed for the disposal of combustible refuse.

(h) All toxic or hazardous waste generated by a school facility shall be collected, stored, and disposed of in accordance with the applicable rules of the Indiana environmental management board. *(Indiana State Department of Health; 410 IAC 6-5.1-10; filed Jan 18, 1985, 10:02 am: 8 IR 603; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-11 Special hazards

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 11. (a) No condition shall be created in any school building that is not conducive to health and safety.

(b) No flammable, explosive, toxic, or hazardous liquids, gases, or chemicals shall be placed, stored, or used in any building or part of a building used for school purposes, except in approved quantities as necessary for use in laboratories, shops, and approved utility rooms. Such liquids, gases, or chemicals shall be kept in tightly sealed containers, and stored in safety cabinets or approved storage rooms when not in actual use, and in accordance with applicable requirements of the Indiana flammable liquids code (675 IAC 11.3 *[675 IAC 11.3 was repealed, filed Aug 26, 1985, 4:01 pm: 9 IR 57, and filed Oct 16, 1985, 8:55 am: 9 IR 515. See 675 IAC 22.]*).

(c) Employees and students who must use machines and equipment in shops, laboratories, and food services shall be supplied with the appropriate safety devices for personal protection.

(d) All prescription drugs dispensed to the students under a doctor's order shall be stored in a locked cabinet or room under adult supervision. All prescription drugs shall be dispensed to the students under adult supervision. *(Indiana State Department of Health; 410 IAC 6-5.1-11; filed Jan 18, 1985, 10:02 am: 8 IR 603; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-12 School facility inspection

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 12. The state health commissioner or local health officer is authorized to make inspections to determine the condition of school buildings and sites. The commissioner or local health officer shall have the authority to enter at reasonable times any private, public, or religious school building for the purpose of inspecting and investigating conditions relating to the enforcement of 410 IAC 6-5.1. *(Indiana State Department of Health; 410 IAC 6-5.1-12; filed Jan 18, 1985, 10:02 am: 8 IR 604; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-13 Enforcement

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 13. The state health commissioner or local health officer is hereby authorized to enforce the provisions of 410 IAC 6-5.1. Ordinances, rules, regulations, and other requirements adopted by local government agencies shall not designate standards that are incompatible with or less stringent than 410 IAC 6-5.1. *(Indiana State Department of Health; 410 IAC 6-5.1-13; filed Jan 18, 1985, 10:02 am: 8 IR 604; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-5.1-14 Severability of rule

Authority: IC 16-19-3-4
Affected: IC 16-41-21

Sec. 14. If any section, paragraph, sentence, clause, phrase or word of 410 IAC 6-5.1, or any other part thereof, be declared invalid for any reason, the remainder of 410 IAC 6-5.1 shall not be affected thereby and shall remain in full force and effect. *(Indiana State Department of Health; 410 IAC 6-5.1-14; filed Jan 18, 1985, 10:02 am: 8 IR 604; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 6. Mobile Home Park Sanitation and Safety

410 IAC 6-6-1 Definitions

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 1. (a) As used in this rule, "mobile home" means any vehicle, including the equipment sold as a part of a vehicle, which is so constructed as to permit its being used as a conveyance upon public streets or highways by either self-propelled or not self-propelled means, which is designed, constructed, or reconstructed, or added to by means of an enclosed addition or room in such a manner as will permit the occupancy thereof as a dwelling for one (1) or more persons, which is both used and occupied as a dwelling having no foundation other than wheels, jacks, skirting, or other temporary supports.

(b) As used in this rule, "mobile home park" means an area of land upon which five (5) or more mobile homes (other than mobile homes on permanent foundations) are harbored on temporary supports for the purpose of being occupied as principal residences and includes all real and personal property used in the operation of the mobile home park. An area of land that is subdivided and contains individual lots which are leased or otherwise contracted for is a mobile home park if five (5) or more mobile homes (other than mobile homes on permanent foundations) are harbored on temporary supports there for the purpose of being occupied as principal residences.

(c) As used in this rule, "dependent mobile home" means a mobile home which does not possess a toilet, sink, bath, or shower facilities.

(d) As used in this rule, "partially dependent mobile home" means a mobile home which possesses a toilet and sink but does not possess a bath or shower facilities.

(e) As used in this rule, "state board" means the state board of health of Indiana.

(f) As used in this rule, "temporary supports" means any structural system of transferring the loads imposed by a mobile home to the earth with its lower surface placed above the frost line as established at 675 IAC 13-2.1-89 *[675 IAC 13-2.1 was repealed filed Dec 1, 1992, 5:00 p.m.: 16 IR 1126, effective Jan 3, 1993.]*.

(g) As used in this rule, "permanent foundation" (as an antonym of "temporary supports") means a structural system of transferring the loads imposed by a mobile home to the earth with its lower surface placed below the frost line as established at 675 IAC 13-2.1-89 *[675 IAC 13-2.1 was repealed filed Dec 1, 1992, 5:00 p.m.: 16 IR 1126, effective Jan 3, 1993.]*. The system shall be constructed of materials such as poured concrete, mortared concrete block, mortared brick, or treated wood, to which the mobile home is attached in such a way to secure the mobile home to the foundation so that the mobile home becomes part of the real estate and is assessed for taxation as an improvement to the real estate.

(h) As used in this rule, "violation" means the failure of a mobile home park owner, operator, adult attendant, caretaker, or other person who has a substantial and direct proprietary interest in the park to abide by a provision of IC 13-1-7 *[IC 13-1-7 was repealed by P.L.2-1993, SECTION 209, effective Apr 30, 1993.]* or this rule.

(i) As used in this rule, "interference with state board of health agent" means, but is not limited to, physical obstruction, attack, or threatened attack on a representative of the board while that representative is conducting inspection, licensing, or enforcement activities pursuant to IC 13-1-7 *[IC 13-1-7 was repealed by P.L.2-1993, SECTION 209, effective Apr 30, 1993.]* or this rule. *(Indiana State Department of Health; Reg HSE 21R, Sec 1; filed Jun 14, 1974, 2:29 p.m.: Rules and Regs. 1975, p. 328; filed Aug 7, 1981, 2:04 p.m.: 4 IR 1819; filed Feb 8, 1988, 4:10 p.m.: 11 IR 1764; filed Oct 6, 1989, 4:30 p.m.: 13 IR 278; errata filed Jan 5, 1990, 5:00 p.m.: 13 IR 902; errata filed Jan 30, 1990, 2:05 p.m.: 13 IR 1066; errata filed Jul 9, 1990, 2:00 p.m.: 13 IR 2004; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2282; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Statutory definition of mobile home park altered by Acts 1977, P.L.144.*

410 IAC 6-6-2 Mobile home park sites; zoning; water and sewer service

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 2. (a) Mobile home parks shall be located on well-drained sites and in areas free from flooding or other conditions which will cause or contribute to a health hazard.

(b) Mobile home park sites shall meet all requirements of the local zoning commission and shall be approved by said commission before construction begins.

(c) Every shelter occupied as a residence in a mobile home park, whether mobile or permanent, shall be equipped with toilet, sink, and bath or shower facilities and shall be connected to water supply and sewer service prior to occupancy. *(Indiana State Department of Health; Reg HSE 21R, Sec 2; filed Jun 14, 1975, 2:29 pm: Rules and Regs. 1975, p. 329; filed Aug 7, 1981, 2:04 pm: 4 IR 1819; filed Feb 8, 1988, 4:10 pm: 11 IR 1765; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-3 Mobile home park lots; construction requirements

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 3. (a) The mobile home park shall be divided into lots and an accurate plat shall be available at the mobile home park office indicating the size and location of each lot.

(b) An occupied mobile home shall not be allowed to remain in a mobile home park unless parked on a lot having water supply, sewage collection, and electrical services in conformance with 410 IAC 6-6.

(c) The following provisions shall apply to all mobile home parks constructed after June 14, 1974, as well as to all additions to parks constructed after that date:

(1) Each mobile home park lot shall contain at least two thousand five hundred (2,500) square feet.

(2) Each mobile home park lot shall abut directly onto a road, driveway or parking lot.

(3) Mobile homes shall not be parked closer than ten (10) feet from an adjoining mobile home or the expanded portions of such mobile home.

(4) No mobile home shall be enclosed around the bottom with a combustible material except that wood may be used for the framework. If mobile homes are enclosed around the bottom, and the water and/or sewer connection is located under the mobile home, an access opening or openings shall be provided in close proximity to the water and sewer connections to permit inspection of those connections.

(5) A hard surface area shall be provided for each mobile home lot of adequate size to provide a base for steps to the mobile home. A hard surface walk shall connect the steps with the road, driveway, or parking lot.

(d) Bales of hay or straw shall not be used for skirting or insulation of mobile homes. *(Indiana State Department of Health; Reg HSE 21R, Sec 3; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 329; filed Aug 7, 1981, 2:04 pm: 4 IR 1820; filed Feb 8, 1988, 4:10 pm: 11 IR 1765; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-4 Streets; parking spaces

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 4. (a) There shall be no dead-end streets less than twenty-four (24) feet in width and in excess of one hundred fifty (150) feet in length for vehicle traffic in a mobile home park.

(b) At least one (1) auto parking space for each mobile home lot shall be provided within the property lines of the park.

(c) Auto parking space may be included on the mobile home lot, on the park street, or on separate parking lots. If separate parking lots are used, each parking space shall be located within three hundred (300) feet of the mobile home lot it will serve.

(d) The following provisions shall apply to all mobile home parks constructed after June 14, 1974, as well as to all additions to mobile home parks constructed after that date:

(1) Turnarounds serving to eliminate dead-end streets in parks shall have a diameter of at least sixty (60) feet.

(2) One-way streets shall be at least twelve (12) feet wide and two-way streets shall be at least twenty-four (24) feet wide. If on-street parking is to be provided, each parking lane shall be at least an additional eight (8) feet wide.

(3) Overflow parking shall be provided in a mobile home park at the rate of one (1) space for each three mobile homes. *(Indiana State Department of Health; Reg HSE 21R, Sec 4; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 330; filed Aug 7, 1981, 2:04 pm: 4 IR 1820; filed Feb 8, 1988, 4:10 pm: 11 IR 1765; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-5 Minimum lighting

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 5. There shall be a minimum of 0.3 footcandles illumination on streets and walkways in a mobile home park, except where an individual yard light is installed on each mobile home park lot. If an individual yard light is installed on each mobile home park lot it shall provide illumination at least equivalent to that of a forty (40) watt incandescent bulb. *(Indiana State Department of Health; Reg HSE 21R, Sec 5; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 330; filed Feb 8, 1988, 4:10 pm: 11 IR 1766; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-6 Community buildings; toilet and laundry facilities

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 6. (a) The community building of a mobile home park, when provided, shall be constructed in accordance with the electrical, plumbing and other building codes of the state and the municipal unit in which the park is located. Construction of the building must be in accordance with a plan approved by the state board as well as by the department of fire and building services.

(b) All exterior openings shall be covered with 16 mesh screen or equivalent during periods of the year when insects are prevalent.

(c) Toilet and laundry rooms shall be constructed so that they can be well-lighted at all times. The laundry rooms shall have illumination of at least forty (40) foot candles on work areas such as washtubs, ironing boards and sorting tables. The toilet rooms shall have illumination of forty (40) foot candles in front of mirrors.

(d) Sufficient hot water heating facilities shall be available so that the temperature of the hot water is maintained at a minimum of 120° F. at all times for laundry facilities.

(e) Laundry trays and automatic washers shall be connected to the sanitary sewer.

(f) Community buildings shall be located at least fifteen (15) feet from any mobile home.

(g) Community buildings shall be maintained in a clean and sanitary condition at all times. *(Indiana State Department of Health; Reg HSE 21R, Sec 6; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 330; filed Feb 8, 1988, 4:10 pm: 11 IR 1766; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-7 Water supply distribution systems (Repealed)

Sec. 7. *(Repealed by Water Pollution Control Board; filed Sep 24, 1987, 3:00 pm: 11 IR 737)*

410 IAC 6-6-8 Sewage disposal systems

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 8. (a) A mobile home park shall dispose of sewage through use of a public sewerage system if the sewerage system is available within a reasonable distance from the mobile home park. If a public sewerage system is not available, sewage may be disposed of through use of a private system constructed in accordance with:

(1) 410 IAC 6-10 in the case of septic tank soil absorption systems; or

(2) applicable rules of the water pollution control board in the case of sewage disposal facilities other than septic tank-soil absorption systems.

(b) All components of the mobile home park sewage collection and disposal system shall be located in accordance with the provisions of 327 IAC 8-8-1(d) *[327 IAC 8-8 was repealed filed Jun 17, 1999, 1:50 p.m.: 22 IR 3379.]*, to prevent the possibility of contaminating the mobile home park water supply and the water supplies of surrounding property owners.

(c) Storm water or surface drainage shall not be discharged to the park sewer system receiving sanitary wastes from mobile homes and service buildings. Surface drainage shall be diverted away from the riser. The rim of the riser tile shall extend at least four (4) inches above ground elevation.

(d) All sewers receiving sanitary wastes shall be constructed as described by the Recommended Standards for Sewage Works

as published by the Great Lakes-Upper Mississippi River Board of State Sanitary Engineers except that sanitary sewers may be six (6) inches in diameter.

(e) All sewage disposal facilities which have an effluent discharging into the waters of the state shall be constructed, operated and maintained in accordance with the requirements and standards of the water pollution control board.

(f) Sewers shall have manholes constructed at intervals of not more than four hundred (400) feet along the sewer. Manholes shall be installed at every change in size, alignment, or grade of the sewer. *(Indiana State Department of Health; Reg HSE 21R, Sec 8; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 332; filed Aug 7, 1981, 2:04 pm: 4 IR 1821; filed Feb 8, 1988, 4:10 pm: 11 IR 1767; errata filed Jan 5, 1990, 5:00 p.m.: 13 IR 902; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-9 Refuse disposal; inoperative motor vehicles

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 9. (Refuse Disposal) (a) The mobile home park owner and/or operator shall be responsible for satisfactory storage, collection and disposal of refuse and for ensuring that (b) through (g) of this section is complied with.

(b) Refuse shall be stored in fly-tight water-tight containers which shall be located not more than 150 feet from any mobile home space. Hopper-type containers may be substituted for refuse cans where service permits. When hopper-type units are used they must be placed within a reasonable walking distance from the mobile home spaces to be served.

(c) The refuse cans and containers shall be placed on racks with at least eight inches clearance off the ground or on a concrete base or by other approved construction. All refuse containers must be kept in a sanitary condition.

(d) The area around the storage cans shall be kept clean and free of litter.

(e) Refuse shall be disposed of at a public disposal site or in such other manner that it will not create fly breeding, rodent harborage, odor or smoke nuisances or health, fire or safety hazards.

(f) Garbage or empty food containers shall not be placed in any incinerator constructed for the disposal of combustible refuse.

(g) No unlicensed or inoperative motor vehicle shall be allowed to remain in a mobile home park for more than thirty (30) days unless stored in a designated, visually screened area which is at least one hundred (100) feet from the nearest mobile home. *(Indiana State Department of Health; Reg HSE 21R, Sec 9; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 333; filed Aug 7, 1981, 2:04 pm: 4 IR 1822; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-10 Electrical and gas facilities

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 10. (Electrical and Gas Utilities). (a) All wiring and lighting fixtures shall be installed and maintained in a safe condition.

(b) All gas outlet risers, regulators, meters, valves or other exposed equipment shall be protected by proper location or other means from mechanical damage by vehicles or other causes.

(c) When gas is used, a properly installed system of gas lines and appurtenances which provides gas service adequate for safe operation of appliances and equipment shall be provided. *(Indiana State Department of Health; Reg HSE 21R,Sec 10; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 334; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-11 Ground anchors

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 11. (Mobile Home Safety) (a) In all mobile home parks and additions to mobile home parks ground anchors shall be installed on each occupied mobile home lot.

(b) When ground anchors are installed they shall be installed on each side of the mobile home stand in a row beginning no more than six (6) feet from the front wall of the mobile home and ending no more than six (6) feet from the rear wall of the mobile home. The ground anchors placed along the side of the mobile home stand shall not be separated by more than 24 feet unless a greater separation distance is certified by a Registered Professional Engineer or Architect as providing the same or better protection as that provided by the specified configuration.

(c) Provision for diagonal ties between ground anchors and the mobile home shall be made in conjunction with each vertical tie-down.

(d) Ground anchors exposed to weathering shall be resistant to weathering deterioration at least equivalent to that provided by a coating of zinc on steel of not less than 0.30 ounces per square foot of surface coated. Each ground anchor shall be designed to resist an allowable working load equal to or exceeding 3,150 pounds and shall be capable of withstanding a 50 percent overload without failure. *(Indiana State Department of Health; Reg HSE 21R, Sec 11; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 334; filed Aug 7, 1981, 2:04 pm: 4 IR 1822; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-12 Submission of construction plans

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27; IC 25-31-1-2

Sec. 12. Any person or persons planning the construction, additions to, or significant change in the construction of any mobile home park shall, prior to the initiation of any such construction, submit plans, drawn to scale, to the state board for review and approval. These plans must be certified by a registered engineer or architect licensed to practice in the state of Indiana except, as provided in IC 25-31-1-2(h), registered land surveyors may certify those portions of plans containing only platting or subdividing of land, and gravity sanitary sewers, storms sewers, and tile drains. *(Indiana State Department of Health; Reg HSE 21R, Sec 12; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 334; filed Aug 7, 1981, 2:04 pm: 4 IR 1823; filed Feb 8, 1988, 4:10 pm: 11 IR 1767; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-13 Swimming pools

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 13. All swimming pools operated as part of a mobile home park shall be operated and maintained in compliance with 410 IAC 6-2. Construction of the pool must be in compliance with a plan approved by the department of fire and building services. *(Indiana State Department of Health; Reg HSE 21R, Sec 13; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 335; filed Aug 7, 1981, 2:04 pm: 4 IR 1823; filed Feb 8, 1988, 4:10 pm: 11 IR 1768; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-14 Reporting communicable diseases

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 14. Conditions for Health and Safety. (a) Every owner, operator or attendant operating a mobile home park shall notify the local health office immediately of any suspected communicable or contagious disease within the mobile home park.

(b) No conditions, situation or installation shall be created, installed or maintained which may cause or result in a health or safety hazard or which may cause or transmit disease or harbor rodents or other vermin. *(Indiana State Department of Health; Reg HSE 21R, Sec 14; filed Jun 14, 1974, 2:29 pm: Rules and Regs. 1975, p. 335; filed Aug 7, 1981, 2:04 pm: 4 IR 1823; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-6-14.1 Civil penalties schedule

Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 4-21.5; IC 16-41-27

Sec. 14.1. (a) The board may commence an action under IC 13-1-7-29 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and IC 4-21.5-3-8 to levy civil penalties against a mobile home park operator who:

(1) fails to comply with IC 13-1-7 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* or this rule; or

(2) interferes with or obstructs the state board or its designated agent in the performance of duties pursuant to IC 13-1-7 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

(b) A civil penalty in an amount in the appropriate range specified in this section may be assessed for each day of each

violation.

(c) In determining the seriousness of the violation and the specific amount of the civil penalty to be sought for each violation, the state board will consider the following:

(1) The potential for harm or imminent threat to public health.

(2) The extent of deviation from statutory or regulatory requirements.

(3) Degree of willfulness or negligence.

(4) History of noncompliance.

The absence of direct harm will not result in assessment of a lower penalty for a violation.

(d) Unless adjusted as provided for in subsection (e), all penalties shall be in accordance with the following schedule:

Violation		Range of Penalty
Mobile Home Sites	(410 IAC 6-6-2)	$50 to $100
Mobile Home Lots	(410 IAC 6-6-3)	$50 to $100
Streets and Parking	(410 IAC 6-6-4) (IC 13-1-7-19 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*)	$10 to $50
Park Lighting	(410 IAC 6-6-5) (IC 13-1-7-21 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*)	$10 to $50
Water Supply	(327 IAC 8-8-1) (IC 13-1-7-12 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*)	$100 to $1,000
Water Risers	(327 IAC 8-8-1(h))	$10 to $50
Sewage Disposal	(410 IAC 6-6-8) (IC 13-1-7-13 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*)	$100 to $1,000
Sewer Risers	(410 IAC 6-6-8(c))	$50 to $100
Refuse Disposal	(410 IAC 6-6-9) (IC 13-1-7-14 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*)	$50 to $100
Unlicensed or Inoperative Motor Vehicles	(410 IAC 6-6-9(g))	$50 to $100
Electrical/Gas Utilities	(410 IAC 6-6-10)	$100 to $500
Mobile Home Safety	(410 IAC 6-6-11)	$10 to $100
Submission of Plans	(410 IAC 6-6-12) (IC 13-1-7-26 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*)	$100 to $1,000
Swimming Pools	(410 IAC 6-6-13)	$100 to $500
Conditions for Health and Safety	(410 IAC 6-6-14)	$100 to $1,000
Domestic Animals and House Pets	(IC 13-1-7-20 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*)	$10 to $100
Attendant or Caretaker	(IC 13-1-7-11 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*)	$100 to $500
Interference with State Board or its Agent		$100 to $1,000

(e) After determining the appropriate penalty based on the schedule in this section, the state board may adjust the penalty to reflect a good faith effort to comply by the owner or operator of a mobile home park.

(f) Each individual penalty will be multiplied by the number of days the particular violation occurred. Penalties for violations occurring in two (2) consecutive inspections by the state board shall be assessed on the basis that the violations have remained uncorrected over the period of time between the two (2) inspections.

(g) Penalties for all violations will be totaled and sought under one (1) cause of action.

(h) After filing an action pursuant to IC 4-21.5, and in an attempt to resolve violations of IC 13-1-7 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* and this rule without resort to a hearing, the state board may negotiate and enter into agreed orders. An agreed order may suspend all or part of the civil penalty calculated under the requirements and deadlines established in the agreed order. *(Indiana State Department of Health; 410 IAC 6-6-14.1; filed Oct 6, 1989, 4:30 p.m.: 13 IR 279;*

errata filed Jan 5, 1990, 5:00 p.m.: 13 IR 902; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-6-15 References for sewage works standards
Authority: IC 16-19-3-4; IC 16-41-27-8
Affected: IC 16-41-27

Sec. 15. (References) "Recommended Standards for Sewage Works," 1978 Edition, A Report of the Committee of the Great Lakes-Upper Mississippi River Board of State Sanitary Engineers, available from:
Health Education Service, Inc.
P.O. Box 7126
Albany, NY 12224
(Indiana State Department of Health; 410 IAC 6-6-15; filed Aug 7, 1981, 2:04 pm: 4 IR 1823; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 7. Camp Sanitation and Safety (Repealed)
(Repealed by Indiana State Department of Health; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3757)

Rule 7.1. Campgrounds

410 IAC 6-7.1-1 Definitions
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 6-7.1-1; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-2 "Bathing beach" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 2. "Bathing beach" means a body of water not contained within a structure, chamber, or tank and used for swimming, diving, or recreational bathing. *(Indiana State Department of Health; 410 IAC 6-7.1-2; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-3 "Campground" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 3. "Campground" means an area or tract of land where campsites are leased or rented and where provisions are made for ten (10) or more tents, recreational vehicles, park models, or vacation mobile homes. A campground is established, operated, and maintained for recreational, health, education, sectarian, business, or tourist activities away from established residences. The term, as used in this rule, does not include primitive campgrounds, youth camps, or tracts of land divided into individually deeded lots. *(Indiana State Department of Health; 410 IAC 6-7.1-3; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-4 "Campsite" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 4. "Campsite" means an individual camping space set aside in a campground for a tent, recreational vehicle, or vacation mobile home. *(Indiana State Department of Health; 410 IAC 6-7.1-4; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-5 "Department" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 5. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 6-7.1-5; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-6 "Dependent campsite" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 6. "Dependent campsite" means a campsite without an individual sewer connection. *(Indiana State Department of Health; 410 IAC 6-7.1-6; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-7 "Gray water" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 7. "Gray water" means wastewater originating from dish washing, hand washing, laundering, showers, or sinks. *(Indiana State Department of Health; 410 IAC 6-7.1-7; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-8 "Independent campsite" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 8. "Independent campsite" means a campsite with individual water and sewer connections. *(Indiana State Department of Health; 410 IAC 6-7.1-8; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-9 "Local health officer" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 9. "Local health officer" means the health officer of any local health department or their authorized representative. *(Indiana State Department of Health; 410 IAC 6-7.1-9; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-10 "Person" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 10. "Person" means any individual, firm, partnership, company, corporation, trustee, association, municipality, county, authority, estate, or public or private entity owning, conducting, controlling, managing, or operating a campground. *(Indiana State Department of Health; 410 IAC 6-7.1-10; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3743)*

410 IAC 6-7.1-11 "Primitive campground" defined
Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 11. "Primitive campground" means an area or tract of land without water supply systems, electricity, or toilets and having no vehicular access. *(Indiana State Department of Health; 410 IAC 6-7.1-11; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-12 "Public sewer" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 12. "Public sewer" means a sewage disposal facility provided by a utility, municipality, conservancy district, or regional sewer district. *(Indiana State Department of Health; 410 IAC 6-7.1-12; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-13 "Public water supply" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 13. "Public water supply" means water supplied by a utility, municipality, conservancy district, regional water district, rural water corporation, or not-for-profit water corporation. *(Indiana State Department of Health; 410 IAC 6-7.1-13; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-14 "Recreational vehicle" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 14. "Recreational vehicle" means a travel trailer, park model, collapsible trailer, truck-mounted camper, or motor home. *(Indiana State Department of Health; 410 IAC 6-7.1-14; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-15 "Sanitary dumping station" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 15. "Sanitary dumping station" means a sewage inlet with cover surrounded by a concrete apron sloped to a drain, and a water outlet. The sanitary dumping station is for disposal of recreational vehicle holding tank waste. *(Indiana State Department of Health; 410 IAC 6-7.1-15; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-16 "Temporary campground" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 16. "Temporary campground" means a campground operated not more than ten (10) consecutive days per event and not more than thirty (30) days a calendar year. Temporary campgrounds are under the jurisdiction of local health officers. *(Indiana State Department of Health; 410 IAC 6-7.1-16; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-17 "Tent" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 17. "Tent" means a shelter with twenty-five percent (25%) or more of its walls or roof, or both, made of fabric. *(Indiana State Department of Health; 410 IAC 6-7.1-17; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-18 "Vacation mobile home" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 18. "Vacation mobile home" means a manufactured housing unit not on a permanent foundation used for recreational living on a temporary basis and not occupied as a principal residence. *(Indiana State Department of Health; 410 IAC 6-7.1-18; filed*

Jun 27, 2002, 1:30 p.m.: 25 IR 3744)

410 IAC 6-7.1-19 "Water station" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 19. "Water station" means a facility for filling water storage containers with potable water from an approved water system. *(Indiana State Department of Health; 410 IAC 6-7.1-19; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-20 Construction permit requirement

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 20. (a) Any person or persons planning the construction, addition to, or significant change in the construction of any campground shall, at least ninety (90) days prior to the initiation of any such construction, submit plans, drawn to scale, for review and approval by the department. These plans must be certified by a registered engineer or architect licensed to practice in Indiana.

(b) The department may waive the requirement for plan review for any project that it deems to be a minor alteration. *(Indiana State Department of Health; 410 IAC 6-7.1-20; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744; errata filed Jul 8, 2002, 1:47 p.m.: 25 IR 3769)*

410 IAC 6-7.1-21 Campgrounds and campsites

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 21. (a) Campgrounds shall have designated campsites, and each site shall be plainly marked with a different number.

(b) No more than one (1) recreational vehicle or one (1) vacation mobile home shall be allowed on a designated campsite at the same time.

(c) The campground owner or operator shall have a plan of the campground. The plan must show the location of each designated campsite with the number assigned to it, and the location of any community buildings, wells, sanitary dumping stations, swimming pools, or sewage disposal systems. *(Indiana State Department of Health; 410 IAC 6-7.1-21; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3744)*

410 IAC 6-7.1-22 Conditions for health and safety

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 22. No condition, situation, or installation shall be created, installed, or maintained that:

(1) may cause or result in a health or safety hazard; or

(2) may cause or transmit disease or harbor rodents or other vermin.

(Indiana State Department of Health; 410 IAC 6-7.1-22; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3745)

410 IAC 6-7.1-23 Campground water supplies

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 23. (a) Campgrounds shall be provided with an adequate and convenient supply of potable water that meets 327 IAC 8. Potable water shall always be available for culinary, drinking, laundry, and bathing purposes.

(b) Wells shall be constructed, installed, and located in accordance 327 IAC 8 and 310 IAC 16. The construction and location of all campground wells with less than fifteen (15) service connections or serving less than twenty-five (25) people shall comply with all the requirements of this rule.

(c) A campground shall exclusively use a public water supply if public water is available within a reasonable distance. If a

public water supply is not available, a campground shall have water supplied from a well that complies with the requirements of 327 IAC 8.

(d) Campground water supply and distribution systems shall have the capacity to deliver a minimum water pressure of twenty (20) pounds per square inch to all water stations and connections during periods of peak water usage. The water supply shall have capacity to meet total daily water demands. If a well or pump cannot meet peak or daily water demand, campgrounds shall be provided with sufficient usable storage capacity to meet the demand.

(e) The casing pipe of a well shall project not less than:

(1) twenty-four (24) inches above floor level or finished grade;

(2) thirty-six (36) inches above the regulatory flood elevation if located in a designated flood hazard area identified by the Federal Emergency Management Agency.

(f) Water supplies shall have no well head, well casing, pump, pumping machinery, exposed pressure tanks, or suction piping located in any pit, room, or space, walled in or enclosed so it does not have free drainage by gravity to the ground surface at all times.

(g) Each campground shall provide one (1) or more accessible water stations of an approved design and located so no campsite is more than two hundred (200) feet from a water station. Water stations and sanitary dumping stations shall be a minimum of fifty (50) feet apart. A water station having an inside or outside threaded faucet shall have a pressure vacuum breaker installed to protect against back-flow.

(h) In lieu of water stations, individual water riser pipes may be installed at each campsite.

(i) Water riser pipes shall be located and constructed to protect against damage from parking of recreational vehicles.

(j) Water riser pipes shall:

(1) be at least one-half (½) inch in diameter;

(2) extend at least four (4) inches above ground; and

(3) be separated from sewer risers by not less than five (5) feet horizontally.

(k) Stop-and-waste valves or yard hydrants that would allow aspiration or backflow of contaminated water into the potable water system shall not be used.

(l) Wells and potable water distribution systems shall be disinfected after construction and after each repair. The water supply shall be tested and be bacteriologically acceptable in at least two (2) consecutive samples collected at least twenty-four (24) hours apart before it can be used. Each camper shall be advised to boil potable water until sample results reveal a safe water supply.

(m) There shall be no direct physical connection between the campground potable water supply system and any nonpotable water supply system. *(Indiana State Department of Health; 410 IAC 6-7.1-23; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3745)*

410 IAC 6-7.1-24 Campground sewage disposal

Authority: IC 16-19-3-4
Affected: IC 13-18-12; IC 16-19-3

Sec. 24. (a) All sewage generated by a campground, including gray water, shall be disposed of via a connection to a public sewer if available within a reasonable distance from the campground. If a public sewer is not available within a reasonable distance, sewage disposal must comply with 410 IAC 6-12, 410 IAC 6-10, Bulletin S.E. 11, Bulletin S.E. 13, or applicable rules of the Indiana department of environmental management.

(b) If individual sewer connections are provided for recreational vehicles, these connections shall meet the following minimum requirements:

(1) Each individual sewer riser shall be at least four (4) inches in diameter.

(2) Each individual sewer connection shall be tightly capped when a recreational vehicle is not connected.

(3) The rim of the riser pipe shall extend four (4) inches above the ground, and surface drainage shall be diverted away from the riser.

(c) Only wastewater management businesses licensed pursuant to IC 13-18-12 shall clean campground privies and portable toilets of waste. Privies must be pumped when the accumulated waste is within eighteen (18) inches of the privy floor. *(Indiana State Department of Health; 410 IAC 6-7.1-24; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3745)*

410 IAC 6-7.1-25 Sanitary dumping station

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 25. (a) All campgrounds, except those having only independent campsites, shall have at least one (1) sanitary dumping station for each two hundred fifty (250) dependent campsites or fraction thereof.

(b) Each sanitary dumping station must be equipped with the following:

(1) A four (4) inch sewer riser pipe with a self-closing hinged cover or other tight-fitting closure.

(2) A concrete apron at least three (3) feet in diameter and sloped to drain the area surrounding the inlet of the riser pipe.

(3) A water outlet for sanitary maintenance of the station.

(4) A sign located at the water outlet which states that the water is not for drinking, but for flushing and cleaning holding tanks and the dump station area.

(5) A vacuum breaker installed downstream of the last shut-off valve that meets the requirements of 675 IAC 16.

(c) Sanitary dumping stations shall be capable of receiving a sewage flow of at least twenty (20) gallons per day for each dependent campsite served.

(d) Sanitary dumping stations utilizing holding tanks shall be capable of receiving a sewage flow of at least sixty (60) gallons per day for each dependent campsite served. *(Indiana State Department of Health; 410 IAC 6-7.1-25; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3746)*

410 IAC 6-7.1-26 Campground sanitary facilities

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 26. (a) A campground with dependent campsites shall have flush toilets, sanitary vault privies, or portable toilets, in the following ratios:

Number of Dependent Campsites	Toilet Facilities		Urinals*
	Men	Women	Men
1–15	1	1	0
16–30	1	2	1
31–45	2	3	1
46–60	2	4	2
61–100	3	5	2

*Toilets may be substituted for the required number of urinals on a one-for-one basis.

(b) Campgrounds with more than one hundred (100) dependent campsites shall be provided with one (1) flush toilet, sanitary vault privy, or portable toilet for each sex in the ratio of one (1) per thirty (30) dependent campsites and one (1) urinal for each one hundred (100) additional campsites.

(c) The entrance to a sanitary facility shall have a sign to designate which sex may use the facility. Solid walls extending from floor to ceiling shall separate facilities for each sex located in the same building.

(d) For all common use rooms that contain sanitary or laundry facilities, excluding sanitary vault privies and portable toilets, the following minimum requirements shall apply:

(1) Floors, walls, and partitions around showers, lavatories, and other plumbing fixtures shall be smooth, nonabsorbent, and easily cleanable.

(2) Bathing and hand washing facilities shall have hot and cold water under pressure. Bathing facilities shall have an approved, properly operating automatic temperature control valve. The valve must control the water temperature at the point of use so it will not exceed one hundred twenty (120) degrees Fahrenheit.

(3) An operating mechanical exhaust device is required and must replace the air in the facility at least six (6) times per hour.

(4) Exterior openings shall be screened utilizing screening of not less than sixteen (16) mesh.

(5) Entrances to toilet and bathing facilities shall have self-closing doors.

(6) Toilet and bathing facilities shall be configured to prevent viewing of the interior through the entrance door.

(7) Light fixtures shall have guards or shields to prevent shattering.

(8) At least twenty (20) foot-candles of light measured thirty (30) inches above the floor must be provided throughout the interior of any permanent facility within a campground.

(e) Campground plumbing fixtures shall comply with 675 IAC 16.

(f) Privies shall be constructed and maintained in compliance with Bulletin S.E. 11.

(g) Where electricity is available, campground privy interiors must have artificial illumination. Where electricity is not available, privies must be configured to allow natural light to enter for illumination.

(h) Campground sanitary facilities shall be:

(1) maintained in a clean condition and in good repair;

(2) properly lighted; and

(3) ventilated.

(Indiana State Department of Health; 410 IAC 6-7.1-26; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3746)

410 IAC 6-7.1-27 Swimming pools and bathing beaches

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 27. (a) Swimming pools shall comply with 410 IAC 6-2 and 675 IAC 20.

(b) Bathing beaches shall comply with the following:

(1) Campground bathing beaches shall have a water surface area of at least one (1) acre.

(2) A minimum of twenty-five (25) square feet of water surface per bather shall be provided in areas having a water depth less than four (4) feet.

(3) At least seventy-five (75) square feet of water surface per bather shall be provided in areas over four (4) feet deep.

(4) A minimum of thirty (35) *[sic.]* square feet of land area shall be provided per bather.

(5) The campground bathing beach, from the shoreline out to a water depth of six (6) feet, shall consist of sand or pea gravel or other material to minimize turbidity.

(6) Floating marker lines securely anchored with buoys, spaced at intervals of no more than twenty-five (25) feet, shall be provided to designate the perimeter of the bathing area. Marker lines shall delineate the separation between the shallow (less than five (5) feet), deep, and diving areas. Depth markers shall be provided at diving areas.

(7) Toilet facilities shall be provided within five hundred (500) feet of the campground bathing beach, in the ratio of one (1) toilet for each fifty (50) bathers. Where flush toilets are provided, lavatories shall be provided in the ratio of one (1) lavatory for each fifty (50) bathers.

(8) Water samples shall be collected at the campground bathing beach for bacteriological examination and submitted to an approved laboratory for analysis. Samples shall be submitted in accordance with the following:

(A) One (1) sample at least two (2) weeks prior to opening.

(B) One (1) sample each week the bathing beach is open thereafter.

(C) One (1) sample after a heavy rainfall of at least one-half (½) inch.

(9) Bathing beach samples shall be collected within one (1) foot of the surface, in water having a depth of at least three (3) feet, but no more than six (6) feet and at least twenty (20) feet from swimmers and animals.

(10) The bathing beach must be closed if the beach water quality does not meet the following water quality standards:

(A) Escherichia coliform bacteria, using the membrane filter count, exceeds one hundred twenty-five (125) colonies per one hundred (100) milliliters as a geometric mean based on no less than five (5) samples equally spaced over a thirty (30) day period.

(B) Escherichia coliform bacteria using the membrane filter count exceeds two hundred thirty-five (235) colonies per one hundred (100) milliliters in any one (1) sample in a thirty (30) day period.

(C) The water has aquatic vegetation, deposits, growths, oil, grease, chemicals, or other substances capable of creating toxic reactions, skin, or membrane irritations, or a health or safety hazard.

(11) Results of each camp bathing beach water sample analysis must be reported to the department.

(12) The minimum safety equipment required at all bathing beaches shall include:

(A) a rescue tube; and

(B) a ring buoy with an attached rope at least forty-five (45) feet in length.

(13) Safety equipment shall be kept clean, in good repair, and ready for use.

(Indiana State Department of Health; 410 IAC 6-7.1-27; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3747)

410 IAC 6-7.1-28 Refuse collection and disposal

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 28. (a) Refuse, including garbage, shall be collected, stored, and disposed of properly so the campground is clean and litter free. Refuse shall not accumulate in a manner that could:

(1) result in rodent harborage or promote insect breeding; or

(2) cause a fire, safety, or health hazard.

(b) Each garbage can and dumpster in a campground shall be covered with a tight-fitting lid.

(c) Garbage and refuse collection and disposal shall occur at least once a week or more often when necessary.

(d) Community dumpsters shall be at least twenty-five (25) feet from any campsite. *(Indiana State Department of Health; 410 IAC 6-7.1-28; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3747)*

410 IAC 6-7.1-29 Electrical distribution system

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 29. (a) After the effective date of this rule, all new wiring, lighting, and electrical hook-ups shall be installed in compliance with 675 IAC 17. Existing wiring, lighting, and electrical hook-ups shall be installed and maintained in a safe condition.

(b) Fifteen (15) and twenty (20) ampere, one hundred twenty-five (125) volt receptacles at sanitary facilities shall have approved ground fault circuit interrupter protection.

(c) Electrical receptacles shall have wiring and circuit breakers or fuses sized to conform to the amperage of the receptacle they supply.

(d) Switches, circuit breakers, receptacles, control equipment, and metering devices located in wet places or outside a building shall be weatherproof.

(e) Splices in electrical wires in accessible locations shall be made in approved junction boxes.

(f) When underground conductors enter or leave a building or a trench, they shall have mechanical protection from physical damage. The protection must be rigid conduit, intermediate metal conduit, rigid nonmetallic conduit, schedule 80 electrical plastic tubing, or other mechanical means. Underground conductors in conduit shall be a minimum of eighteen (18) inches below finished grade. Underground conductors not in conduit shall be a minimum of twenty-four (24) inches below finished grade.

(g) Electrical equipment and conductors shall not be attached to trees. *(Indiana State Department of Health; 410 IAC 6-7.1-29; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3748)*

410 IAC 6-7.1-30 Emergency equipment and services

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 30. Telephone service shall be made available to all campers, and access shall be provided at all times to such service for emergency use. *(Indiana State Department of Health; 410 IAC 6-7.1-30; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3748)*

410 IAC 6-7.1-31 Registration

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 31. A register containing the name and home address of the campsite occupant and the dates of arrival and departure must be maintained and available for inspection by the department or the local health officer. *(Indiana State Department of Health; 410 IAC 6-7.1-31; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3748)*

410 IAC 6-7.1-32 Right of entry

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 32. The department or the local health officer may enter public or private property at reasonable times and, upon presentation of credentials, to do any of the following:

(1) Inspect facilities, equipment, or records.

(2) Investigate allegations, conduct tests, or collect samples.

(3) Obtain information necessary to the issuance of a permit pursuant to this rule.

(4) Determine whether any person is subject to, or in violation of, this rule or a permit issued pursuant to this rule.

(Indiana State Department of Health; 410 IAC 6-7.1-32; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3748)

410 IAC 6-7.1-33 Local authorities

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 33. Local health officers may enforce the rules of the department. County and municipal authorities within their respective jurisdictions have jurisdiction over zoning, building codes, and ordinances pertaining to campgrounds. *(Indiana State Department of Health; 410 IAC 6-7.1-33; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3748)*

410 IAC 6-7.1-34 Incorporation by reference

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 34. Bulletin S.E. 11 and Bulletin S.E. 13 are incorporated by reference as part of this rule. Copies of these bulletins may be obtained by request to the department. *(Indiana State Department of Health; 410 IAC 6-7.1-34; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3748)*

410 IAC 6-7.1-35 Enforcement

Authority: IC 16-19-3-4
Affected: IC 4-21.5-3-6; IC 4-21.5-3-8; IC 16-19-3

Sec. 35. The department may commence an action under IC 16-19-3-4, IC 16-19-3-5, and IC 4-21.5-3-6, or IC 4-21.5-3-8 against a campground operator who:

(1) fails to comply with this rule; or

(2) interferes with or obstructs the department or its designated agent in the performance of duties pursuant to this rule.

(Indiana State Department of Health; 410 IAC 6-7.1-35; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3748)

Rule 7.2. Youth Camps

410 IAC 6-7.2-1 Definitions

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 6-7.2-1; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-2 "Bathing beach" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 2. "Bathing beach" means a body of water not contained within a structure, chamber, or tank and used for swimming, diving, or recreational bathing. *(Indiana State Department of Health; 410 IAC 6-7.2-2; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-3 "Camp" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 3. "Camp" means a youth camp. *(Indiana State Department of Health; 410 IAC 6-7.2-3; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-4 "Department" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 4. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 6-7.2-4; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-5 "Designated adult" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 5. "Designated adult" means the individual with the primary responsibility for health matters, food, staff supervision, the administration of program operations, and business and transportation services. *(Indiana State Department of Health; 410 IAC 6-7.2-5; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-6 "Gray water" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 6. "Gray water" means wastewater originating from dish washing, hand washing, laundering, showers, or sinks. *(Indiana State Department of Health; 410 IAC 6-7.2-6; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-7 "Local health officer" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 7. "Local health officer" means the health officer of any local health department or their authorized representative. *(Indiana State Department of Health; 410 IAC 6-7.2-7; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-8 "Person" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 8. "Person" means any individual, firm, partnership, company, corporation, trustee, association, municipality, county, authority, estate, or public or private entity owning, conducting, controlling, managing, or operating a camp. *(Indiana State Department of Health; 410 IAC 6-7.2-8; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-9 "Primitive camp" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 9. "Primitive camp" means a youth camp that operates at a site having only tents. *(Indiana State Department of Health; 410 IAC 6-7.2-9; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-10 "Public sewer" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 10. "Public sewer" means a sewage disposal facility provided by a utility, municipality, conservancy district, or regional sewer district. *(Indiana State Department of Health; 410 IAC 6-7.2-10; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-11 "Public water supply" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 11. "Public water supply" means water supplied by a utility, municipality, conservancy district, regional water district, rural water corporation, or not-for-profit water corporation. *(Indiana State Department of Health; 410 IAC 6-7.2-11; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-12 "Tent" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 12. "Tent" means a shelter having twenty-five percent (25%) or more of its walls or roof, or both, covered by fabric material. *(Indiana State Department of Health; 410 IAC 6-7.2-12; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3749)*

410 IAC 6-7.2-13 "Water station" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 13. "Water station" means a facility for filling water storage containers with potable water from an approved water system. *(Indiana State Department of Health; 410 IAC 6-7.2-13; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3750)*

410 IAC 6-7.2-14 "Youth camp" defined

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 14. "Youth camp" means any area or tract of land established, operated, or maintained to provide more that seventy-two (72) continuous hours of outdoor group living experiences away from established residences for educational, recreational, sectarian, or health purposes to ten (10) or more children who are under eighteen (18) years of age and not accompanied by a parent or guardian. *(Indiana State Department of Health; 410 IAC 6-7.2-14; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3750)*

410 IAC 6-7.2-15 Construction permit requirement

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 15. Any person planning the construction, addition to, or significant change in the construction of any youth camp shall, at least ninety (90) days prior to the initiation of any such construction, submit plans, drawn to scale, for review and approval by the department. These plans must be certified by a registered engineer or architect licensed to practice in Indiana. *(Indiana State Department of Health; 410 IAC 6-7.2-15; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3750)*

410 IAC 6-7.2-16 General supervision

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 16. When a youth camp is in session, there shall be a designated adult on the premises who is responsible for compliance with this rule. *(Indiana State Department of Health; 410 IAC 6-7.2-16; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3750)*

410 IAC 6-7.2-17 General health

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 17. (a) When a youth camp is in session, there shall be an individual present who is designated as the health supervisor and who has completed at least the Red Cross Standard First Aid Course or its equivalent.

(b) A member of the camp health staff shall conduct a health screening of each camper to identify any illness or communicable disease. The screening shall:

(1) occur not more than twelve (12) hours after arrival at camp; and

(2) include a check of medications in use by each camper.

(c) Youth camps shall maintain an up to date medical log. The medical log shall be in permanent ink and be a record of the dates, times, patient names, ailments, treatments, names of attending staff, and signature of the staff member who made the entries into the log.

(d) Medication prescribed for campers or staff members shall be dispensed from original containers.

(e) Medications, except those a physician prescribed for self-administration, shall be locked in a cabinet, box, or drawer or stored in a safe place inaccessible to children.

(f) Whenever there is an injury or illness to a camper that results in hospitalization, a positive x-ray or laboratory analysis, or the camper is being sent home, a report shall be sent to the department. This report shall be:

(1) made on a form acceptable to the department; and

(2) filed with the department within ten (10) days of an incident.

(g) Whenever there is an injury or illness that results in the death of a camper or staff member, a report of the incident and death shall be filed with the department within twenty-four (24) hours of the death.

(h) The use of tobacco products or alcohol is prohibited in buildings used by children, in the presence of children, or in areas that will be occupied by children. *(Indiana State Department of Health; 410 IAC 6-7.2-17; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3750)*

410 IAC 6-7.2-18 Infirmary

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 18. (a) Youth camps constructed after the effective date of this rule shall include a separate room with toilet and lavatory facilities to be used as an infirmary and isolation area.

(b) The separate room described in subsection (a) shall have the following:

(1) Ventilation to keep it free of excessive heat, condensation, vapors, noxious odors, and fumes.

(2) Heating equipment capable of maintaining a temperature of at least sixty-eight (68) degrees Fahrenheit.

(3) At least one (1) cot per one hundred (100) campers and staff, with a minimum of two (2) cots.

(4) At least one (1) adult shall be present when campers are in the infirmary.

(5) At least seventy (70) foot-candles of light measured thirty (30) inches from the floor.

(Indiana State Department of Health; 410 IAC 6-7.2-18; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3750)

410 IAC 6-7.2-19 First aid kits

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 19. (a) First aid kits shall be available to camp staff at food service operations, beaches, the infirmary, the camp office, primitive camps, and readily available in a timely manner to all program areas. First aid may be administered only by properly trained staff.

(b) As a minimum, each first aid kit must include the following:

(1) One (1) watertight medication canister.
(2) Thirty (30) adhesive bandages, each measuring one (1) inch by three (3) inches.
(3) One (1) roll of adhesive tape measuring one-half (½) inch by ten (10) yards.
(4) Nine (9) antiseptic towelettes.
(5) Two (2) disposable gloves, such as surgical or examination type.
(6) One (1) triangular bandage.
(7) Six (6) sponge dressing pads, each measuring two (2) inches by two (2) inches.
(8) Four (4) sponge dressing pads, each measuring three (3) inches by three (3) inches.
(9) Two (2) sponge dressing pads, each measuring four (4) inches by four (4) inches.
(10) One (1) instant ice compress measuring at least six (6) inches by four (4) inches.
(11) Two (2) large fabric fingertip bandages.
(12) Two (2) large fabric knuckle bandages.
(13) Two (2) island bandages each measuring two (2) inches by three (3) inches.
(14) Two (2) adhesive Telfa bandages each measuring two (2) inches by two (2) inches.
(15) One (1) eye pad.
(16) Three (3) providone-iodine pads.
(17) Six (6) alcohol cleansing pads.
(18) Three (3) tubes of triple-antibacterial cream.
(19) One (1) conform bandage roll measuring two (2) inches by five (5) yards.
(20) One (1) pair of scissors.
(21) One (1) pair of tweezers.
(22) One (1) emergency blanket.
(23) One (1) refillable plastic case.

(c) First aid materials shall be wrapped and stored so they do not become contaminated. *(Indiana State Department of Health; 410 IAC 6-7.2-19; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3751)*

410 IAC 6-7.2-20 Records

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 20. (a) A record for each camper must be maintained by the designated adult operating a camp and shall contain the following:

(1) The camper's name and address.
(2) The name, address, and telephone number of the camper's parent, legal guardian, or designated adult emergency contact.
(3) Authorization from the parent or guardian for emergency medical care.
(4) A list of relevant health conditions that camp personnel may encounter.

(b) Records required by this rule shall be kept on file by the designated adult for a period of at least two (2) years. *(Indiana State Department of Health; 410 IAC 6-7.2-20; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3751)*

410 IAC 6-7.2-21 Campsites and safety

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 21. (a) No condition, situation, or installation shall be created, installed, or maintained that:

(1) may cause or result in a health or safety hazard; or
(2) cause or transmit disease or harbor rodents or other vermin.

(b) An accurate plat of the camp shall be maintained that shows the location of buildings, wells, privies, sewage disposal

systems, sanitary facilities, swimming areas, and water and sewer lines.

(c) The central camp areas, primitive camps, and program areas shall be maintained to minimize the growth of poison ivy, poison oak, poison sumac, and other noxious plants.

(d) The camp shall be free of debris or other hazards.

(e) Building stairways over four (4) steps in height shall have handrails.

(f) Equipment and facilities in camps shall be designed, installed and maintained in a safe condition. Playground equipment shall be securely anchored.

(g) When not in use, archery equipment, firearms, and ammunition shall be locked in a cabinet or building.

(h) Poisonous substances, pool chemicals, pesticides, and toxic chemicals shall be clearly marked and stored in locked cabinets or enclosures. *(Indiana State Department of Health; 410 IAC 6-7.2-21; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3751)*

410 IAC 6-7.2-22 Emergency equipment and procedures

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 22. (a) Telephone service shall be provided to each youth camp as follows:

(1) Telephone service shall always be accessible at youth camps.

(2) The telephone number of the nearest fire department, police department, poison control center, and emergency medical service shall be posted next to each telephone. Where 911 service is available, only the poison control center telephone number must be posted.

(b) A written emergency plan for dealing with natural disasters, lost campers, and other emergencies must be developed and maintained. At a minimum, the plan shall include procedures for evacuation and transportation to emergency facilities. Camp staff shall be trained on the plan and a record of the training shall be kept by a responsible adult. Campers shall be advised of their responsibilities in following the plan.

(c) Camps offering aquatic activities must have an emergency plan that includes procedures for rescues, accounting for each camper, evacuations, and the method for notification of emergency services. Weekly orientation in using the aquatic emergency plan must be conducted. *(Indiana State Department of Health; 410 IAC 6-7.2-22; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3752)*

410 IAC 6-7.2-23 Fire and building safety

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 23. (a) Each youth camp shall be equipped with a minimum of a 4-A, 60-B:C, ten (10) pound, multipurpose, dry chemical, pressure fire extinguisher within one hundred (100) feet of of *[sic.]* each kitchen, furnace room, and sleeping facilities.

(b) Fire extinguishers must be readily accessible and maintained in an operable condition.

(c) Exits from structures must be maintained free of obstructions and have exit signs clearly posted.

(d) Buildings with occupancy of more than ten (10) persons shall have at least two (2) separate and independent exits. Exits shall not be closer to each other than fifty percent (50%) of the longest exterior dimension of the building.

(e) Buildings with occupancy above the first floor shall have two (2) separate and independent exits. At least one (1) exit shall lead directly to the outside.

(f) A one-room building used for sleeping shall be equipped with a smoke detector.

(g) Buildings with two (2) or more compartmentalized sleeping rooms shall have hard-wired interconnected smoke detectors.

(h) All required smoke detectors shall be UL listed.

(i) All required smoke detectors shall be kept clean and tested monthly.

(j) Fire drills shall be held within twenty-four (24) hours of the beginning of each camping session and weekly thereafter.

(k) Gasoline and other flammable fluids shall be marked and stored in locked containers or in locked buildings not occupied by campers.

(l) Gasoline and other flammable fluids shall be stored at least fifty (50) feet from sleeping quarters. *(Indiana State Department of Health; 410 IAC 6-7.2-23; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3752)*

410 IAC 6-7.2-24 Electrical safety

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 24. (a) Wiring, lighting, and electrical receptacles shall be installed and maintained in a safe condition.

(b) Fifteen (15) and twenty (20) ampere, one hundred twenty-five (125) volt receptacles in sanitary facilities, bathrooms, garages, or maintenance buildings or located outside of buildings shall be equipped with ground-fault circuit interrupter protection.

(c) Electrical receptacles shall have wiring and circuit breakers or fuses sized to conform to the amperage of the receptacles they supply.

(d) Electrical switches, circuit breakers, receptacles, control equipment, and metering devices located in wet places or outside of a building shall be weatherproof.

(e) Splices to electrical wires at accessible locations shall be made utilizing approved junction boxes.

(f) In areas subject to vehicle movement, service drop conductors of not over six hundred (600) volts nominal, shall be at least eighteen (18) feet above the ground surface. In other areas, the minimum clearance shall be ten (10) feet above the ground surface.

(g) Electrical equipment and conductors shall not be attached to trees.

(h) Electrical receptacles shall be grounded and shall not have an open neutral, open hot conductor, or reverse polarity.

(i) Loose electrical equipment shall be secured. Face plates and panel fronts shall be in place to prevent accidental contact. *(Indiana State Department of Health; 410 IAC 6-7.2-24; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3752)*

410 IAC 6-7.2-25 Water supplies

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 25. (a) Camps shall be provided with an adequate and convenient supply of potable water that meets the Indiana department of environmental management public water supply drinking water quality standard found in 327 IAC 8. Potable water shall always be available for culinary, drinking, laundry, and bathing purposes.

(b) Wells shall be constructed, installed, and located in accordance with 327 IAC 8 and 310 IAC 16.

(c) A camp shall exclusively use a public water supply if public water is available within a reasonable distance. If a public water supply is not available, a camp shall have water supplied from a well that complies with 327 IAC 8.

(d) The construction and location of all camp wells with less than fifteen (15) service connections or serving less than twenty-five (25) people shall comply with all the requirements of this rule.

(e) Camp water supply and distribution systems shall have the capacity to deliver a minimum water pressure of twenty (20) pounds per square inch to all water stations and connections during periods of peak water usage. The water supply shall have capacity to meet total daily water demands. If a well or pump cannot meet peak or daily water demand, camps shall be provided with sufficient usable storage capacity to meet the demand.

(f) The casing pipe of a well shall project not less than:

(1) twenty-four (24) inches above floor level or finished grade;

(2) thirty-six (36) inches above the regulatory flood elevation if located in a designated flood hazard area identified by the Federal Emergency Management Agency.

(g) Water supplies shall have no well head, well casing, pump, pumping machinery, exposed pressure tanks, or suction piping located in any pit, room, or enclosed space that does not have free drainage, by gravity, to the ground surface at all times.

(h) Wells and potable water distribution systems shall be disinfected after construction and after a repair. The water shall be tested and be bacteriologically acceptable in at least two (2) consecutive samples collected at least twenty-four (24) hours apart before the potable water system can be used.

(i) There shall be no direct physical connection between the camp potable water supply system and any nonpotable water supply system.

(j) Stop-and-waste valves or yard hydrants that would allow aspiration or back flow of contaminated water into the potable water system shall not be used.

(k) Common drinking cups are not permitted.

(l) When potable water is transported, it shall be in closed, disinfected containers used for no other purpose.

(m) Plumbing fixtures shall comply with 675 IAC 16. *(Indiana State Department of Health; 410 IAC 6-7.2-25; filed Jun 27,*

2002, 1:30 p.m.: 25 IR 3753)

410 IAC 6-7.2-26 Sewage disposal

Authority: IC 16-19-3-4
Affected: IC 13-18-12; IC 16-19-3

Sec. 26. (a) Sewage shall be disposed of by a connection to a public sewer, if available within a reasonable distance from the camp. If a public sewer is not available within a reasonable distance from the camp, sewage disposal must comply with 410 IAC 6-12, 410 IAC 6-10, Bulletin S.E. 11, Bulletin S.E. 13, or applicable rules of the Indiana department of environmental management for sewage disposal facilities other than sanitary vault privies or septic tank soil-absorption systems.

(b) Only wastewater management businesses licensed pursuant to IC 13-18-12 shall clean camp privies and portable toilets of waste. Privies must be pumped when the accumulated waste is within eighteen (18) inches of the privy floor. *(Indiana State Department of Health; 410 IAC 6-7.2-26; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3753)*

410 IAC 6-7.2-27 Sanitary facilities

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 27. (a) The entrance to a sanitary facility shall have a sign to designate which sex may use the facility. Solid walls extending from floor to ceiling shall separate facilities for each sex located in the same building.

(b) Toilets, urinals, hand washing, and bathing facilities shall be provided as follows:

Males

Individuals to be served	Showers	Lavatories	Toilets	Urinals*
1–10	1	2	1	1
11–20	2	2	1	1
21–30	2	3	2	1
31–40	3	4	2	2
41–50	4	5	3	2
51–60	5	6	3	3
61–70	6	7	4	3

*Toilets may be substituted for the appropriate number of urinals.

Females

Individuals to be served	Showers	Lavatories	Toilets
1–10	1	2	2
11–20	2	2	2
21–30	2	3	3
31–40	3	4	4
41–50	4	5	5
51–60	5	6	6
61–70	6	7	7

(c) Camps serving more than seventy (70) campers shall have sanitary facilities for each sex in the ratio of one (1) shower, lavatory, and toilet or urinal for each fifteen (15) additional campers.

(d) Showers or lavatories are not required at primitive camps.

(e) For all common use rooms that contain sanitary or laundry facilities, excluding sanitary vault privies and portable toilets, the following minimum requirements shall apply:

(1) Floors, walls, and partitions around showers, lavatories, and other plumbing fixtures shall be smooth, nonabsorbent, and easily cleanable. Floors in hand washing and shower rooms shall have a nonskid finish and trapped floor drains.

(2) Bathing and hand washing facilities shall have hot and cold water under pressure. Bathing facilities shall have an approved properly operating, approved automatic hot water temperature control valve. The valve must control the water temperature at the point of use so it will not exceed one hundred twenty (120) degrees Fahrenheit.

(3) An operating mechanical exhaust device must replace the air in the facility at least six (6) times per hour.

(4) Exterior openings shall be screened with at least sixteen (16) mesh screen to prevent the entrance of insects.
(5) Entrances to toilets and bathing facilities shall have self-closing doors.
(6) Toilet and bathing facilities shall be configured to prevent viewing of the interior through the entrance door.
(7) Light fixtures shall have guards or shields to prevent shattering.
(8) At least twenty (20) foot-candles of light measured thirty (30) inches above the floor must be provided throughout the interior of the facility.
(9) Lavatories shall have mixing or combination faucets. Self-closing, slow closing, or metering faucets shall provide a flow of water for at least fifteen (15) seconds.
(10) Lavatories and hand washing facilities shall be located within twenty-five (25) feet of toilets. Water, soap, and paper towels or a mechanical hand drying device shall be provided at hand washing facilities that are available to all campers. Common towels are prohibited.
(11) Sanitary facilities must have a roof with an overhang to prevent drainage into the structure.
(12) Sanitary facilities shall be maintained in a clean condition and in good repair.
(f) Toilet paper shall be available at all times in toilets and privies.
(g) Privies shall be constructed and maintained in compliance with Bulletin S.E. 11.
(h) Where electricity is available, the privy interior must have artificial illumination. Where electricity is not available, the privy must allow natural light to enter for illumination.
(i) Hand washing facilities, or a dispenser with moistened disposable towelettes, shall be located within twenty-five (25) feet of a privy.
(j) Toilet facilities shall be located within five hundred (500) feet of each sleeping area. *(Indiana State Department of Health; 410 IAC 6-7.2-27; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3753)*

410 IAC 6-7.2-28 Cooking and eating facilities

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 28. (a) Central kitchen and dining halls shall comply with 410 IAC 7-20.
(b) Kitchens separate from the central dining hall and used for individual campers to prepare meals shall meet the following requirements:
(1) Provide a refrigerator and a range with a ventilation hood.
(2) Provide a three (3) compartment sink or a two (2) compartment sink and a dishwasher or use only single service dishes and utensils.
(3) Provide a numerically scaled indicating thermometer in each refrigerator accurate to plus or minus three (3) degrees Fahrenheit, located as to be easily readable.
(4) Provide shielded or guarded light fixtures providing at least seventy (70) foot-candles of light on all food preparation surfaces and at equipment or utensil washing areas.
(5) Provide a hand washing lavatory having hot and cold water and a combination faucet.
(6) Provide the hand washing lavatory with a supply of hand cleansing soap and a supply of sanitary towels or a hand drying device. Sinks used for food preparation or food washing equipment shall not be used for hand washing.
(7) Common towels are prohibited.
(8) Provide a mop sink for use and disposal of mop water. Food preparation sinks shall not be used for this purpose.
(Indiana State Department of Health; 410 IAC 6-7.2-28; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3754; errata filed Jul 8, 2002, 1:47 p.m.: 25 IR 3769)

410 IAC 6-7.2-29 Buildings and sleeping shelters

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 29. (a) Buildings, structures, tents, and cabins shall be kept in good repair and maintained in a safe and sanitary condition.
(b) Floors and floor coverings in buildings used for sleeping or camp activities shall be in good repair and easily cleanable.
(c) Buildings used for sleeping shall have screened openable windows equal to at least ten percent (10%) of the floor area.

(d) Outside openings shall be screened with at least sixteen (16) mesh screen to prevent the entrance of insects.

(e) Screened doors shall be tight-fitting, in good repair, and self-closing.

(f) At least thirty (30) square feet of floor space per camper must be provided in rooms used for sleeping.

(g) Beds shall be arranged so the heads of the sleepers are at least six (6) feet apart and there is at least thirty (30) inches between the sides of the beds.

(h) Sleeping rooms shall have a minimum ceiling height of seven (7) feet.

(i) Bedding provided by the camp operator shall be clean and washed before use by a new camper.

(j) Foam bed mattresses shall be provided with easily cleanable mattress covers.

(k) Vertical separation between the top of the lower mattress of a double deck bunk and the upper bunk shall be a minimum of twenty-seven (27) inches. The vertical separation from the top of the upper mattress to the ceiling shall be a minimum of thirty-six (36) inches.

(l) Bunk beds used by campers shall be equipped with guardrails on the upper bunk. Guardrails are required on any side of a bunk not placed tightly against a wall.

(m) At least twenty (20) foot-candles of light shall be provided throughout buildings used for sleeping.

(n) Tent material shall be flame-retardant. *(Indiana State Department of Health; 410 IAC 6-7.2-29; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3755)*

410 IAC 6-7.2-30 Water recreation

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 30. (a) An individual currently certified as a lifeguard and having a current cardiopulmonary resuscitation (CPR) certification must direct swimming, boating, canoeing, watercraft, water skiing, and other aquatic activities.

(b) A minimum of one (1) counselor for each fifteen (15) campers shall supervise watercraft and swimming activities.

(c) At each aquatic site, a minimum of one (1) currently certified lifeguard for each thirty (30) campers must be provided.

(d) Swimming pools shall comply with 410 IAC 6-2 and 675 IAC 20.

(e) In addition to the requirements of 410 IAC 6-2 and 675 IAC 20, swimming pools less than two thousand (2,000) square feet shall have one (1) or more qualified lifeguards on duty when the pool is in use by campers.

(f) Watercraft activity participants must wear a Type II or Type III U.S. Coast Guard approved personal flotation device.

(g) Bathing beaches shall comply with the following:

(1) Camp bathing beaches shall have a water surface area of at least one (1) acre.

(2) A minimum of twenty-five (25) square feet of water surface per bather shall be provided in areas having a water depth less than four (4) feet.

(3) At least seventy-five (75) square feet of water surface per bather shall be provided in areas over four (4) feet deep.

(4) A minimum of thirty-five (35) square feet of land area shall be provided per bather.

(5) The camp bathing beach, from the shoreline out to a water depth of six (6) feet, shall consist of pea gravel or other material approved by the department of natural resources to minimize turbidity.

(6) Floating marker lines securely anchored with buoys, spaced at intervals of no more than twenty-five (25) feet, shall be provided to designate the perimeter of the bathing area. Marker lines shall delineate the separation between the shallow (less than five (5) feet), deep, and diving areas. Depth markers shall be provided at diving areas.

(7) Toilet facilities shall be provided within five hundred (500) feet of camp bathing beaches, in the ratio of one (1) toilet for each fifty (50) bathers. Where flush toilets are provided lavatories shall be provided in the ratio of one (1) lavatory for each fifty (50) bathers.

(8) Water samples shall be collected at the camp bathing beach for bacteriological examination and submitted to an approved laboratory for analysis. Samples shall be submitted in accordance with the following:

(A) One (1) sample at least two (2) weeks prior to opening.

(B) One (1) sample each week the bathing beach is open thereafter.

(C) One (1) sample after a heavy rainfall of at least one-half (½) inch.

(9) Bathing beach samples shall be collected within one (1) foot of the surface, in water having a depth of at least three (3) feet, but no more than six (6) feet and at least twenty (20) feet from swimmers and animals.

(10) The bathing beach must be closed if the beach water quality does not meet the following water quality standards:

(A) Escherichia coliform bacteria, using the membrane filter count, exceeds one hundred twenty-five (125) colonies per one hundred (100) milliliters as a geometric mean based on no less than five (5) samples equally spaced over a thirty (30) day period.

(B) Escherichia coliform bacteria using the membrane filter count exceeds two hundred thirty-five (235) colonies per one hundred (100) milliliters in any one (1) sample in a thirty (30) day period.

(C) The water has aquatic vegetation, deposits, growths, oil, grease, chemicals, or other substances capable of creating toxic reactions, skin or membrane irritations, or a health or safety hazard.

(11) Results of each camp bathing beach water sample analysis must be reported to the department.

(12) At least one (1) qualified lifeguard shall be on duty when the bathing beach is open to swimmers.

(13) A lifeguard shall be stationed at each diving area.

(14) Each lifeguard station shall have a clear and unobstructed view of the lifeguard's area of responsibility and at least one (1) lifeguard station at the diving area and on shore shall be an elevated stand.

(15) Land based lifeguard stations shall be located within thirty (30) feet of the shoreline.

(16) Lifeguard stations shall be equipped with a whistle or megaphone and sunglasses.

(17) When performing as a lifeguard, lifeguards shall not perform any other tasks and shall not be in the water except in the line of duty.

(18) A spine board with ties and cervical collar shall be provided at each aquatic location.

(19) A rescue tube shall be provided at each lifeguard station.

(20) Required safety equipment shall be kept clean, in good repair, and ready for use.

(Indiana State Department of Health; 410 IAC 6-7.2-30; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3755)

410 IAC 6-7.2-31 Refuse collection

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 31. (a) Refuse, including garbage, shall be collected, stored, and disposed of properly so the camp is clean and litter free. Refuse shall not accumulate in a manner that could:

(1) result in rodent harborage or promote insect breeding; or

(2) cause a fire, safety, or health hazard.

(b) Each garbage can and dumpster in a camp shall be covered with a tight-fitting lid at all times except during use.

(c) Garbage and refuse shall be collected at least once per week or more often when necessary.

(d) Burning of garbage and refuse is not permitted.

(e) Garbage and refuse shall be stored in watertight, rodent proof, fly proof containers. Unless plastic liners are used, garbage containers shall be cleaned when emptied.

(f) Dumpsters shall be located at least fifty (50) feet from sleeping areas. *(Indiana State Department of Health; 410 IAC 6-7.2-31; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3756)*

410 IAC 6-7.2-32 Animal and pest control

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 32. (a) Animal shelters, corrals, tie rails, or hitching posts shall not be located within two hundred (200) feet of a dining hall, kitchen, or other place where food is prepared, cooked, or served.

(b) Buildings, grounds, and storage areas shall be kept free of insect and rodent infestations and free of refuse that could harbor rodents, mosquitoes, flies, and other pests.

(c) Lumber, pipe, and other building materials shall be stored at least four (4) inches above the ground. *(Indiana State Department of Health; 410 IAC 6-7.2-32; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3756)*

410 IAC 6-7.2-33 Right of entry

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 33. The department or the local health officer may enter public or private property at reasonable times and, upon presentation of credentials, to do any of the following:

(1) Inspect facilities, equipment, or records.

(2) Investigate allegations, conduct tests, or collect samples.

(3) Obtain information necessary to the issuance of a permit pursuant to this rule.

(4) Determine whether any person is subject to, or in violation of, this rule or a permit issued pursuant to this rule.

(Indiana State Department of Health; 410 IAC 6-7.2-33; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3757)

410 IAC 6-7.2-34 Incorporation by reference

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 34. Bulletin S.E. 11 and Bulletin S.E. 13 are incorporated by reference as part of this rule. Copies of these bulletins may be obtained free of charge by mailing a request to the department. *(Indiana State Department of Health; 410 IAC 6-7.2-34; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3757)*

410 IAC 6-7.2-35 Local authorities

Authority: IC 16-19-3-4
Affected: IC 16-19-3

Sec. 35. Local health officers may enforce the rules of the department. County and municipal authorities within their respective jurisdictions have jurisdiction over zoning, building codes, and ordinances pertaining to camps. *(Indiana State Department of Health; 410 IAC 6-7.2-35; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3757)*

410 IAC 6-7.2-36 Enforcement

Authority: IC 16-19-3-4
Affected: IC 4-21.5-3-6; IC 4-21.5-3-8; IC 16-19-3-5

Sec. 36. The department may commence an action under IC 16-19-3-4, IC 16-19-3-5, and IC 4-21.5-3-6, or IC 4-21.5-3-8 against a camp operator who:

(1) fails to comply with this rule; or

(2) interferes with or obstructs the department or its designated agent in the performance of duties pursuant to this rule.

(Indiana State Department of Health; 410 IAC 6-7.2-36; filed Jun 27, 2002, 1:30 p.m.: 25 IR 3757)

Rule 8. Residential Sewage Disposal Systems (Repealed)

(Repealed by Indiana State Department of Health; filed Nov 20, 1990, 12:45 p.m.: 14 IR 651)

Rule 8.1. Residential Sewage Disposal Systems

410 IAC 6-8.1-1 "ABS" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 1. As used in this rule, "ABS" means acrylonitrile-butadiene-styrene. *(Indiana State Department of Health; 410 IAC 6-8.1-1; filed Nov 20, 1990, 12:45 p.m.: 14 IR 625; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-2 "ASTM" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 2. As used in this rule, "ASTM" means American Society for Testing and Materials. *(Indiana State Department of Health; 410 IAC 6-8.1-2; filed Nov 20, 1990, 12:45 p.m.: 14 IR 625; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-3 "Board" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 3. As used in this rule, "board" means the Indiana state board of health. *(Indiana State Department of Health; 410 IAC 6-8.1-3; filed Nov 20, 1990, 12:45 p.m.: 14 IR 625; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-4 "Commissioner" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 4. As used in this rule, "commissioner" means the commissioner of the Indiana state board of health or his legally authorized representative. *(Indiana State Department of Health; 410 IAC 6-8.1-4; filed Nov 20, 1990, 12:45 p.m.: 14 IR 625; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-5 "Distribution box" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 5. As used in this rule, "distribution box" means a structure designed to distribute effluent by gravity from a septic tank equally into the pipes of an absorption system connected thereto. *(Indiana State Department of Health; 410 IAC 6-8.1-5; filed Nov 20, 1990, 12:45 p.m.: 14 IR 625; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-6 "Drainageway" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 6. As used in this rule, "drainageway" means the channel portion of the landscape in which surface water or rainwater run-off gathers intermittently to flow to a lower elevation. *(Indiana State Department of Health; 410 IAC 6-8.1-6; filed Nov 20, 1990, 12:45 p.m.: 14 IR 625; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-7 "Dwelling" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 7. As used in this rule, "dwelling" means any house or place used or intended to be used as a place of seasonal or permanent human habitation or for sleeping for one (1) or two (2) families. *(Indiana State Department of Health; 410 IAC 6-8.1-7; filed Nov 20, 1990, 12:45 p.m.: 14 IR 625; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-8 "Residential sewage disposal system failure" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 8. As used in this rule, "residential sewage disposal system failure" means a residential sewage disposal system which exhibits one (1) or more of the following:

(1) The system refuses to accept sewage at the rate of design application thereby interfering with the normal use of residential plumbing fixtures.

(2) Effluent discharge exceeds the absorptive capacity of the soil, resulting in ponding, seepage, or other discharge of the

effluent to the ground surface or to surface waters.

(3) Effluent is discharged from the system causing contamination of a potable water supply, ground water, or surface waters. A failed residential sewage disposal system is a health hazard.

(Indiana State Department of Health; 410 IAC 6-8.1-8; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-8.1-9 "Fill" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 9. As used in this rule, "fill" means soil transported and deposited by man, as well as soil recently transported and deposited by natural erosion forces. Fill is evidenced by one (1) or more of the following:

(1) No soil horizons or indistinct soil horizons.

(2) Depositional stratification.

(3) Presence of a soil horizon which has been covered.

(4) Materials in a horizon such as cinders or construction debris.

(5) Position in the landscape.

(Indiana State Department of Health; 410 IAC 6-8.1-9; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-8.1-10 "Foundation drain" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 10. As used in this rule, "foundation drain" means that portion of a residential drainage system provided to drain only ground water from outside of the foundation of the house or from under the basement floor. *(Indiana State Department of Health; 410 IAC 6-8.1-10; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-11 "Health officer" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 11. As used in this rule, "health officer" means the health officer of a local board of health. *(Indiana State Department of Health; 410 IAC 6-8.1-11; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-12 "Loading rate" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 12. As used in this rule, "loading rate" means the allowable rate of application of septic tank effluent to the soil. It is expressed in gallons per day per square foot. *(Indiana State Department of Health; 410 IAC 6-8.1-12; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-13 "Owner" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 13. As used in this rule, "owner" means the owner of a dwelling or his agent. *(Indiana State Department of Health; 410 IAC 6-8.1-13; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-14 "Person" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 14. As used in this rule, "person" means any individual, partnership, copartnership, firm, company, corporation, association, trust, estate, or any other legal entity, its or their successors, or assigns or agents of the aforesaid. *(Indiana State Department of Health; 410 IAC 6-8.1-14; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-15 "PVC" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 15. As used in this rule, "PVC" means polyvinyl chloride. *(Indiana State Department of Health; 410 IAC 6-8.1-15; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-16 "Residential drain" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 16. As used in this rule, "residential drain" means the horizontal piping in a house drainage system which receives the discharge from soil, waste, and drainage pipes inside the walls of the house and conveys the same to the residential sewer. *(Indiana State Department of Health; 410 IAC 6-8.1-16; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-17 "Residential sewage disposal system" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 17. As used in this rule, "residential sewage disposal system" means all equipment and devices necessary for proper conduction, collection, storage, treatment, and on-site disposal of sewage from a one (1) or two (2) family dwelling. Included within, but not limited to the scope of this definition, are residential sewers, septic tanks, soil absorption systems, temporary sewage holding tanks, and sanitary vault privies. *(Indiana State Department of Health; 410 IAC 6-8.1-17; filed Nov 20, 1990, 12:45 p.m.: 14 IR 626; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-18 "Residential sewer" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 18. As used in this rule, "residential sewer" means the horizontal piping beginning two (2) feet outside the house which carries discharges from the residential drain to its connection with a sanitary sewerage system or a residential sewage disposal system. *(Indiana State Department of Health; 410 IAC 6-8.1-18; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-19 "Sanitary sewerage system" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 19. As used in this rule, "sanitary sewerage system" means a sewer or a system of sewers which convey sewage away from the lot on which it originates to a wastewater treatment facility owned and operated by an incorporated city or town, conservancy district, regional sewer district, or private utility. *(Indiana State Department of Health; 410 IAC 6-8.1-19; filed Nov*

20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-8.1-20 "SCS" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 20. As used in this rule, "SCS" means United States Department of Agriculture, Soil Conservation Service. *(Indiana State Department of Health; 410 IAC 6-8.1-20; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-21 "SDR" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 21. As used in this rule, "SDR" means standard dimension ratio. *(Indiana State Department of Health; 410 IAC 6-8.1-21; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-22 "Septic tank" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 22. As used in this rule, "septic tank" means a water tight structure into which sewage is discharged for settling and solids digestion. *(Indiana State Department of Health; 410 IAC 6-8.1-22; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-23 "Sewage" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 23. As used in this rule, "sewage" means all water-carried waste derived from ordinary living processes. *(Indiana State Department of Health; 410 IAC 6-8.1-23; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-24 "Sludge" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 24. As used in this rule, "sludge" means the digested or partially digested solid material accumulated in a septic tank. *(Indiana State Department of Health; 410 IAC 6-8.1-24; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-25 "Soil absorption" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 25. As used in this rule, "soil absorption" means a process which utilizes the soil to treat and dispose of effluent from a septic tank. *(Indiana State Department of Health; 410 IAC 6-8.1-25; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-26 "Soil absorption system" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 26. As used in this rule, "soil absorption system" means pipes laid in a system of trenches or elevated beds into which the effluent from the septic tank is discharged for soil absorption. *(Indiana State Department of Health; 410 IAC 6-8.1-26; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-27 "Soil horizon" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 27. As used in this rule, "soil horizon" means a layer of soil or soil material approximately parallel to the land surface and differing from adjacent genetically related layers in physical, chemical, and biological properties or characteristics such as color, structure, texture, consistency, kinds and numbers of organisms present, and degree of acidity or alkalinity. *(Indiana State Department of Health; 410 IAC 6-8.1-27; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-28 "Soil profile analysis" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 28. As used in this rule, "soil profile analysis" means the observation and evaluation of the physical characteristics of the soil horizons or layers to a depth of at least five (5) feet or, if shallower, to a layer which cannot be readily penetrated. *(Indiana State Department of Health; 410 IAC 6-8.1-28; filed Nov 20, 1990, 12:45 p.m.: 14 IR 627; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-29 "Soil scientist" defined

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 29. As used in this rule, "soil scientist" means an individual with a baccalaureate degree with a major in agronomy, soils, or a closely allied field of science who is proficient in the application of the principles of pedology to soil classification, investigation, education, and consultation and on the effect of measured, observed, and inferred soil properties and their use. *(Indiana State Department of Health; 410 IAC 6-8.1-29; filed Nov 20, 1990, 12:45 p.m.: 14 IR 628; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-30 Administrative authority

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 30. (a) This rule shall be administered by the local boards of health through their health officer and his authorized representatives.

(b) Local boards of health which wish to adopt or amend a local ordinance governing the design, construction, and operation of residential sewage disposal systems shall do so only after the commissioner has confirmed in writing that the ordinance does not violate this rule or state sewage disposal statutes.

(c) Each local health department residential sewage disposal system permit program is subject to review by the board. Such review may include, but not be limited to, a review of the permits issued, supporting documentation, and a review of system installations.

(d) Whenever the board determines that there has been a violation of this rule, the commissioner shall notify the health officer. Such notice shall:

(1) be in writing;

(2) be sent to the health officer by certified mail;

(3) include a statement of the reasons for the issuance of the notice;

(4) specify the remedial action necessary to effect compliance with the rule; and

(5) allow reasonable time as determined by the board for the performance of any act it requires to correct the problem.

(e) If a health officer fails to comply with a directive issued in accordance with subsection (d), the board may require the health officer to submit all, or any portion thereof deemed appropriate by the board, of the permits proposed for issuance for residential sewage disposal system construction, together with all documentation upon which the proposed permit issuance will be based, to the commissioner for review and written approval prior to permit issuance by the health officer. Such review shall continue until the board is satisfied that compliance with the rule has been obtained and is likely to continue, and has so notified the health officer in writing. *(Indiana State Department of Health; 410 IAC 6-8.1-30; filed Nov 20, 1990, 12:45 p.m.: 14 IR 628; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-31 General sewage disposal requirements

Authority: IC 16-19-3-5

Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 31. (a) No person shall throw, run, drain, seep, or otherwise dispose into any of the surface waters or ground waters of this state, or cause, permit, or suffer to be thrown, run, drained, allowed to seep, or otherwise disposed into such waters, any organic or inorganic matter from a dwelling or residential sewage disposal system that would cause or contribute to a health hazard or water pollution.

(b) The design, construction, installation, location, maintenance, and operation of residential sewage disposal systems shall comply with the provisions of this rule.

(c) All residential sewage disposal systems utilizing sanitary privies shall conform to Indiana state board of health bulletin SE 11, "The Sanitary Vault Privy," 1986 Edition.

(d) Any dwelling which is not connected, or cannot be connected, to a sanitary sewerage system and which does not utilize a sanitary privy for its residential sewage disposal system shall be provided with a residential sewage disposal system which includes a septic tank and a soil absorption system that has not failed.

(e) A temporary sewage holding tank is an alternative method of sewage disposal subject to the written approval of the commissioner required in subsection (f). A temporary sewage holding tank shall not be used as a primary means of residential sewage disposal except where necessary to prevent continued discharge of wastewater from a failed existing system. A temporary sewage holding tank may be used as follows:

(1) As a temporary storage facility for no more than one (1) year where occupancy of the home must continue while the system is being renovated.

(2) Where such facility is owned and operated temporarily by a conservancy district, sewer district, private utility, or municipality as a part of its sewage disposal plan or for no more than one (1) year while connection to sanitary sewer is being secured.

(f) If any conditions preclude the installation of a residential sewage disposal system as described in this rule, the local board of health may not approve the use of any other alternative residential sewage disposal system without the express written approval of the commissioner.

(g) In order to permit development of new or more efficient sewage treatment or disposal processes, the commissioner may approve the installation of experimental equipment, facilities, or pollution control devices for which extensive experience or records of use have not been developed in Indiana. The applicant for such approval must submit evidence of sufficient clarity and conclusiveness to convince the commissioner that the proposal has a reasonable and substantial probability of satisfactory operation without failure.

(h) No portion of the residential sewage disposal system or its associated drainage system shall be constructed upon property other than that from which the sewage originates unless easements, which grant permission for such construction and access for system maintenance, have been obtained for that property and have been legally approved and recorded by the proper authority or commission.

(i) Residential sewage disposal systems shall not be used for the disposal of water from roof drains, foundation drains, swimming pool main drains, hot tub drains, or area drains. Neither shall they be used for the disposal of chemical wastes in quantities

which would pollute ground water or inhibit solids settling or digestion in the septic tank.

(j) Any jetted bathtub with a capacity of greater than one hundred twenty-five (125) gallons will be treated as an extra bedroom for the system sizing requirements of this rule. *(Indiana State Department of Health; 410 IAC 6-8.1-31; filed Nov 20, 1990, 12:45 p.m.: 14 IR 628; errata filed Jan 25, 1991, 4:20 p.m.: 14 IR 1287; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-32 System failure correction

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 32. Should a residential sewage disposal system fail, the failure shall be corrected by the owner within the time limit set by the health officer. *(Indiana State Department of Health; 410 IAC 6-8.1-32; filed Nov 20, 1990, 12:45 p.m.: 14 IR 629; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-33 Written permit

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 33. (a) The owner or agent of the owner shall obtain a written permit, signed by the health officer, for construction of a residential sewage disposal system prior to:

(1) Construction of a residence or placement of a mobile home which will not be connected to a sanitary sewerage system.

(2) Any replacement, reconstruction of, expansion or remodeling of a residence which may increase the number of bedrooms.

(3) Any addition to, alteration of, or repair of an existing residential sewage disposal system.

The application for such a permit shall be made on a form approved by the commissioner, which application shall contain information outlined in section 48 of this rule, the profile analysis of all the soils in which the system is to be constructed, and any other information deemed necessary by the health officer. Other than the approval referenced in subsection (c), the approval of a site by the local plan commission or the county recorder does not constitute approval by the local health officer. The provisions of this rule relating to system design and installation shall not apply where alterations become necessary due to system defect, failure, or malfunction. Such alterations shall be made in accordance with the best judgment of the local board of health except that such alterations shall not be contrary to section 31(a) of this rule, and no portion of a soil absorption system shall be constructed to a depth greater than forty-eight (48) inches below the ground surface.

(b) If it is determined that the proposed system design does not meet the minimum requirements of this rule, the permit shall be denied and the owner shall be notified in writing of the basis for the denial. The notification shall also state that the owner has the right to appeal the denial and shall state the procedure for registering any such appeal.

(c) Individual lots in subdivisions designed to utilize on-site residential sewage disposal systems, for which the plats were approved by the local plan commission, county health department, or the county recorder, and recorded prior to the effective date of this rule are exempt from the provisions of sections 49(4) and 52(a) of this rule if the soils on the individual lot have characteristics which would allow the soil to be rated "slight" or "moderate" in accordance with guidelines as set forth in the soils manuals and handbooks of the Soil Conservation Service. The soil absorption system to serve each lot which is exempted by this section shall meet the sizing criteria of Table I.

TABLE I

PERMEABILITY RATING	SQUARE FEET NEEDED IN TRENCH BOTTOM PER BEDROOM
2″ to 6″ per hour	250 square feet per bedroom
1″ to 2″ per hour	330 square feet per bedroom

(d) Individual lots in subdivisions designed to utilize on-site residential sewage disposal systems, the plats for which were approved by the local plan commission and recorded prior to the effective date of this rule will be granted an exemption by the state board from the provisions of section 49(4) of this rule if the health officer of the county in which the development is located certifies to the commissioner, in writing, that:

(1) the health department has reviewed and recommended approval to the local plan commission, either verbally, in writing, or by other locally acceptable routine procedure, when the subdivision plat was being considered by that agency; and

(2) that no lots in the subdivision currently have system failures as defined in section 8 of this rule.

The certification must be accompanied by a brief description of the system approved for each lot for which exemption is requested including information on the design of the system as well as information on the type of soil on the site. An affirmative response to subdivisions (1) through (2) must be included in the certification for the exemption to the provisions of subsection 49(4) of this rule *[section 49(4) of this rule]* to be granted.

(e) The permittee shall notify the health officer or his designee when the work is ready for final inspection and at least forty-eight (48) hours or two (2) working days before any subsurface portions are to be covered. The permit for a residential sewage disposal system that has been covered less than forty-eight (48) hours or two (2) working days after said notification has been made may be revoked by the health officer. Requirements of permits issued for the construction of residential sewage disposal systems shall not be considered as fulfilled until the installation is completed to the satisfaction of the health officer or his duly authorized representative.

(f) The board, its agent, or the health officer or his or her agent shall be permitted to enter upon all properties at the proper time for purposes of inspection, observation, measurement, sampling, and testing necessary to assure compliance with this rule. *(Indiana State Department of Health; 410 IAC 6-8.1-33; filed Nov 20, 1990, 12:45 p.m.: 14 IR 629; errata filed Oct 2, 1991, 11:30 a.m.: 15 IR 110; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-34 Violation

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 34. (a) Any person found to be violating this rule may be served by the health officer with a written order stating the nature of the violation and providing a time limit for satisfactory correction thereof.

(b) After receiving an order in writing from the local board of health or the health officer, the owner of the property shall comply with the provisions of this rule as set forth in said order and within the time limit specified therein. Said order shall be served on the owner or the agent of the owner, but may be served on any person who, by contract with the owner, has assumed the duty of complying with the provisions of an order. *(Indiana State Department of Health; 410 IAC 6-8.1-34; filed Nov 20, 1990, 12:45 p.m.: 14 IR 630; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-35 Revocation of permit

Authority: IC 16-19-3-5
Affected: IC 4-21.5; IC 16-19-3-4; IC 16-20-1-19

Sec. 35. (a) If an applicant is refused a permit, the local board of health shall, upon request, afford the applicants the opportunity for a fair hearing. The parties involved may agree to use the procedures set forth in IC 4-21.5, the Administrative Procedure and Orders Act.

(b) The local board of health may revoke a permit which had been issued for construction of a residential sewage disposal system if it finds that the owner of the permit has failed to comply with this rule. Upon such notice the local board shall, upon request, afford the applicant the opportunity for a fair hearing. The parties involved may agree to use the procedures set forth in IC 4-21.5, the Administrative Procedure and Orders Act. *(Indiana State Department of Health; 410 IAC 6-8.1-35; filed Nov 20, 1990, 12:45 p.m.: 14 IR 630; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-36 Location and size

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 36. (a) The residential sewer shall be located at least fifty (50) feet from any water supply well or subsurface pump suction line. Sewers constructed of water works grade ductile iron pipe with mechanical joints or PVC pressure sewer pipe with an SDR rating of twenty-six (26) or less, having mechanical or compression gasket joints, may be located within the fifty (50) foot distance. In no case, however, shall sewers be located closer than twenty (20) feet to dug and bored water supply wells nor closer than ten (10) feet to drilled and driven water supply wells or subsurface pump suction lines.

(b) Water lines and sewers shall not be laid in the same trench. A horizontal separation of ten (10) feet shall be maintained

between water lines and sewers. Where crossings are necessary, a minimum of eighteen (18) inches vertical clearance must be maintained. When it is impossible to maintain proper horizontal and vertical separation, the sewer shall be constructed of ductile iron pipe with mechanical joints or PVC pressure sewer pipe with an SDR rating of twenty-six (26) or less, having mechanical or compression gasket joints within ten (10) feet of the water line; said sewer shall be pressure tested to assure water tightness prior to back filling.

(c) The residential sewer shall be a minimum of four (4) inches in diameter. Four (4) inch sewers shall be installed with a positive slope of not less than four (4) inches in twenty-five (25) feet and not more than thirty-six (36) inches in twenty-five (25) feet. Six (6) inch sewers, if utilized, shall be installed with a positive slope of not less than two (2) inches in twenty-five (25) feet and not more than thirty-six (36) inches in twenty-five (25) feet. *(Indiana State Department of Health; 410 IAC 6-8.1-36; filed Nov 20, 1990, 12:45 p.m.: 14 IR 630; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-37 Septic tanks; general requirements

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 37. (a) All septic tanks, dosing tanks, lift stations, and soil absorption systems shall be located in accordance with Table II as follows:

Minimum Distance in Feet From	Septic Tank, Dosing Tank, Lift Station	Upslope From Absorption System	Downslope From Absorption System
Private water supply well	50*	50*	50*
Private geothermal well	50*	50*	50*
Commercial water supply well	100*	100*	100*
Commercial geothermal well	100*	100*	100*
Public water supply well or reservoir	200*	200*	200*
Other lake or reservoir	50	50	50
Stream, ditch, or drainage tile**	25	25	25
Dwelling, inground swimming pool, or other structure	10	10	50***
Front, side, or rear lot lines	5	5	5
Water lines continually under pressure	10	10	10
Suction water lines	50	50	50

*The distances enumerated shall be doubled for soil absorption systems constructed where there exist horizons, layers, or strata within thirty-four (34) inches of the ground surface with a loading rate greater than seventy-five hundredths (0.75) gallons per day per square foot as determined from Table V of section 49(4) of this rule, unless that hazard can be overcome through system design.

**See Table IV of section 43(d) of this rule for perimeter drain separation.

***If the slope of the site on which the absorption system is to be built is greater than two percent (2%), or if the loading rate of the soil in the dispersal area has a loading rate of three-tenths (0.3) gallons per day per square foot or less, at least fifty (50) feet of dispersal area must be provided downslope of the absorption system. If the slope of the site on which the absorption system is to be built is two percent (2%) or less, and if the loading rate of the soil in the dispersal area is not less than five-tenths (0.5) gallons per day per square foot, at least thirty (30) feet of dispersal area must be provided downslope of the absorption system. No obstruction to horizontal flow of water such as parking areas, building foundations, swimming pools, or any other facility that would compact soil in the dispersal area, may be placed in the dispersal area.

(b) Septic tanks shall be water tight and constructed of durable material such as concrete, fiber glass, or plastic and shall be protected from corrosion. *(Indiana State Department of Health; 410 IAC 6-8.1-37; filed Nov 20, 1990, 12:45 p.m.: 14 IR 631; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-38 Septic tanks; capacity

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 38. (a) Every septic tank shall have a minimum capacity below the water line as specified in Table III as follows:

TABLE III

REQUIRED MINIMUM CAPACITIES FOR SEPTIC TANKS

Number of Bedrooms in Dwelling	Normal Liquid Capacity of Tank in Gallons
2 or less	750
3	1,000
4	1,250
5	1,500
5 +	1,500 plus 150 multiplied by the number of bedrooms over 5

(b) Minimum water depth in any compartment shall be thirty (30) inches.

(c) Maximum depth of water for calculating capacity of tank shall not exceed six and one-half (6½) feet.

(d) All septic tank effluent including effluent from tanks fitted with aeration units for aerobic digestion shall discharge into a soil absorption system or other treatment system as approved in accordance with section 31(g) of this rule. *(Indiana State Department of Health; 410 IAC 6-8.1-38; filed Nov 20, 1990, 12:45 p.m.: 14 IR 631; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-39 Septic tanks; construction details

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 39. (a) The septic tank inlet baffle or sanitary tee shall extend six (6) inches below the liquid level and at least to the top of the inlet sewer.

(b) The septic tank outlet baffle or sanitary tee, and baffles or submerged pipes between compartments, shall extend below the liquid level a distance of four-tenths (0.4) times the tank liquid depth. A gas deflection baffle shall be provided below the outlet of the tank. This baffle shall be constructed of durable materials not subject to corrosion or decay and shall be configured to deflect rising gas bubbles away from the outlet structure and toward the interior of the tank.

(c) There shall be at least one (1) inch clear space between the underside of the septic tank cover and the top of the inlet and outlet baffles or tees.

(d) Scum storage capacity (space between the liquid level and the top of the outlet baffle) shall be not less than fifteen percent (15%) of the total liquid depth of the septic tank.

(e) The septic tank inlet baffle shall not be more than twelve (12) inches nor less than eight (8) inches from the inside of the inlet end of the tank. The outlet baffle shall not be more than six (6) inches nor less than four (4) inches from the outlet end of the tank. Baffles shall be constructed of durable materials not subject to corrosion or decay.

(f) The bottom of the inlet to the septic tank or the first compartment receiving the flow shall not be less than three (3) inches above the flow line of the outlet from that compartment.

(g) Access manholes at least eight (8) inches in diameter extending to the ground surface and fitted with safely secured, gas tight covers, shall be provided for each septic tank or compartment.

(h) Access for inspection shall be provided in the top of the septic tank above the inlet and outlet baffles of each tank and compartment.

(i) Reinforced or unreinforced concrete septic tanks wherein the concrete has a compressive strength of less than four thousand (4,000) pounds per square inch shall have walls of four (4) inch or greater thickness.

(j) Reinforced concrete septic tanks wherein the concrete has a compressive strength of four thousand (4,000) pounds per square inch or greater shall have walls of two and one-half (2½) inch or greater thickness.

(k) Cast-in-place concrete septic tanks shall have the walls and floor at least six (6) inches thick poured from a 1:2:3 mix in one (1) operation.

(l) Concrete block septic tanks shall have at least eight (8) inch walls with cores filled with concrete, and shall be reinforced at the corners. The walls shall be set on a concrete slab at least six (6) inches thick and the wall-to-floor connection shall be satisfactorily sealed.

(m) Septic tank bottoms shall conform to the specifications set forth for septic tank walls.

(n) Concrete septic tank tops shall be a minimum of four (4) inches in thickness and reinforced with one-fourth (¼) inch

reinforcing rods in a six (6) inch grid or equivalent.

(o) All drain holes shall be plugged after the septic tank has been set.

(p) All septic tanks shall be installed level and the tank checked prior to covering to assure that it is level.

(q) Tanks fitted with aeration units for aerobic digestion shall conform to Standard 40 of the National Sanitation Foundation or to the standards of an equivalent testing laboratory and shall provide a minimum aerobic treatment capacity of one hundred fifty (150) gallons per bedroom per day or five hundred (500) gallons per day, whichever is greater. *(Indiana State Department of Health; 410 IAC 6-8.1-39; filed Nov 20, 1990, 12:45 p.m.: 14 IR 632; errata filed Jan 25, 1991, 4:20 p.m.: 14 IR 1287; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-40 Septic tanks; connecting pipes

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 40. (a) All inlet and outlet connections to the septic tank shall be sealed to the tank in a water tight manner.

(b) All joints in the sewer connecting septic tanks in series shall be water tight. *(Indiana State Department of Health; 410 IAC 6-8.1-40; filed Nov 20, 1990, 12:45 p.m.: 14 IR 632; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-41 Gravity distribution of effluent; distribution boxes

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 41. (a) For gravity distribution of effluent, a distribution box or series of distribution boxes shall be installed between the septic tank and the subsurface absorption system, and each absorption line shall connect directly thereto.

(b) The preferred material for use in constructing distribution boxes is concrete (three thousand (3,000) pounds per square inch). Other materials may be considered on a case-by-case basis. All materials must be resistant to corrosion and decay and must have sufficient structural strength to contain sewage and resist lateral compressive and bearing loads. The minimum interior width of a distribution box shall be twelve (12) inches. The distribution box shall be fitted with a water tight, removable lid for access.

(c) Each distribution box shall be designed to split the effluent flow equally among the effluent ports. All effluent ports shall be at the same elevation and be of the same diameter. The effluent ports shall be located at an elevation at least one (1) inch lower than the influent port. The influent port shall be located or baffled to prevent unequal distribution of effluent to the distribution system. If baffles are provided, the baffles and their mounts or retainers shall provide a passageway for effluent between the box bottom and the bottom edge of the baffle of no more than two (2) inches. The baffle shall extend to one (1) inch above the top of the inlet. An elbow may be used in place of a baffle. The elbow must be a ninety (90) degree elbow and be turned down into the distribution box. The end of the elbow must be not more than two (2) inches above the bottom of the distribution box. The interior bottom of the distribution box shall be at least four (4) inches below the invert elevation of the effluent ports. A minimum of eight (8) inches freeboard above the invert elevation of the effluent port shall be provided.

(d) The distribution box shall be placed on a stable foundation of undisturbed soil. The box shall be leveled, and the outlets shall be checked to assure that they are at a uniform elevation. *(Indiana State Department of Health; 410 IAC 6-8.1-41; filed Nov 20, 1990, 12:45 p.m.: 14 IR 633; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-42 Piping

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 42. Piping used in a residential sewage disposal system shall meet or exceed the following applicable standards:

(1) Gravity sewer standards as follows:

(A) The following for PVC piping:

(i) ASTM-D 2665-89a for four (4) inch and six (6) inch pipe only.

(ii) ASTM-D 3034-89 for the following:

(AA) SDR 35 for four (4) inch through fifteen (15) inch pipe.

(BB) SDR 26 with compression fittings for special crossings above or below potable water lines.

(B) The following for ABS piping:
(i) ASTM-D 2661-87a for four (4) inch and six (6) inch pipe only.
(ii) ASTM-D 2680-89 for eight (8) inch through fifteen (15) inch pipe.
(iii) ASTM-D 2751-89 SDR 23.5 or SDR 35 for six (6) inch pipe.
(2) Pressure sewers and pressure effluent distribution lines as follows:
(A) The following for PVC piping:
(i) ASTM-D 2241-89 SDR 13.5, 17, 21, or 26.
(ii) ASTM-D 1785-89 Schedule 40, 80, or 120.
(B) The following for ABS piping:
(i) ASTM-D 1527-89 Schedule 40, 80.
(ii) ASTM-D 2282-89 SDR 13.5, 17, 21, or 26.
Compression fittings must be used on pressure sewers when they are located ten (10) feet or less from a water line.
(3) Absorption field laterals standards as follows:
(A) Only sewer pipe listed in subdivisions (1) through (2), potable water pipe (four (4) inches or more in diameter), or pipe meeting ASTM-D 2729-89 or ASTM F810-85, is suitable for absorption field gravity laterals.
(B) The distribution pipe used in absorption field trenches for gravity fed absorption systems must have at least two (2) rows of holes, but no more than three (3) rows. The rows shall be separated by one hundred twenty (120) degrees; the holes must be one-half (½) inch to three-fourths (¾) inch in diameter, and be spaced laterally as follows:
(i) One-half (½) inch holes at two and one-fourth (2¼) inch or closer spacing in each row of holes.
(ii) Five-eighths (⅝) inch holes at three and one-half (3½) inch or closer spacing in each row of holes.
(iii) Three-fourths (¾) inch holes at five (5) inch or closer spacing in each row of holes.
(4) Pipe for water table modification standards as follows:
(A) ASTM C412-83 for concrete pipe.
(B) ASTM C4-62 for vitrified pipe.
(C) ASTM 498-65 for clay pipe.
(D) The following for polyethylene pipe:
(i) ASTM F405-89.
(ii) ASTM F667-85.
(iii) SCS 606.

(Indiana State Department of Health; 410 IAC 6-8.1-42; filed Nov 20, 1990, 12:45 p.m.: 14 IR 633; errata filed Dec 10, 1990, 4:30 p.m.: 14 IR 760; errata filed Jan 25, 1991, 4:20 p.m.: 14 IR 1287; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-8.1-43 Drainage

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 43. (a) A diversion or drainageway to divert surface drainage away from the absorption system site, is required when the elevation of the landscape adjoining the proposed subsurface soil absorption system site is equal to or higher than that of the proposed site, and the higher landscape may be expected to discharge water onto the proposed site. Diversion ditches or drainageways shall have a positive grade of at least two-tenths (0.2) feet per one hundred (100) feet.

(b) When a subsurface drainage system is constructed to lower a perched or apparent seasonal high water table, the following shall apply:

(1) If the seasonal high water table is perched, the subsurface drain trench around the system shall be constructed at least two (2) inches into the massive clay, glacial till, or fragipan. If the site has a slope of equal to or less than two percent (2%), the subsurface drain shall surround the system. If the site slope exceeds two percent (2%), the subsurface drain shall be constructed only on the upslope side of the system.

(2) The subsurface drain tile shall be at least four (4) inches in diameter, shall be slotted, and, when installed in sands, loamy sands, sandy loams, fine sandy loams, loams, silt loams, or silts shall be wrapped with a geotextile fabric with an effective opening size no smaller than two-tenths (0.2) millimeter and no larger than eighty-five hundredths (0.85) millimeter.

(3) The subsurface drain trench shall have a positive slope of at least two-tenths (0.2) feet per one hundred (100) feet and shall be constructed with no sags in the line.

(4) A subsurface drain trench installed upslope from a residential sewage disposal system shall be backfilled with aggregate no larger than that to be used in the absorption system. The trench shall be backfilled to the surface or to a point no more than six (6) inches from the ground surface.

(5) The subsurface drain trench and the associated discharge piping shall be constructed to permit water to flow by gravity throughout its length. No pumps or siphons shall be utilized to effect the movement of the collected water.

(c) When a subsurface drain is provided, it shall be sufficiently deep to lower the seasonal water table at least twenty-four (24) inches below the center of the absorption system.

(d) The subsurface drain and the soil absorption system shall be located so as to comply with the clearances listed in Table IV, as follows, but at no point shall they be separated by less than ten (10) feet:

TABLE IV
PERIMETER DRAIN CLEARANCE FROM SOIL
ABSORPTION FIELDS

Soil Absorption System Loading Rate in Gallons per Day per Square Foot	Required Clearance in Feet
0.75 or greater	25
0.6 or less	10

(e) The subsurface drain shall not cross any portion of the soil absorption system.

(f) Tile outlets shall be provided with rodent guards. *(Indiana State Department of Health; 410 IAC 6-8.1-43; filed Nov 20, 1990, 12:45 p.m.: 14 IR 634; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-44 Dosing tanks

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 44. (a) Dosing tanks must be water tight and constructed of durable material such as concrete, fiber glass, or plastic and shall be protected from corrosion.

(b) Reinforced or unreinforced concrete dosing tanks wherein the concrete has a compressive strength of less than four thousand (4,000) pounds per square inch shall have walls of four (4) inch or greater thickness.

(c) Reinforced concrete dosing tanks wherein the concrete has a compressive strength of four thousand (4,000) pounds per square inch or greater shall have walls of two and one-half (2½) inch or greater thickness.

(d) Cast in place concrete dosing tanks shall have the walls and floor at least six (6) inches thick poured from a 1:2:3 mix in a single operation.

(e) Concrete block dosing tanks shall have at least eight (8) inch thick walls with cores filled with concrete and shall be reinforced at the corners. The blocks shall be laid with tight mortar joints. The walls shall be set on a concrete slab at least six (6) inches thick, and the wall-to-floor connection shall be satisfactorily sealed.

(f) The required liquid holding capacity of the dosing tank shall not be considered as any portion of the required liquid volume of the septic tank.

(g) The liquid holding capacity of a dosing tank must equal the daily average wastewater volume, in addition to the volume of liquid that will drain back from any pressure sewer when pumping ceases. Additional capacity must be provided to keep the dosing tank pump submerged at all times and to provide sufficient freeboard for a high water alarm.

(h) Each dosing tank shall be fitted with an effluent pump sized in conformance with section 45 or 53 of this rule, with controls, and with a high water alarm switch set at a level above the design high water mark. The alarm shall be on a separate circuit from the pump and shall include an audible and visible alarm.

(i) Switches which are comparable to mercury float level switches shall be used for dosing tank pump start and stop controls and for high water alarms.

(j) Dosing tanks shall be provided with access ports, extending to the ground surface which are sufficiently large to allow access to maintain the tank and pumps. Safely secured, gas tight covers shall be provided for each required access port. *(Indiana State Department of Health; 410 IAC 6-8.1-44; filed Nov 20, 1990, 12:45 p.m.: 14 IR 634; errata filed Oct 2, 1991, 11:30 a.m.: 15 IR 110; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-45 Effluent pumps

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 45. (a) All effluent pumps must be submersible pumps suitable for operation in a corrosive atmosphere.

(b) Effluent pumps shall be sized to deliver the total design flow rate while meeting the total dynamic head requirements of the system.

(c) Pumps must be fitted with breakaway flanges and lifting chains.

(d) Controls other than liquid level sensors shall not be located within the dosing tank. *(Indiana State Department of Health; 410 IAC 6-8.1-45; filed Nov 20, 1990, 12:45 p.m.: 14 IR 635; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-46 Barrier materials

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 46. Barrier materials used to cover aggregate in an absorption system must be a six (6) inch thick layer of straw, or else a geotextile fabric with an effective opening size no smaller than twenty-hundredths (0.20) millimeters and no larger than eighty-five hundredths (0.85) millimeters. Building paper shall not be used as a barrier material. *(Indiana State Department of Health; 410 IAC 6-8.1-46; filed Nov 20, 1990, 12:45 p.m.: 14 IR 635; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-47 Aggregate

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 47. (a) Aggregate to be used in absorption systems shall be gravel, stone, or other approved materials. Crushed limestone, if used, must have a hardness of not less than three (3) on the Mohs scale of hardness.

(b) Aggregate shall be a mixture with no aggregate smaller in size than one-half (½) inch in diameter nor any aggregate larger than two and one-half (2½) inches in diameter. The aggregate must be larger than the openings in the laterals. Fines, dust, sand, and clay shall be removed from the aggregate prior to its placement in the trench. *(Indiana State Department of Health; 410 IAC 6-8.1-47; filed Nov 20, 1990, 12:45 p.m.: 14 IR 635; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-48 On-site evaluation

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 48. (a) Before issuance of any permit for construction of a residential sewage disposal system or the alteration of a soil absorption field, an on-site evaluation, which shall include an evaluation of the soil profile, shall be conducted. System feasibility, location, selection, and design shall be based on the site evaluation and information obtained from the soil profile. The site and soil information needed is outlined and further defined in subsection (e). Properties of the soil at each site shall be determined using the guidelines set forth in the soil manuals, technical bulletins, and handbooks of the SCS. The local health department may, when necessary, provide or require to be provided, a direct soil profile observation by a soil scientist, using the guidelines set forth in the soil manuals, technical bulletins, and handbooks of the SCS.

(b) When direct soils profile observations are made, soil profile information shall be recorded to a depth of five (5) feet or until a layer is encountered which cannot be readily penetrated, whichever is shallower.

(c) The on-site evaluation shall be conducted before construction begins. No construction on the residential sewage disposal system may take place if the residential sewage disposal system site is disturbed or altered after the on-site evaluation by the addition of fill material, (other than construction necessary for the residential sewage disposal system) or by cutting, scraping, compaction, or the removal of soil, until a new evaluation has been conducted and a modified permit has been issued.

(d) When any site limitations and soil information for the site has been thusly determined, the owner is responsible for designing a residential sewage disposal system which addresses the demands of the site in accordance with this rule, and which will meet local health department approval.

(e) The information needed to evaluate a site includes the following:

(1) Topographic information including the following:

(A) Slope and slope aspect.

(B) Surface drainage characteristics and patterns including swales, ditches, and streams.

(C) Proposed or existing location of house and well.

(D) Location of other major features or structures.

(E) Location of soil evaluation sites and appropriate soil type boundaries.

(F) Topographic position of the site.

(2) Soil characteristics as follows:

(A) Approximate depths of soil horizons.

(B) Soil color, structure, and texture at each horizon.

(C) Depth to any layer which has a loading rate greater than seventy-five hundredths (0.75) gallons per day per square foot.

(D) Depth to seasonal high ground water as indicated by soil wetness characteristics.

(E) Depth to bedrock.

(F) Foil *[sic.]* consistence at each horizon.

(G) Soil effervescence at each horizon.

(H) Presence or absence of roots.

(f) Soil absorption systems shall not be constructed in areas where surface drainage or run-off will have an adverse effect on the system, unless the surface run-off can be effectively diverted around the system.

(g) Soil absorption systems shall not be constructed below the floodway elevation of any flood having a peak discharge equaled or exceeded on the average of once in any one hundred (100) year period.

(h) Soil absorption systems shall not be constructed in areas subject to ponding. *(Indiana State Department of Health; 410 IAC 6-8.1-48; filed Nov 20, 1990, 12:45 p.m.: 14 IR 635; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-49 Subsurface system selection criteria

Authority: IC 16-19-3-5

Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 49. Subsurface soil absorption systems are the systems of choice. All of the site conditions in this section must be met if subsurface soil absorption systems are to be constructed:

(1) Sufficient area exists on the lot for an appropriately sized system.

(2) The site has a slope of fifteen percent (15%) or less.

(3) The topographic position of the site on which the system is to be built is convex, hill slope, or flat. If surface and subsurface drainage can be diverted around the site, a toe slope position can be utilized.

(4) All soil horizons at the site from the ground surface to twenty-four (24) inches below the proposed trench bottom have a loading rate of not less than twenty-five hundredths (0.25) and not more than one and twenty-hundredths (1.20) gallons per day per square foot as determined from Table V, as follows:

Table V

Loading Rates for Subsurface Systems (in gpd/ft^2)

	SOIL STRUCTURE CLASSES							
Soil Texture Class	Single Grain	Granular Platy *	Strong: Angular, Subangular, Blocky, Prismatic	Moderate: Angular, Subangular Blocky, Prismatic	Weak: Angular, Subangular Blocky, Prismatic	Fragipan: Very Coarse Prismatic	Structureless, Massive, Friable, V. Friable	Structureless, Massive, Compact, Firm, V. Firm
Gravel Coarse Sand	>1.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Loamy Coarse Sand Medium Sand	1.20	1.20	N/A	N/A	1.20	N/A	N/A	N/A

Fine Sand Loamy Sand Loamy Fine Sand	0.75	0.60	N/A	0.75	0.75	N/A	0.75	N/A
Very Fine Sand Loamy V. Fine Sand	0.50	0.50	N/A	0.75	0.60	N/A	0.60	N/A
Sandy Loam Coarse Sandy Loam	N/A	0.75	N/A	0.60	0.60	0.00	0.60	N/A
Fine Sandy Loam V. Fine Sandy Loam	N/A	0.75	N/A	0.60	0.60	0.00	0.60	N/A
Sandy Clay Loam	N/A	0.75	0.75	0.50	0.50	0.00	0.50	0.00
Loam	N/A	0.75	0.75	0.50	0.30	0.00	0.30	0.00
Silt Loam	N/A	0.60	0.60	0.50	0.30	0.00	0.30	0.00
Silty Clay Loam Clay Loam Sandy Clay	N/A	0.60	0.60	0.30	0.25	0.00	0.25	0.00
Silty Clay Clay	N/A	0.60	0.50	0.30	0.25	N/A	0.25	0.00
Muck	N/A	N/A	N/A	N/A	N/A	N/A	0.00	N/A
Marl Bedrock	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.00

N/A–NOT APPLICABLE

* Except where platy structure has been caused by soil compaction. Platy structure caused by compaction has a loading rate of 0.00 gpd/ft.^{2}

(5) Any seasonal high water table at the site of the proposed system can be lowered to thirty-four (34) inches or more below the surface.

(6) Site conditions must permit distribution of effluent to each trench of the system so that each square foot of absorptive area can be loaded with an equal volume of effluent.

(Indiana State Department of Health; 410 IAC 6-8.1-49; filed Nov 20, 1990, 12:45 p.m.: 14 IR 636; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-8.1-50 Subsurface system type selection criteria

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 50. (a) A subsurface gravity feed trickle flow system may be constructed if:

(1) the design daily flow of the project is equal to or greater than four hundred fifty (450) gallons per day;

(2) the loading rate of the site is equal to or greater than twenty-five hundredths (0.25) gallons per day per square foot and equal to or less than seventy-five hundredths (0.75) gallons per day per square foot, as determined from Table V of section 49(4) of this rule;

(3) the trench bottom will be at least thirty (30) inches above any horizon with a loading rate less than twenty-five hundredths (0.25) gallons per day per square foot; and

(4) the absorption field, including either half of an alternating field, is designed with a total absorption trench length which does not exceed five hundred (500) lineal feet.

(b) A subsurface gravity feed trickle flow system may also be constructed if:

(1) the design daily flow of the proposed system is less than four hundred fifty (450) gallons per day;

(2) the site has a loading rate of equal to or greater than twenty-five hundredths (0.25) gallons per day per square foot and equal to or less than seventy-five hundredths (0.75) gallons per day per square foot, as determined from Table V of section 49(4) of this rule;

(3) the trench bottom will be at least twenty-four (24) inches above any horizon with a loading rate less than twenty-five hundredths (0.25) gallons per day per square foot; and

(4) the absorption field, including either half of an alternating field, is designed with a total absorption trench length which

does not exceed five hundred (500) lineal feet.

(c) A subsurface gravity feed trickle flow system which utilizes alternating fields or is dosed using pump assisted distribution may be constructed if:

(1) the design daily flow of the project is equal to or greater than four hundred fifty (450) gallons per day;

(2) the loading rate of the site is equal to or greater than twenty-five hundredths (0.25) gallons per day per square foot and equal to or less than seventy-five hundredths (0.75) gallons per day per square foot, as determined from Table V of section 49(4) of this rule; and

(3) the trench bottom will be at least twenty-four (24) inches above any horizon with a loading rate less than twenty-five hundredths (0.25) gallons per day per square foot.

(d) If any soil absorption field, including either half of an alternating field, is designed with a total absorption trench length greater than five hundred (500) lineal feet, the absorption field shall be dosed using pump assisted distribution.

(e) If any soil horizon within twenty-four (24) inches of the proposed trench bottom has a loading rate of one and twenty-hundredths (1.20) gallons per day per square foot as determined from Table V of section 49(4) of this rule, the subsurface soil absorption system shall utilize pressure distribution. *(Indiana State Department of Health; 410 IAC 6-8.1-50; filed Nov 20, 1990, 12:45 p.m.: 14 IR 638; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-51 Elevated system selection criteria

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 51. Elevated sand mound systems may be constructed if the following site conditions are met:

(1) Sufficient area exists on the lot for an appropriately sized system.

(2) The site on which the system is to be built has a slope of six percent (6%) or less.

(3) The topographic position of the site on which the system is to be built is convex, hill slope, or flat. If surface and subsurface drainage can be diverted around the site, a toe slope position can be utilized.

(4) There are no soil horizons within twenty (20) inches from the ground surface which have a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot as determined from Table VI, as follows:

Table VI

Loading Rates for Above-Ground Systems (in gpd/ft^2)

	SOIL STRUCTURE CLASSES							
Soil Texture Class	Single Grain	Granular Platy *	Strong: Angular, Subangular, Blocky, Prismatic	Moderate: Angular, Subangular Blocky, Prismatic	Weak: Angular, Subangular Blocky, Prismatic	Fragipan: Very Coarse Prismatic	Structureless, Massive, Friable, V. Friable	Structureless, Massive, Compact, Firm, V. Firm
Gravel Coarse Sand	>1.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Loamy Coarse Sand Medium Sand	1.20	1.20	N/A	N/A	1.20	N/A	N/A	N/A
Fine Sand Loamy Sand Loamy Fine Sand	0.60	0.60	N/A	0.60	0.60	N/A	0.60	N/A
Very Fine Sand Loamy V. Fine Sand	0.50	0.50	N/A	0.50	0.50	N/A	0.50	N/A
Sandy Loam Coarse Sandy Loam	N/A	0.60	N/A	0.60	0.60	0.00	0.60	N/A
Fine Sandy Loam V. Fine Sandy Loam	N/A	0.60	N/A	0.60	0.60	0.00	0.60	N/A
Sandy Clay Loam	N/A	0.50	0.50	0.50	0.50	0.00	0.50	0.00
Loam	N/A	0.50	0.50	0.50	0.50	0.00	0.50	0.00
Silt Loam	N/A	0.50	0.50	0.50	0.50	0.00	0.50	0.00
Silty Clay Loam Clay Loam Sandy Clay	N/A	0.25	0.25	0.25	0.25	0.00	0.25	0.00

Silty Clay Clay	N/A	0.25	0.25	0.25	0.25	N/A	0.25	0.00
Muck	N/A	N/A	N/A	N/A	N/A	N/A	0.00	N/A
Marl Bedrock	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.00

N/A–NOT APPLICABLE

* Except where platy structure has been caused by soil compaction. Platy structure caused by compaction has a loading rate of 0.00 gpd/ft.^{2}

(5) There are no soil horizons within twenty (20) inches from the ground surface which have a loading rate of more than one and twenty-hundredths (1.20) gallons per day per square foot as determined from Table VI of subdivision (4) unless that hazard can be overcome through system design.

(6) Any seasonal high water table at the site of the proposed system can be lowered to twenty (20) inches or more from the surface.

(7) There is at least thirty (30) feet of dispersal area down slope of the downslope toe of the mound if the slope of the site on which the mound is to be built is two percent (2%) or less and if the loading rate of the soil in the dispersal area is not less than five-tenths (0.5) gallons per day per square foot. If the slope of the site on which the mound is to be built is greater than two percent (2%) or if the loading rate of the soil in the dispersal area has a loading rate of three-tenths (0.3) gallons per day per square foot or less, at least fifty (50) feet of dispersal area must be provided down slope of the downslope toe of the mound. No obstruction to horizontal flow of water such as parking areas, building foundations, swimming pools, or any other facility that would compact soil in the dispersal area, may be placed in the dispersal area.

(Indiana State Department of Health; 410 IAC 6-8.1-51; filed Nov 20, 1990, 12:45 p.m.: 14 IR 638; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-8.1-52 Subsurface gravity feed trickle flow systems; construction requirements

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 52. (a) The minimum absorption area (in square feet) required for each gravity feed trickle flow subsurface soil absorption system shall be based on the following:

(1) The number of bedrooms and bedroom equivalents in the dwelling.

(2) The appropriate soil loading rate (in gallons per day per square foot) determined from Table V of section 49(4) of this rule.

(3) The vertical separation distance between the bottom of the proposed trench and any soil layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot. The loading rate used for this computation shall be the loading rate of the most restrictive horizon within twenty-four (24) inches of the trench bottom.

(4) The absorption area shall be computed using the following formula:

$$\text{area} = \frac{150\text{g} \times \text{number of bedrooms and bedroom equivalents}}{\text{loading rate in gpd/sq.ft.}}$$

(5) If the loading rate determined from Table V of section 49(4) of this rule is twenty-five hundredths (0.25) gallons per day per square foot or thirty-hundredths (0.30) gallons per day per square foot, the system may be reduced in size from the absorption area determined in subdivision (1) by nine-tenths of one percent (0.9%) for each inch over twenty-four (24) inches to a maximum of sixty (60) inches between the trench bottom and a layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot. The new absorption area shall then be computed using the following formula:

New Absorption Area* = A.A. - [A.A. × 0.009 (D.L. - D.T. - 24)] where:

A.A. = Absorption area determined in subdivision (4).

D.L. = Depth in inches from the ground surface to a layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot.

D.T. = Depth in inches from the ground surface to the proposed trench bottom.

*Note: The value for the quantity (D.L. - D.T. - 24) may not exceed thirty-six (36). If a value of greater than thirty-six (36) is obtained, then thirty-six (36) must be used for the computations.

(b) All gravity feed trickle flow subsurface soil absorption systems shall be located in accordance with the separation distances shown in Table II of section 37(a) of this rule. Gravity feed trickle flow subsurface soil absorption systems shall not be constructed

where there exist horizons, layers, or strata within thirty-four (34) inches of the ground surface with a loading rate greater than seventy-five hundredths (0.75) gallons per day per square foot as determined from Table V of section 49(4) of this rule.

(c) Soil absorption systems shall not be wholly or partly located in a drainage way subject to intermittent flooding.

(d) In order to provide equal flow distribution in gravity feed trickle flow subsurface soil absorption systems, each absorption trench must be individually connected to a distribution box by at least five (5) feet of unperforated pipe which is laid with a gravel free backfill. All absorption trenches served by a common distribution box must be constructed so that each square foot of the absorptive area served by the distribution box is loaded with an equal volume of effluent. The distal ends on the distribution lines may be manifolded together by piping on sites with slopes of two percent (2%) or less, but shall not be tied together on sites with slopes of greater than two percent (2%). When the distal ends of the absorption trenches are manifolded, the manifold trench area shall not count as meeting any of the minimum absorption area required by subsection (a).

(e) Each trench and distribution line in a gravity feed trickle flow subsurface soil absorption system shall be uniformly level throughout its length.

(f) No single absorption trench in a gravity feed trickle flow subsurface soil absorption system shall exceed one hundred (100) feet in length.

(g) On sloping sites, absorption trenches of a gravity feed trickle flow soil absorption system shall be constructed along the contour.

(h) There shall be a minimum separation of seven and one-half (7½) feet, on center, between absorption field trenches.

(i) All gravity feed trickle flow subsurface soil absorption fields shall be designed to utilize trenches with a minimum width of eighteen (18) inches and a maximum trench width of thirty-six (36) inches.

(j) The minimum depth from original grade to the bottom of a trench of a gravity feed trickle flow subsurface soil absorption system shall not be less than ten (10) inches, and the maximum depth to the bottom of a trench of a gravity feed trickle flow subsurface soil absorption system shall not be more than thirty-six (36) inches.

(k) Perforated pipe distribution lines in the absorption trench of a gravity feed trickle flow subsurface soil absorption system shall be completely surrounded by aggregate which meets the specifications in section 47 of this rule. There shall be at least six (6) inches of aggregate below the pipe and at least two (2) inches of aggregate above the pipe.

(l) The aggregate used in a gravity feed trickle flow subsurface soil absorption system shall be covered with a six (6) inch layer of straw, or else a geotextile fabric barrier which meets the minimum requirements in section 46 of this rule, in such a manner as to prevent the aggregate from becoming clogged with the earth fill.

(m) A minimum of twelve (12) inches of cover shall be provided over the aggregate in the trenches, and any fill required to provide cover shall be crowned over the entire field to promote surface run-off.

(n) Subsurface soil absorption systems shall not be constructed in clayey soils during periods of wet weather when the soil is sufficiently wet at the depth of installation to exceed its plastic limit. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. For the purpose of this rule, the plastic limit of a soil shall be considered to have been exceeded when the soil can be rolled between the palms of the hands to produce threads one-eighth (⅛) inch in diameter without breaking apart and crumbling.

(o) Special caution shall be taken to prevent wheeled and tracked vehicles from compacting the area selected for placement of the absorption system before, during, and after construction of the trenches, especially during wet weather. Precaution is especially important where clayey soils are involved. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. Alteration of soil structure by movement of vehicles may be grounds for rejection of the site and/or the system.

(p) Excessive smearing of the usable absorption trench sidewalls or bottom during construction may result in irreversible damage to the soil infiltrative surface and may be grounds for rejection of the site and/or the system. *(Indiana State Department of Health; 410 IAC 6-8.1-52; filed Nov 20, 1990, 12:45 p.m.: 14 IR 640; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-53 Subsurface gravity feed flood dosed systems

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 53. (a) The minimum absorption area (in square feet) required for each gravity feed flood dosed subsurface soil absorption system shall be based on the following:

(1) The number of bedrooms and bedroom equivalents in the dwelling.

(2) The appropriate soil loading rate (in gallons per day per square foot) determined from Table V of section 49(4) of this rule.

(3) The vertical separation distance between the bottom of the proposed trench and any soil layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot. The loading rate used for this computation shall be the loading rate of the most restrictive horizon within twenty-four (24) inches of the trench bottom.

(4) The absorption area shall be computed using the following formula:

$$\text{area} = \frac{150\text{g} \times \text{number of bedrooms and bedroom equivalents}}{\text{loading rate in gpd/sq.ft.}}$$

(5) If the loading rate determined from Table V of section 49(4) of this rule is twenty-five hundredths (0.25) gallons per day per square foot or thirty-hundredths (0.30) gallons per day per square foot, the system may be reduced in size from the absorption area determined in subdivision (1) by nine-tenths of one percent (0.9%) for each inch over twenty-four (24) inches to a maximum of sixty (60) inches between the trench bottom and a layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot. The new absorption area shall then be computed using the following formula:

New Absorption Area* = A.A. - [A.A. × 0.009 (D.L. - D.T. - 24)] where:

A.A. = Absorption area determined in subdivision (4).

D.L. = Depth in inches from the ground surface to a layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot.

D.T. = Depth in inches from the ground surface to the proposed trench bottom.

*Note: The value for the quantity (D.L. - D.T. - 24) may not exceed thirty-six (36). If a value of greater than thirty-six (36) is obtained, then thirty-six (36) must be used for the computations.

(b) All subsurface gravity feed flood dosed absorption systems shall be located in accordance with the separation distances shown in Table II of section 37(a) of this rule. Subsurface gravity feed flood dosed soil absorption systems shall not be constructed where there exist horizons, layers, or strata within thirty-four (34) inches of the ground surface with a loading rate greater than seventy-five hundredths (0.75) gallons per day per square foot as determined from Table V of section 49(4) of this rule.

(c) Subsurface gravity feed flood dosed soil absorption systems shall not be wholly or partly located in a drainage way subject to intermittent flooding.

(d) In order to provide equal flow distribution in gravity feed flood dosed systems, each absorption trench must be individually connected to a distribution box by at least five (5) feet of unperforated pipe which is laid with a gravel free backfill. All absorption trenches served by a common distribution box must be constructed so that each square foot of the absorptive area served by the distribution box is loaded with an equal volume of effluent.

(e) No single absorption trench shall exceed one hundred (100) feet in length.

(f) On sloping sites, absorption trenches shall be constructed along the contour.

(g) There shall be a minimum separation of seven and one-half (7½) feet, on center, between absorption field trenches.

(h) All subsurface gravity feed flood dosed absorption fields shall be designed to utilize trenches with a minimum width of eighteen (18) inches and a maximum trench width of thirty-six (36) inches.

(i) The minimum depth from original grade to the bottom of a subsurface gravity feed flood dosed absorption trench shall not be less than ten (10) inches, and the maximum depth to the bottom of such trench shall not be more than thirty-six (36) inches.

(j) Perforated pipe distribution lines in the subsurface gravity feed flood dosed soil absorption trench shall be completely surrounded by aggregate which meets the specifications in section 47 of this rule. There shall be at least six (6) inches of aggregate below the pipe and at least two (2) inches of aggregate above the pipe.

(k) The aggregate shall be covered with a six (6) inch layer of straw, or else a geotextile fabric barrier which meets the minimum requirements in section 46 of this rule, in such a manner as to prevent the aggregate from becoming clogged with the earth fill.

(l) A minimum of twelve (12) inches of cover shall be provided over the aggregate in the trenches, and any fill required to provide cover shall be crowned over the entire field to promote surface run-off.

(m) Subsurface gravity feed flood dosed soil absorption systems shall not be constructed in clayey soils during periods of wet weather when the soil is sufficiently wet at the depth of installation to exceed its plastic limit. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. For the purpose of this rule, the plastic limit of a soil shall be considered to have been exceeded when the soil can be rolled between the palms of the hands to produce

threads one-eighth (⅛) inch in diameter without breaking apart and crumbling.

(n) Special caution shall be taken to prevent wheeled and tracked vehicles from compacting the area selected for placement of the subsurface gravity feed flood dosed soil absorption system before, during, and after construction of the trenches, especially during wet weather. Precaution is especially important where clayey soils are involved. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. Alteration of soil structure by movement of vehicles may be grounds for rejection of the site and/or the system.

(o) Excessive smearing of the usable absorption trench sidewalls or bottom during construction may result in irreversible damage to the soil infiltrative surface and may be grounds for rejection of the site and/or the system.

(p) Trenches in a subsurface gravity feed flood dosed system shall not be manifolded together at the distal end of the trench.

(q) Each trench and distribution line in a subsurface gravity feed flood dosed system shall be uniformly level throughout its length.

(r) When a subsurface gravity feed flood dosed soil absorption system is used, the dosing pump shall be sized, and its controls set to deliver the design daily flow in one (1) dose each day. Pump selection shall be based on manufacturers pump curves for the required discharge rate from Table VII, as follows, at the total head imposed on the pump:

TABLE VII
REQUIRED PUMP DISCHARGE RATES FOR FLOOD DOSED SYSTEMS

Number of Bedrooms	Discharge Rate in Gallons per Minute
1	30
2	30
3	30-45
4	30-60
5	38-75
6	45-90

The total head for a subsurface soil absorption system using flood dosing shall be the elevation difference between the pump and the outlet in the distribution box in addition to the friction loss in the delivery pipe expressed in feet.

(s) The liquid holding capacity of a dosing tank must equal the design daily average wastewater volume as further modified herein. The delivery pipe from the pumping chamber to the absorption field must drain between doses. If the delivery pipe drains to the absorption field, the dosing tank volume shall be the daily average wastewater volume, minus the volume contained in the delivery pipe. If the delivery pipe drains back to the dosing tank, the dosing tank volume shall be the daily average wastewater volume plus the volume contained in the delivery pipe. Additional capacity must be provided to keep the dosing tank pump submerged at all times and to provide sufficient freeboard for a high water alarm.

(t) The distal end of the delivery pipe from the pumping chamber must be fitted with an elbow turned down, or else the distribution box must be baffled.

(u) The minimum inside diameter of the delivery pipe shall be one (1) inch; the maximum inside diameter of the delivery pipe shall be four (4) inches.

(v) Table VIII, as follows, shall be used in determining friction losses in the delivery pipes and manifold when plastic pipe is used:

TABLE VIII
FRICTION LOSSES IN PLASTIC PIPE
Friction Losses in Plastic Pipe (C = 150) Versus Flow Rate and Pipe Diameter
(1 in = 2.54 cm, 1 ft = 0.305 m, 1 gpm = $6.3 \times 10^{-5} m^{3/5}$)

Diameter	1″	1¼″	1½″	2″	3″	4″	
Flow gpm	Friction Loss in feet/100 feet						Flow gpm
1	0.10						1
2	0.35	0.12					2
3	0.75	0.25	0.10				3
4	1.28	0.43	0.18				4
5	1.93	0.65	0.27	0.07			5
6	2.70	0.91	0.38	0.09			6
7	3.59	1.21	0.50	0.12			7

8	4.60	1.55	0.64	0.16			8
9	5.72	1.93	0.80	0.20			9
10	6.95	2.35	0.97	0.24			10
11		2.80	1.15	0.28			11
12		3.29	1.35	0.33			12
13		3.91	1.57	0.39			13
14		4.37	1.80	0.44	0.06		14
15		4.97	2.05	0.50	0.07		15
16		5.60	2.31	0.57	0.08		16
17		6.27	2.58	0.64	0.09		17
18		6.96	2.87	0.71	0.10		18
19			3.17	0.78	0.11		19
20			3.49	0.86	0.12		20
25			5.27	1.30	0.18		25
30				1.82	0.23	0.06	30
35				2.42	0.35	0.08	35
40				3.10	0.43	0.11	40
45				3.85	0.54	0.13	45
50				4.86	0.65	0.16	50
60					0.91	0.23	60
70					1.21	0.30	70
80					1.55	0.38	80
90					1.93	0.48	90
100					2.35	0.58	100
125					3.55	0.88	125
150					4.97	1.23	150
175						1.63	175
200						2.09	200
250						3.16	250
300						4.42	300

(Indiana State Department of Health; 410 IAC 6-8.1-53; filed Nov 20, 1990, 12:45 p.m.: 14 IR 641; errata filed Oct 2, 1991, 11:30 a.m.: 15 IR 110; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-8.1-54 Subsurface gravity feed trickle flow alternating systems

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 54. (a) The minimum absorption area (in square feet) required for each gravity feed alternating field subsurface soil absorption system shall be based on the following:

(1) The number of bedrooms and bedroom equivalents in the dwelling.

(2) The appropriate soil loading rate (in gallons per day per square foot) determined from Table V of section 49(4) of this rule.

(3) The vertical separation distance between the bottom of the proposed trench and any soil layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot. The loading rate used for this computation shall be the loading rate of the most restrictive horizon within twenty-four (24) inches of the trench bottom.

(4) The absorption area shall be computed using the following formula:

$$\text{area} = \frac{150g \times \text{number of bedrooms and bedroom equivalents}}{\text{loading rate in gpd/sq.ft.}}$$

(5) If the loading rate determined from Table V of section 49(4) of this rule is twenty-five hundredths (0.25) gallons per day per square foot or thirty-hundredths (0.30) gallons per day per square foot, the system may be reduced in size from the

absorption area determined in subdivision (1) by nine-tenths of one percent (0.9%) for each inch over twenty-four (24) inches to a maximum of sixty (60) inches between the trench bottom and a layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot. The new absorption area shall then be computed using the following formula:

New Absorption Area* = A.A. - [A.A. × 0.009 (D.L. - D.T. - 24)] where:

A.A. = Absorption area determined in subdivision (4).

D.L. = Depth in inches from the ground surface to a layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot.

D.T. = Depth in inches from the ground surface to the proposed trench bottom.

*Note: The value for the quantity (D.L. - D.T. - 24) may not exceed thirty-six (36). If a value of greater than thirty-six (36) is obtained, then thirty-six (36) must be used for the computations.

(b) All subsurface gravity feed trickle flow alternating field systems shall be located in accordance with the separation distances shown in Table II of section 37(a) of this rule. Subsurface gravity feed trickle flow alternating systems shall not be constructed where there exist horizons, layers, or strata within thirty-four (34) inches of the ground surface with a loading rate greater than seventy-five hundredths (0.75) gallons per day per square foot as determined from Table V of section 49(4) of this rule.

(c) Subsurface gravity feed trickle flow alternating field systems shall not be wholly or partly located in a drainage way subject to intermittent flooding.

(d) A diversion valve shall be installed between the septic tank and the distribution boxes. An access riser, extending to the ground surface, shall be installed over the diversion valve.

(e) Each trench and distribution line in a subsurface gravity feed flood dosed system shall be uniformly level throughout its length.

(f) In order to provide equal flow distribution in gravity feed trickle flow alternating field subsurface soil absorption systems, the absorption trenches in each side of the system must be individually connected to a distribution box by at least five (5) feet of unperforated pipe which is laid with a gravel free backfill. All absorption trenches served by a common distribution box must be constructed so that each square foot of the absorptive area served by the distribution box is loaded with an equal volume of effluent. The distal ends of the distribution lines may be manifolded together by piping on sites with slopes of two percent (2%) or less, but shall not be tied together on sites with slopes of greater than two percent (2%). When the distal ends of the absorption trenches are manifolded, the manifold trench area shall not count as meeting any of the minimum absorption area required by subsection (a).

(g) All absorption field distribution lines shall have an internal diameter of four (4) inches.

(h) No single absorption trench shall exceed one hundred (100) feet in length.

(i) On sloping sites, absorption trenches shall be constructed along the contour.

(j) There shall be a minimum separation of seven and one-half (7½) feet, on center, between absorption field trenches.

(k) All subsurface gravity feed flood dosed absorption fields shall be designed to utilize trenches with a minimum width of eighteen (18) inches and a maximum trench width of thirty-six (36) inches.

(l) The minimum depth from original grade to the bottom of a subsurface gravity feed trickle flow alternating field absorption trench shall not be less than ten (10) inches, and the maximum depth to the bottom of such trench shall not be more than thirty-six (36) inches.

(m) Perforated pipe distribution lines in the subsurface gravity feed trickle flow alternating field soil absorption trench shall be completely surrounded by aggregate which meets the specifications in section 47 of this rule. There shall be at least six (6) inches of aggregate below the pipe and at least two (2) inches of aggregate above the pipe.

(n) The aggregate shall be covered with a six (6) inch layer of straw, or else a geotextile fabric barrier which meets the minimum requirements in section 46 of this rule. The barrier shall be installed in such a manner as to prevent the aggregate from becoming clogged with the earth fill.

(o) A minimum of twelve (12) inches of cover shall be provided over the aggregate in the trenches, and any fill required to provide cover shall be crowned over the entire field to promote surface run-off.

(p) Subsurface gravity feed trickle flow alternating field soil absorption systems shall not be constructed in clayey soils during periods of wet weather when the soil is sufficiently wet at the depth of installation to exceed its plastic limit. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. For the purpose of this rule, the plastic limit of a soil shall be considered to have been exceeded when the soil can be rolled between the palms of the hands to produce threads one-eighth (⅛) inch in diameter without breaking apart and crumbling.

(q) Special caution shall be taken to prevent wheeled and tracked vehicles from compacting the area selected for placement of the subsurface gravity feed trickle flow alternating field soil absorption system before, during, and after construction of the trenches, especially during wet weather. Precaution is especially important where clayey soils are involved. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. Alteration of soil structure by movement of vehicles may be grounds for rejection of the site and/or the system.

(r) Excessive smearing of the usable absorption trench sidewalls or bottom during construction may result in irreversible damage to the soil infiltrative surface and may be grounds for rejection of the site and/or the system. *(Indiana State Department of Health; 410 IAC 6-8.1-54; filed Nov 20, 1990, 12:45 p.m.: 14 IR 644; errata filed Jan 25, 1991, 4:20 p.m.: 14 IR 1287; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-55 Subsurface pressure distribution systems

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 55. (a) The minimum absorption area (in square feet) required for each subsurface pressure distribution soil absorption system shall be based on the following:

(1) The number of bedrooms and bedroom equivalents in the dwelling.

(2) The appropriate soil loading rate (in gallons per day per square foot) determined from Table V of section 49(4) of this rule.

(3) The vertical separation distance between the bottom of the proposed trench and any soil layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot. The loading rate used for this computation shall be the loading rate of the most restrictive horizon within twenty-four (24) inches of the trench bottom.

(4) The absorption area shall be computed using the following formula:

$$\text{area} = \frac{150\text{g} \times \text{number of bedrooms and bedroom equivalents}}{\text{loading rate in gpd/sq.ft.}}$$

(5) If the loading rate determined from Table V of section 49(4) of this rule is twenty-five hundredths (0.25) gallons per day per square foot or thirty-hundredths (0.30) gallons per day per square foot, the system may be reduced in size from the absorption area determined in subdivision (1) by nine-tenths of one percent (0.9%) for each inch over twenty-four (24) inches to a maximum of sixty (60) inches between the trench bottom and a layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot. The new absorption area shall then be computed using the following formula:

New Absorption Area* = A.A. - [A.A. × 0.009 (D.L. - D.T. - 24)] where:

A.A. = Absorption area determined in subdivision (4).

D.L. = Depth in inches from the ground surface to a layer with a loading rate of less than twenty-five hundredths (0.25) gallons per day per square foot.

D.T. = Depth in inches from the ground surface to the proposed trench bottom.

*Note: The value for the quantity (D.L. - D.T. - 24) may not exceed thirty-six (36). If a value of greater than thirty-six (36) is obtained, then thirty-six (36) must be used for the computations.

(b) All subsurface pressure distribution systems shall be located in accordance with the separation distances shown in Table II of section 37(a) of this rule. Subsurface pressure distribution systems shall not be constructed where there exist horizons, layers, or strata within thirty-four (34) inches of the ground surface with a loading rate greater than one and twenty-hundredths (1.20) gallons per day per square foot as determined from Table V of section 49(4) of this rule unless that hazard can be overcome through system design.

(c) Subsurface pressure distribution soil absorption systems shall not be wholly or partly located in a drainage way subject to intermittent flooding.

(d) On sloping sites, absorption trenches in subsurface pressure distribution systems shall be constructed along the contour.

(e) There shall be a minimum separation of seven and one-half (7½) feet, on center, between absorption field trenches in subsurface pressure distribution systems.

(f) All subsurface pressure distribution systems shall be designed to utilize trenches with a minimum width of eighteen (18) inches and a maximum trench width of thirty-six (36) inches.

(g) The minimum depth from original grade to the bottom of a trench in a subsurface pressure distribution system shall not

be less than ten (10) inches, and the maximum depth to the bottom of a trench in a subsurface pressure distribution system shall not be more than thirty-six (36) inches.

(h) Perforated pipe distribution lines in the absorption trench of a subsurface pressure distribution system shall be completely surrounded by aggregate which meets the specifications in section 47 of this rule. There shall be at least six (6) inches of aggregate below the pipe and at least two (2) inches of aggregate above the pipe.

(i) The aggregate in a subsurface pressure distribution system shall be covered with a six (6) inch layer of straw, or else a geotextile fabric barrier which meets the minimum requirements in section 46 of this rule, in such a manner as to prevent the aggregate from becoming clogged with the earth fill.

(j) A minimum of twelve (12) inches of cover shall be provided over the aggregate in the trenches, and any fill required to provide cover shall be crowned over the entire field to promote surface run-off.

(k) Subsurface pressure distribution systems shall not be constructed in clayey soils during periods of wet weather when the soil is sufficiently wet at the depth of installation to exceed its plastic limit. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. For the purpose of this rule, the plastic limit of a soil shall be considered to have been exceeded when the soil can be rolled between the palms of the hands to produce threads one-eighth (⅛) inch in diameter without breaking apart and crumbling.

(l) Special caution shall be taken to prevent wheeled and tracked vehicles from compacting the area selected for placement of the subsurface pressure distribution system before, during, and after construction of the trenches, especially during wet weather. Precaution is especially important where clayey soils are involved. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. Alteration of soil structure by movement of vehicles may be grounds for rejection of the site and/or the system.

(m) Excessive smearing of the usable absorption trench sidewalls or bottom during construction may result in irreversible damage to the soil infiltrative surface and may be grounds for rejection of the site and/or the system.

(n) Each pipe connected to an outlet in the manifold of a subsurface pressure distribution system shall be counted as a separate distribution pipe.

(o) Trenches in a subsurface pressure distribution system shall not be manifolded together at the distal end of the trench.

(p) Each trench and distribution line in a subsurface pressure distribution system shall be uniformly level throughout its length.

(q) The pump shall be sized, and its controls set as follows:

(1) When a subsurface pressure distribution system is designed using a loading rate of less than one and two-tenths (1.2) gallons per day per square foot, the pump shall deliver the design daily flow in one (1) dose each day while maintaining an in-line residual pressure of two and five-tenths (2.5) to three (3) feet of head in the distribution line at the highest elevation in the soil absorption system during pumping.

(2) When a subsurface pressure distribution system is designed using a loading rate of one and two-tenths (1.2) gallons per day per square foot, the pump shall deliver four (4) doses each day, each dose being approximately one-fourth (¼) of the daily design flow, while maintaining an in-line residual pressure of two and five-tenths (2.5) to three (3) feet of head in the distribution line at the highest elevation in the soil absorption system during pumping.

(r) The delivery pipe from the pumping chamber to the subsurface pressure distribution system must drain between doses. If the delivery pipe drains to the subsurface pressure distribution system, the dosing tank volume shall be the dose calculated using subsection (q)(1) or (q)(2), whichever is applicable, minus the volume contained in the delivery pipe. If the delivery pipe drains back to the dosing tank, the dosing tank volume shall be the dose calculated using subsection (q)(1) or (q)(2), whichever is applicable, plus the volume contained in the delivery pipe. Additional dosing tank capacity must be provided to keep the dosing tank pump submerged at all times and to provide sufficient freeboard for a high water alarm.

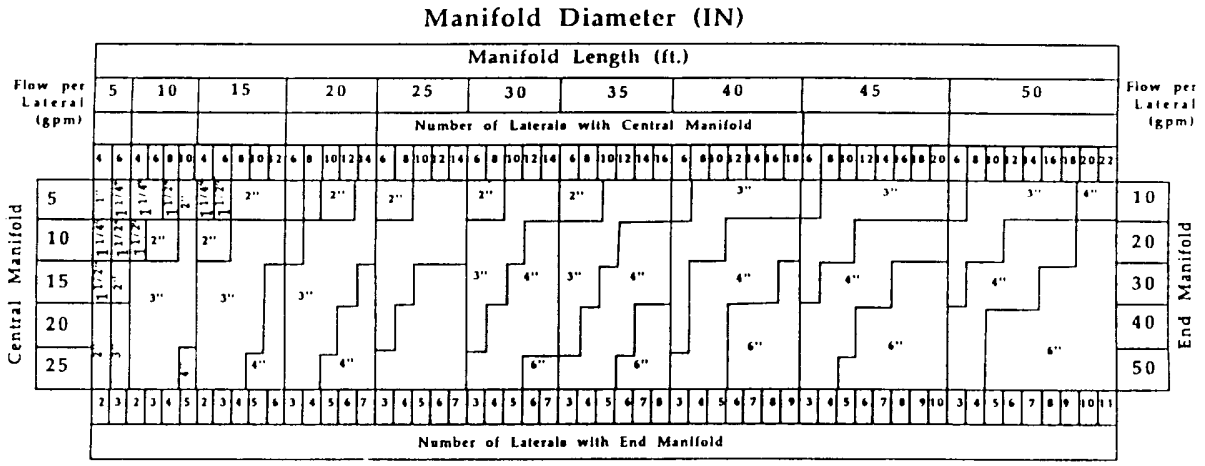
(s) The minimum inside diameter of the delivery pipe shall be two (2) inches; the maximum inside diameter of the delivery pipe shall be four (4) inches.

(t) Table VIII of section 53(v) of this rule, shall be used in determining friction losses in the delivery pipes and manifold when plastic pipe is used.

(u) The delivery manifold piping diameter shall be determined from Table IX of this subsection. The minimum inside diameter of the manifold shall be two (2) inches; the maximum inside diameter of the manifold shall be four (4) inches.

Table IX

MANIFOLD DIAMETERS FOR VARIOUS MANIFOLD LENGTHS, NUMBER OF LATERALS AND LATERAL DISCHARGE RATES (FOR PLASTIC PIPE ONLY)



Computed for plastic pipe only. The Hazen-Williams equation was used to compute headlosses through each segment (Hazen-Williams C - 150). The maximum manifold length for a given lateral discharge rate and spacing was defined as that length at which the difference between the heads at the distal and supply ends of the manifold exceeded 10 percent of the head at the distal end.

(v) The minimum inside diameter of the distribution pipes from the delivery manifold shall be one (1) inch; the maximum inside diameter of the distribution pipes shall be three (3) inches.

(w) The distribution pipes shall have one (1) row of holes spaced in accordance with Table X as follows:

TABLE X

SOIL LOADING RATES VERSUS LATERAL HOLE SPACING

Soil Loading Rates Gallons per Day per Square Foot	Lateral Hole Spacing Feet Between Holes
1.2	3
0.75	3 to 5
0.5 and 0.6	3 to 6
0.25 and 0.3	3 to 7

(x) The holes in the lateral piping shall be placed in the trenches facing down, and all burrs shall be removed from the edges of the holes.

(y) The hole size in the laterals shall be one-fourth (¼) inch.

(z) The perforation discharge rate shall be determined in accordance with the formula used to compute the flow from a hole in the distribution line at in-line head as follows:

$$Q = 11.78(d^2)(\sqrt{H})$$

Where: "Q" = the volume of the flow from the hole

"d" = the diameter of the hole in the pipe

"H" = the in-line head at the hole

Table XI gives the discharge rates at varying heads which would be obtained using the formula above in which "d" equals one-fourth (¼) inch diameter holes.

TABLE XI

PERFORATION DISCHARGE RATES IN GPM AT VARYING HEADS FOR ¼ INCH DIAMETER HOLE SIZE

In-Line Head (feet)	Perforation Discharge Rate (gallons per minute)
1.5	0.90
2.0	1.04
2.5	1.17
3.0	1.28
3.5	1.38
4.0	1.47
4.5	1.56

(aa) Pump selection for soil absorption systems using pressure distribution shall be based on the manufacturers pump curves for the required pump discharge rate at the total head imposed on the pump. The pump discharge rate for level systems is calculated by using the following formula:

$$\frac{\text{Perforation discharge rate} \times \text{number of perforations per 100 feet of distribution pipe} \times \text{total length of distribution pipe}}{100}$$

To obtain the pump discharge rate required for sloping sites the rate must be calculated individually for each distribution line, using the pump discharge rate formula based on the pressure on that line, and the sum of the calculated discharge rates determined for each individual line.

(bb) The end of each lateral shall be capped, and a one-fourth (¼) inch hold shall be drilled in the upper half of the end cap.

(cc) All joints, including the end cap, shall withstand the pressures exerted on them. *(Indiana State Department of Health; 410 IAC 6-8.1-55; filed Nov 20, 1990, 12:45 p.m.: 14 IR 646; errata filed Oct 2, 1991, 11:30 a.m.: 15 IR 110; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-56 Elevated sand mound systems

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 56. (a) The minimum basal area (in square feet) required for each elevated sand mound system shall be based on the following:

(1) The number of bedrooms and bedroom equivalents in the dwelling, and the appropriate soil loading rate (in gallons per day per square foot) determined from Table VI of section 51(4) of this rule. The absorption area shall be computed using the formula:

$$\text{Absorption area} = \frac{150g \times \text{number of bedrooms and bedroom equivalents}}{\text{loading rate in gpd/sq.ft.}}$$

The loading rate used for this computation shall be the loading rate of the most restrictive horizon within twenty (20) inches of the soil surface.

(2) On level sites, the basal area shall be the entire area under the mound excluding the end slope areas. On sloping sites, the basal area shall be the area underneath and down slope of the aggregate bed.

(b) All elevated sand mound systems shall be located in accordance with the separation distances shown in Table II of section 37(a) of this rule. Elevated sand mound systems shall not be constructed where there exist horizons, layers, or strata within twenty (20) inches of the ground surface with a loading rate greater than one and twenty-hundredths (1.20) gallons per day per square foot as determined from Table VI of section 51(4) of this rule unless that hazard can be overcome through system design.

(c) Elevated sand mound systems shall not be wholly or partly located in a drainage way subject to intermittent flooding.

(d) The elevated sand mound site as well as the downslope absorption area shall be staked out and protected from vehicular traffic.

(e) The elevated sand mound must be designed and constructed so that its longest axis is located along the contour. The mound dimensions should be as long and narrow as possible for the site.

(f) Elevated sand mound systems shall not be constructed in clayey soils during periods of wet weather when the soil is sufficiently wet at the depth of installation to exceed its plastic limit. This includes those soils classified as sandy loam, silt loam, loam, clay loam, silty clay loam, sandy clay, silty clay, and clay. For the purpose of this rule, the plastic limit of a soil shall be considered to have been exceeded when the soil can be rolled between the palms of the hands to produce threads one-eighth (⅛) inch in diameter without breaking apart and crumbling.

(g) Excessive vegetation at the mound site must be cut and removed. If present, trees must be cut off at ground level and the stumps left in place.

(h) The delivery line from the dosing tank to the manifold shall be installed prior to plowing the mound site.

(i) The area within the mound perimeter shall be plowed to a depth of seven (7) to eight (8) inches, parallel to the contour, with a moldboard or chisel plow. If a moldboard plow is used, it shall have at least two (2) bottoms (shares) and the soil shall be turned upslope.

(j) The sand fill shall meet the following conditions:

(1) Sand fill must be placed on the plowed area immediately after plowing the site.

(2) The sand utilized must be medium textured sand which meets the size criteria of Table XII as follows:

TABLE XII

Sieve Size	Percent Passing Sieve*
⅜ inch	100
No. 4	95-100
No. 8	80-100
No. 16	50-85
No. 30	25-60
No. 50	5-30
No. 100	0-10
No. 200	0-3

*Note: The fine aggregate shall not have more than forty-five percent (45%) retained between any two (2) consecutive sieves. Aggregate which meets Indiana state highway Specification 23 meets this criteria.

(3) The sand shall be placed on the plowed area starting from the upslope edge. At least six (6) inches of sand fill must be kept between the vehicle wheels or tracks and the native soil of the mound site at all times.

(4) There shall be a minimum of twelve (12) inches of sand fill. The surface of the sand fill shall be raked smooth to eliminate any ruts. The toes of the fill shall be constructed to a minimum of a 3:1 slope.

(k) Aggregate shall be placed over the sand fill to form a bed, not trenches. The bottom of this aggregate bed shall be level.

(l) The aggregate used in the gravel bed shall meet the minimum requirements of section 47 of this rule. There shall be at least six (6) inches of aggregate beneath and two (2) inches of aggregate above the lateral lines.

(m) The aggregate bed shall be covered with a barrier material which meets the minimum requirements of section 46 of this rule.

(n) The total area of the aggregate bed (in square feet) shall be determined using the formula:

$$\text{Area} = \frac{150\text{g} \times \text{number of bedrooms and bedroom equivalents}}{1.2 \text{ gpd/sq.ft.}}$$

Aggregate beds shall not be less than four (4) feet nor more than ten (10) feet in width. If more than one (1) aggregate bed must be constructed, each bed shall provide equal absorption area.

(o) A pressure distribution network shall be used for elevated sand mound systems. The pressure distribution system network shall be sized, and its controls set, to deliver four (4) doses each day, each dose being approximately one-fourth (¼) of the daily design flow, while maintaining an in-line residual pressure of two and five-tenths (2.5) to three (3) feet of head in the distribution line during pumping.

(p) The pressure distribution network must drain between doses. If the delivery pipe drains to the distribution network, the dosing tank volume shall be the dose calculated using subsection (o), minus the volume contained in the delivery pipe. If the delivery pipe drains back to the dosing tank, the dosing tank volume shall be the dose calculated using subsection (o), plus the volume contained in the delivery pipe. Additional dosing tank capacity must be provided to keep the dosing tank pump submerged at all

times and to provide sufficient freeboard for a high water alarm.

(q) The minimum inside diameter of the delivery pipe shall be two (2) inches; the maximum inside diameter of the delivery pipe shall be four (4) inches.

(r) Table VIII of section 53(v) of this rule, shall be used in determining friction losses in the delivery pipes and manifold when plastic pipe is used.

(s) The delivery manifold piping diameter shall be determined from Table IX of section 55(u) of this rule. The minimum inside diameter of the manifold shall be two (2) inches; the maximum inside diameter of the manifold shall be four (4) inches.

(t) The minimum inside diameter of the distribution pipes from the delivery manifold shall be one (1) inch; the maximum inside diameter of the distribution pipes shall be three (3) inches.

(u) The holes in the lateral pipes shall be placed in the trenches facing down, and all burrs shall be removed from the edges of the holes.

(v) The hole size in the laterals shall be one-fourth (¼) inch.

(w) The end of each lateral shall be capped and a one-fourth (¼) inch hole drilled in the upper half of the end cap.

(x) The system shall maintain an in-line residual pressure of two and five-tenths (2.5) to three (3) feet of head during pumping.

(y) All joints, including the end cap, shall withstand the pressures exerted on them.

(z) The lateral lines in the absorption bed shall not be manifolded together.

(aa) The separation distance between laterals shall not be less than twenty-four (24) inches nor more than thirty-six (36) inches.

(bb) The holes on the bottom of the laterals shall be spaced thirty-six (36) inches on center, with the first hole located eighteen (18) inches from the manifold.

(cc) The elevated sand mound shall be designed and constructed to maintain at least a 3:1 slope on all sides.

(dd) The entire mound shall be covered with six (6) inches of a clayey textured soil with an additional six (6) inches of topsoil covering the clayey textured soil.

(ee) The elevated sand mound shall be seeded or sodded with grasses and legumes adapted to the area. If the mound is seeded, the mound shall be protected by a cover of straw, burlap, or some other material that will protect it against erosion until a vegetative cover develops. *(Indiana State Department of Health; 410 IAC 6-8.1-56; filed Nov 20, 1990, 12:45 p.m.: 14 IR 649; errata filed Oct 2, 1991, 11:30 a.m.: 15 IR 110; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-8.1-57 Matters incorporated by reference

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 57. (a) Bulletin SE 11, "The Sanitary Vault Privy," 1986 Edition, is incorporated by reference as part of this rule. It may be obtained free of charge by request mailed to the board at 1330 West Michigan Street, Indianapolis, Indiana 46206-1964.

(b) National Sanitation Foundation Standard Number 40, "Individual Aerobic Wastewater Treatment Plants," 1983 Edition, is incorporated by reference as part of this rule. Two (2) copies of the standard are available for reference in the files of the board. Copies of the standard may be obtained by mailing a request and fifteen dollars ($15) to the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106.

(c) Two (2) copies of ASTM Standards D 1527-89, D 1785-89, D 2241-89, D 2282-89, D 2661-87a, D 2665-89a, D 2680-89, D 2729-89, D 2751-89, D 3034-89, F405-89, F667-85, F810-85, C412-83, C4-62, and 498-65 and SCS Standard 606 are available for reference in the files of the board. *(Indiana State Department of Health; 410 IAC 6-8.1-57; filed Nov 20, 1990, 12:45 p.m.: 14 IR 651; errata filed Dec 10, 1990, 4:30 p.m.: 14 IR 760; errata filed Jan 25, 1991, 4:20 p.m.: 14 IR 1287; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 9. Agricultural Labor Camp Sanitation and Safety

410 IAC 6-9-1 Definitions

Authority: IC 16-19-3-4; IC 16-41-26-8
Affected: IC 16-41-26

Sec. 1. (a) The definitions in this section apply throughout this rule.

(b) "Adult" means any person who is eighteen (18) years of age or older.

(c) "Agricultural labor camp" means one (1) or more buildings or structures, tents, trailers, or vehicles, together with the land appertaining thereto, established, operated, and used as living quarters for five (5) or more adult seasonal or temporary workers engaged in agricultural activities, including related food processing.

(d) "Board" means the Indiana state board of health.

(e) "Camp operator" means any person who, within the meaning of the act, operates a camp or holds a permit issued pursuant to the provisions of IC 13-1-9 *[IC 13-1-9 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-26.]*.

(f) "Community building" means any building provided for general use and in which is located, for general use, any of the following:

(1) Toilet facilities.

(2) Washrooms.

(3) Bathrooms.

(4) Laundry facilities.

(5) Recreation facilities.

(6) Space for other communal activities.

(g) "Garbage" means all putrescible wastes resulting from the handling, processing, preparation, and consumption of food.

(h) "Habitable room" means any enclosed space used or intended to be used in the normal activities of daily living.

(i) "Interference with state board of health agent" means, but is not limited to, physical obstruction, attack, or threatened attack on a representative of the board while that representative is conducting inspection, licensin *[sic.]*, or enforcement activities pursuant to IC 13-1-9 *[IC 13-1-9 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-26.]* or this rule.

(j) "Living quarters" means any habitable room as well as any building or structure in which is located toilet facilities, washrooms, bathrooms, and laundry facilities.

(k) "Refuse" means all solid wastes, including garbage, rubbish, and ashes, but excluding body wastes.

(l) "Residents" means those persons who dwell in one (1) shelter at an agricultural labor camp.

(m) "Shelter" means any facility used for the normal activities of daily living.

(n) "Toilet facilities" means those devices provided for individual convenience in the sanitary disposal of body wastes and the structures for their installation and maintenance.

(o) "Violation" means the failure of an agricultural labor camp owner, operator, caretaker, or other person who has a substantial and direct proprietary interest in the camp to abide by a provision of IC 13-1-9 *[IC 13-1-9 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-26.]* or this rule. *(Indiana State Department of Health; Reg HSE 29R, Sec 1; filed Aug 29, 1972, 11:00 a.m.: Rules and Regs. 1973, p. 382; filed Sep 29, 1989, 2:02 p.m.: 13 IR 269; filed Dec 4, 1991, 9:30 a.m.: 15 IR 487; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-9-2 Construction notice; permit

Authority: IC 16-19-3-4; IC 16-41-26-8
Affected: IC 4-21.5; IC 16-41-26

Sec. 2. (a) Any person planning to construct or enlarge for occupancy or use any camp or facility thereto appertaining, or to convert any premises to use as a camp, shall give written notice to the board on such forms as the board may require. This notice shall be given not later than sixty (60) days before the starting date of such construction, enlargement, or conversion. Upon receipt of said notice, the board shall provide necessary information to the notifier, including consultation as indicated. The board may require, and the notifier shall provide, such further information as the board shall need.

(b) Compliance with local laws and regulations shall be accomplished by the notifier.

(c) Application for a permit to operate an agricultural labor camp shall be made to the board in such form and manner as the board may prescribe, and said application shall be made not later than sixty (60) days prior to the start of the operation of the camp.

(d) If, after necessary investigation and inspection, the board is satisfied that the camp is in substantial compliance with statutory and regulatory requirements, a permit shall be issued.

(e) In case of single ownership of multiple camps, each camp, within the meaning of the act, shall have a permit.

(f) When a change of camp operator is contemplated, the new operator shall file an application for a permit with the board within fifteen (15) days of the effective date of the transfer. *(Indiana State Department of Health; Reg HSE 29R, Sec 2; filed Aug 29, 1972, 11:00 a.m.: Rules and Regs. 1973, p. 382; filed Sep 29, 1989, 2:02 p.m.: 13 IR 270; filed Dec 4, 1991, 9:30 a.m.: 15 IR*

488; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2283; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-9-3 Camp facilities

Authority: IC 16-19-3-4; IC 16-41-26-8
Affected: IC 16-41-26

Sec. 3. (a) The following requirements pertain to housing sites:
(1) Housing sites shall be well-drained and free from depressions in which water may stagnate. They shall be located where the disposal of sewage is provided in a manner which neither creates nor is likely to create a nuisance or hazard to health.
(2) Housing shall not be subject to, or in proximity to, conditions that create or are likely to create a health or safety hazard.
(3) Grounds within the housing site shall be free from debris, noxious plants such as poison ivy, and uncontrolled weeds or brush.
(4) A minimum distance equal to the height of the structure plus five (5) feet shall be required between all shelters.
(5) A slotted or perforated removable landing or permanent concrete slab having a length and width not less than the width of the door opening shall be located at the outside entrance of each habitable room.
(6) The housing site shall provide a space for recreation reasonably related to the size of the facility and the type of occupancy.
(7) Farm implements shall not be stored in the camp area when the camp is occupied.
(8) All shelters must be located at least five hundred (500) feet from any livestock harborage which might create nuisance conditions or a health hazard.
(9) Vehicles, refrigerators, or other abandoned appliances must be removed from the camp as soon as they are discarded.
(10) Prior to camp occupancy, any shelter which does not comply with subsection (d) must be razed, removed, or secured to prevent access.
(11) All containers such as used tires, buckets, or pans which might accumulate rainwater must either be removed or kept indoors.
(b) The following requirements pertain to water supplies:
(1) An adequate and convenient supply of water which meets the quality standards of the water pollution control board shall be available at all times in each camp for culinary, drinking, bathing, and laundry purposes. Where a public water supply is available, it shall be used to provide water for the camp.
(2) When wells are used as the source of the camp water supply, they shall be in full compliance with the rules of the water pollution control board.
(3) A cold water tap and an approved drinking fountain with sanitary type angle-stream jet head shall be available within one hundred (100) feet of each individual living unit when water under pressure is not provided in the unit. Adequate drainage facilities shall be provided for overflow and spillage.
(4) Common drinking cups shall not be permitted.
(c) The following requirements pertain to excreta and liquid waste disposal:
(1) Facilities shall be provided and maintained for effective disposal of excreta and liquid waste.
(2) Where public sewer systems are available, all facilities for disposal of excreta and liquid wastes shall be connected thereto.
(3) Where conditions will permit and a public sewage system is not available, sewage treatment or disposal facilities utilizing septic tanks and absorption systems shall be constructed in accordance with 410 IAC 6-10 concerning commercial on-site wastewater disposal.
(4) Sewage treatment facilities which have an effluent discharging into the waters of the state shall be designed, constructed, and maintained in compliance with all applicable rules of the water pollution control board.
(5) Privies must be constructed and maintained in a sanitary condition. In addition:

(A) a vault of sufficient capacity to serve the daily and long term needs of users must be provided;
(B) the vault must be inaccessible to rodents and insects;
(C) a concrete floor slab, base, or vault lid must be provided on which the privy housing or superstructure can be erected; wood floors cannot be utilized;
(D) an earth mound must be maintained around the privy base to divert surface water away from the vault;
(E) seat risers must extend directly from the concrete base, or floor slab, and be constructed of impervious material;
(F) comfortable seats must be provided with tight fitting lids which completely cover the privy seat hole when not in use;

(G) the privy housing structure must afford privacy, and the shelter must be fly-tight, enclosing walls and roof must have no openings or cracks which are not sealed or screened;

(H) a tight fitting door must be provided which is equipped with a self-closing device;

(I) vents, windows, and other openings must be completely screened;

(J) a vertical pipe or enclosed moisture-proof vent duct must extend from the privy vault to a point above the roof peak, be protected by a screening of not less than sixteen (16) mesh at the outlet, and be capped to divert precipitation;

(K) a properly sloped roof of impervious material must be provided with an overhang to prevent ponding of water and leakage into the structure;

(L) adequate illumination of the privy interior must be provided at all times;

(M) the privy must provide user privacy through the installation of privacy partitions around the structure or by use of inside door latches;

(N) privy vaults must be pumped when accumulated wastes are within eighteen (18) inches of the floor slab; and

(O) privies shall not be located closer than fifty (50) feet from any habitable room or any facility where food is prepared or served.

(d) The following requirements pertain to housing:

(1) Housing shall be structurally sound, in good repair, in a sanitary condition, and shall provide protection to the residents against the elements. In addition:

(A) all shelters must have walls free of cracks and holes;

(B) wood shelters must have walls of cleanable, smooth, hard surfaces;

(C) all shelters must have exterior doors and screen doors on all exits;

(D) doors must have latches or door knobs and must fit tightly in their frames;

(E) latches must latch from both the inside and outside;

(F) shelter floors must be reasonably level;

(G) the interior walls and ceilings of the shelters must either be painted in a light-reflecting color or be constructed or *[sic., of]* easily cleanable materials approved by the board; and

(H) all mobile home type shelters shall be installed on a permanent foundation or securely anchored to the ground.

(2) Housing shall have flooring constructed of rigid materials, smooth finished, readily cleanable, and so located as to prevent the entrance of ground water and surface water, insects, and rodents. All floors shall have a smooth finish and be free of cracks.

(3) The following minimum space requirements shall be provided until December 31, 1992:

(A) For sleeping purposes only in family units and in dormitory accommodations using single beds, not less than fifty (50) square feet of floor space per occupant.

(B) For sleeping purposes only in family units and in dormitory accommodations using double bunk beds only, not less than forty (40) square feet per occupant.

(C) For combined cooking, eating, and sleeping purposes, not less than sixty (60) square feet of floor space per occupant.

(D) In mobile home type units provided by a person other than occupant, there shall be at least forty (40) square feet of floor area for each person sleeping therein.

(4) Separate sleeping accommodations shall be provided for each sex or family.

(5) Adequate arrangements for handling clothing and storing personal effects for each person or family shall be provided. Three (3) feet of bar and three (3) feet of shelving for each one hundred (100) square feet of floor space will be considered adequate.

(6) Each living unit shall have a minimum ceiling height of seven (7) feet.

(7) Each habitable room shall have at least one (1) window or skylight opening directly outdoors. The minimum total glazed area shall equal at least ten percent (10%) of the usable floor area. The total openable area shall equal at least forty-five percent (45%) of the minimum glazed area required, except where comparably adequate ventilation is supplied by mechanical or some other method. In addition:

(A) all windows shall fit tightly in their frames; and

(B) all operable windows must open easily and must be fitted with a latching mechanism.

(8) All living quarters shall be assigned the same number. Numbers must be at least two (2) inches high and must be painted near the primary entrances in a color contrasting with that of the shelter.

(9) Each shelter must have the same maximum number of residents allowed under subdivision (3) posted near the primary entrance to the shelters as follows: “Maximum residents” in English, and “Maximos residentes” in Spanish.
(10) Effective January 1, 1993, all mobile homes used as shelters and equipped with an operable toilet, shower, lavatory, and hot and cold water under pressure, shall provide a minimum floor space of sixty (60) square feet per resident; and all other shelters shall provide a minimum floor space of eighty (80) square feet per resident.
(e) The following requirements pertain to screening:
(1) All outside openings shall be protected with screening of not less than sixteen (16) mesh.
(2) All screen doors shall be tight fitting, in good repair, and equipped with self-closing devices.
(f) The following requirements pertain to heating:
(1) Any camp which is occupied between August 31 and June 1, shall be provided with operable heating equipment of capacity adequate to maintain a temperature of at least sixty-five degrees Fahrenheit (65° F) in each habitable room during the period of occupancy. A facility provided for cooking purposes does not satisfy the requirements of this subdivision.
(2) Any sources of heat utilizing combustible fuel shall be installed and vented in such a manner as to prevent fire hazards and a dangerous concentration of gases. No portable heaters other than those operated by electricity shall be provided. If a solid or liquid fuel stove is used in a room with wooden or other combustible flooring, there shall be a concrete slab, insulated metal sheet, or other fireproof material on the floor under each stove, extending at least eighteen (18) inches beyond the perimeter of the base of the stove. No facility intended or used for cooking purposes shall be used to heat the living quarters.
(3) Any wall or ceiling within eighteen (18) inches of a solid or liquid fuel stove or a stovepipe shall be fireproof material. A vented metal collar shall be installed around a stovepipe or vent passing through a wall, ceiling, floor, or roof.
(4) When a heating system has automatic controls, the controls shall be of the type which cut off the fuel supply upon the failure or interruption of the flame or ignition, or whenever a predetermined safe temperature or pressure is exceeded.
(5) When gas heaters are used, they must have pilot lights in operation at all times between August 31 and June 1 each year when the shelter is occupied, and each room where gas heaters are installed must have operating instructions posted in English and Spanish.
(6) Unvented kerosene heaters and catalytic type heaters are prohibited.
(7) Venting, fire resistivity, fuel storage and supply, and all other parts of the heating system shall comply with 675 IAC 22-2.1, the Indiana Fire Prevention Code.
(g) The following requirements pertain to electricity and lighting:
(1) Each habitable room and enclosed area in a shelter shall contain:
    (A) an overhead light or lights that provide at least twenty (20) foot-candles of illumination throughout the room; and
    (B) a minimum of three (3) operable wall-type duplex electrical outlets in each room, located so that at least two (2) walls have outlets.
(2) Adequate lighting shall be provided for the yard area and pathways to common use facilities.
(3) All wiring and lighting fixtures shall be installed and maintained in a safe condition. After the effective date of this rule, all newly installed wiring and lighting fixtures shall be installed and maintained in compliance with 675 IAC 17, the Indiana Electrical Code.
(4) Hallways and stairways shall be adequately lighted. Stairways shall have two (2) switches, one (1) at each end controlling an overhead light fixture.
(5) In cooking areas of family living units, at least twenty (20) foot-candles of illumination shall be provided.
(6) Each shelter shall have a fuse box with circuit breaker or fuses, sized to meet the requirements of 675 IAC 17, the Indiana Electrical Code.
(h) The following requirements pertain to toilets:
(1) Toilets shall be constructed, located, and maintained so as to prevent any nuisance or public health hazard.
(2) Water closets or privy seats for each sex shall be in the ratio of not less than one (1) such unit for each fifteen (15) residents, with a minimum of one (1) unit for each sex in common use facilities.
(3) Urinals, constructed of nonabsorbent materials, may be substituted for men's toilet seats on the basis of one (1) urinal for one (1) toilet seat up to a maximum of one-third (⅓) of the required toilet seats.
(4) Except in individual family units, separate toilet accommodations for men and women shall be provided. If toilet facilities for men and women are in the same building, they shall be separated by a solid wall from floor to roof or ceiling. Toilets shall be distinctly marked “men” and “women” in English and in Spanish. International symbols may be used in lieu of English and Spanish designations.

(5) All common use rooms containing sanitary or laundry facilities shall have the following:

(A) Walls and partitions around toilets, showers, lavatories, and other plumbing fixtures, constructed of smooth, nonabsorbent, easily cleanable materials.

(B) Bathing and handwashing facilities supplied with hot and cold water under pressure. Hot water provided for showers and handwashing facilities shall be maintained between one hundred five degrees Fahrenheit (105° F) and one hundred twenty degrees Fahrenheit (120° F). An approved antiscald device shall be provided to automatically control the hot water temperature so that it cannot exceed one hundred twenty degrees Fahrenheit (120° F). All new and replacement faucets installed on bathing and handwashing facilities after the effective date of this rule shall be mixing type faucets.

(C) At least one (1) window which can be easily opened or a mechanical device which will exchange air in the room at least six (6) times per hour.

(D) All openings to the outside from the building shall be effectively screened, and the doors shall be self-closing.

(E) All entrances to toilet and bathing facilities shall be screened to prevent a direct view of the interior from the exterior when the door is opened.

(F) Floors in handwashing and shower rooms shall have a smooth nonskid finish and be impervious to moisture. All floors shall slope to a properly trapped floor drain.

(G) Hot water heaters must have a capacity and recovery rate capable of supplying at least four (4) gallons of hot water per hour, per resident.

(H) Restrooms, laundry rooms, toilets, and privies shall contain adequate ceiling light fixtures to provide at least ten (10) foot-candles of illumination throughout the rooms.

(I) Restrooms shall have at least one (1) wall-type electrical convenience outlet, and all restroom outlets shall be protected by a ground fault circuit interrupter.

(6) Toilet facilities shall be located within two hundred (200) feet of each living unit.

(i) The following requirements pertain to bathing, laundry, and handwashing facilities:

(1) Bathing and handwashing facilities, supplied with hot and cold water under pressure, shall be provided for the use of all residents. These facilities shall be clean and sanitary and located within two hundred (200) feet of each living unit.

(2) There shall be a minimum of one (1) shower head per ten (10) residents. Shower heads shall be spaced at least three (3) feet apart with a minimum of nine (9) square feet of floor space per unit. Adequate, dry dressing space shall be provided in common use facilities. Shower floors shall be constructed of nonabsorbent, nonskid materials and sloped to properly constructed floor drains. Except in individual family units, separate shower facilities shall be provided each sex. When common use shower facilities for both sexes are in the same building, they shall be separated by a solid, nonabsorbent wall extending from the floor to ceiling or roof and shall be plainly designated "men" or "women" in English or in Spanish. International symbols may be used in lieu of English or Spanish designations.

(3) Lavatories or equivalent units shall be provided in a ratio of one (1) per fifteen (15) residents or fraction thereof.

(4) Laundry facilities, supplied with hot and cold water under pressure, shall be provided for the use of all residents. Laundry trays or tubs shall be provided in the ratio of one (1) per twenty-five (25) residents or fraction thereof. Mechanical washers may be provided in the ratio of one (1) per fifty (50) residents or fraction thereof, in lieu of laundry trays, although a minimum of one (1) laundry tray per one hundred (100) residents, or fraction thereof, shall be provided in addition to the mechanical washers.

(5) Camps in which all units are not provided with sinks must have common dishwashing facilities served by hot and cold water under pressure and discharging into existing approved camp sewage disposal systems. Such facilities must be provided in the ratio of one (1) for each twenty-five (25) residents or fraction thereof.

(j) The following requirements pertain to cooking and eating facilities:

(1) When residents are permitted or required to cook in their individual unit, a space shall be provided and equipped for cooking and eating. Such space shall be provided with:

(A) a cookstove or hot plate with a minimum of two (2) burners;

(B) adequate food storage shelves and a counter for food preparation;

(C) provisions for mechanical refrigeration of food at a temperature of not more than forty-five degrees Fahrenheit (45° F); and

(D) a table and chairs or equivalent seating and eating arrangements, all commensurate with the capacity of the unit.

(2) When residents or their families are permitted or required to cook and eat in a common facility, a room or building separate

from the sleeping facilities shall be provided for cooking and eating. Such room or building shall be provided with:

(A) stoves or hot plates, with a minimum equivalent of two (2) burners, in a ratio of one (1) stove or hot plate to ten (10) persons, or one (1) stove or hot plate to two (2) families;

(B) a counter for food preparation;

(C) mechanical refrigeration for food at a temperature of not more than forty-five degrees Fahrenheit (45° F);

(D) tables and chairs or equivalent seating adequate for the intended use of the facility;

(E) adequate sinks with hot and cold water under pressure;

(F) adequate lighting and ventilation; and

(G) floors of nonabsorbent, easily cleanable materials.

(3) Camps providing a central dining or multifamily food service shall provide and maintain the kitchen and dining hall in accordance with the provisions of 410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984]*.

(4) When central mess facilities are provided, the kitchen and mess hall shall be in proper proportion to the capacity of the housing and shall be separate from the sleeping quarters. The physical facilities, equipment, and operation shall be in accordance with provisions of applicable state codes.

(5) Wall surface adjacent to all food preparation and cooking areas shall be of nonabsorbent, easily cleaned material. In addition, the wall surface adjacent to cooking areas shall be of fire-resistant material.

(6) Work table, counter, and dining table surfaces shall be constructed of materials presenting a smooth, nonabsorbent, easily cleaned surface.

(Indiana State Department of Health; Reg HSE 29R, Sec 3; filed Aug 29, 1972, 11:00 a.m.: Rules and Regs. 1973, p. 383; filed Sep 24, 1987, 3:00 p.m.: 11 IR 737; filed Sep 29, 1989, 2:02 p.m.: 13 IR 271; errata filed Jul 9, 1990, 2:00 p.m.: 13 IR 2004; filed Dec 4, 1991, 9:30 a.m.: 15 IR 489; errata, 15 IR 1027; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-9-4 Operation and sanitation; safety requirements

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 4. (a) The following requirements pertain to garbage and other refuse:

(1) Garbage and refuse shall be stored in watertight containers having a tight-fitting lid and shall be maintained in a sanitary condition and in good repair at all times. Covered washable containers of at least twenty (20) and no larger than thirty-five (35) gallon capacity shall be provided adjacent to each shelter and service building for the storage of refuse and garbage.

(2) Garbage and refuse shall be collected at least two (2) times a week, or whenever the containers are full. After emptying, the cans shall be cleaned. Garbage and refuse shall not be burned.

(3) Approved community dumpsters can be utilized in lieu of other garbage containers provided that:

(A) the dumpsters are of adequate size;

(B) the dumpsters have lids;

(C) dumpsters are located within two hundred (200) feet of all living quarters; and

(D) a garbage container of at least five (5) gallon capacity is provided inside all living quarters.

(b) Insect and rodent control requires that housing and facilities shall be free of insects, rodents, and other vermin.

(c) The following requirements pertain to sleeping facilities:

(1) Sleeping facilities shall be provided for each resident. Such facilities shall consist of comfortable beds, cots, or bunks provided with clean mattresses.

(2) Any bedding provided by the housing operator shall be clean and sanitary.

(3) Triple and quadruple deck bunks shall not be provided.

(4) Vertical separation between the top of the lower mattress of a double deck bunk and the upper bunk shall be a minimum of twenty-seven (27) inches. The vertical separation from the top of the upper mattress to the ceiling shall be a minimum of thirty-six (36) inches.

(5) Beds used for double occupancy may be provided only in family accommodations.

(6) Foam mattresses must be provided with clean mattress covers.

(d) The following requirements pertain to fire, safety, and first aid:

(1) All buildings in which residents sleep or eat shall be constructed and maintained in accordance with applicable state or local fire and safety laws.

(2) One (1) story shelters far less than ten (10) residents shall have two (2) means of escape. One (1) of the two (2) required means of escape may be a readily accessible window with an openable space of not less than twenty-four (24) inches by twenty-four (24) inches.
(3) All living quarters intended for use by ten (10) or more residents, central dining facilities, and common assembly rooms shall have at least two (2) doors remotely separated so as to provide alternate means of escape to the outside or to an interior hall.
(4) Living quarters and common assembly rooms on the second story shall have a stairway and a permanent, affixed exterior ladder or a second stairway.
(5) Living quarters and common assembly rooms located above the second story shall comply with the state and local fire and building codes relative to multiple story dwellings.
(6) A 4A60BC ten (10) pound or greater multipurpose dry chemical pressure fire extinguisher shall be provided in a readily accessible place located not more than one hundred (100) feet from each shelter. A minimum of one (1) such fire extinguisher for each ten (10) residents or fraction thereof must be provided.
(7) First-aid facilities shall be provided and readily accessible for use at all times. Such facilities shall be equivalent to the sixteen (16) unit first-aid kit recommended by the American Red Cross and shall be provided in a ratio of one (1) per fifty (50) residents or fraction thereof.
(8) No flammable or volatile liquids or materials shall be stored in or adjacent to rooms used for living purposes, except for those needed for current household use.
(9) Agricultural pesticides and toxic chemicals, excluding household products, shall not be stored within fifty (50) feet of any shelter.
(10) Telephone service shall be made reasonably available to all residents of the camp, either by providing a pay phone or a telephone in the crew leader's unit. The telephone number of the nearest fire department and ambulance service shall be prominently posted near the telephone.
(11) Each shelter shall be provided with at least one (1) ceiling-mounted smoke detector which shall be maintained in a working condition at the time of occupancy and repaired on request as needed.
(12) The camp owner shall provide a centrally located bulletin board where notices and permits can be displayed. Instructions in English and Spanish for reporting emergency situations shall be posted on this board.
(13) If workers are allowed to bring their own recreational vehicles to the camp, acceptable water, sewer, and electrical hook-ups must be provided for each such unit. Such recreational vehicles are exempt from the space and construction standards enumerated in section 3(d) through 3(g) of this rule.
(e) The following requirements pertain to operators' and residents' responsibilities:
(1) The camp operator is specifically responsible for the following:
(A) Obtaining a current permit before workers arrive.
(B) Ensuring that the camp area and sanitary facilities are kept clean and in good repair.
(C) Routine upkeep and maintenance on shelters.
(D) Keeping the grass mowed.
(2) Those persons residing in the agricultural labor camp are responsible for the following:
(A) Keeping their shelters clean.
(B) Cleaning their appliances and notifying the operator of any problems or breakdowns.
(C) Providing their own bedding, such as sheets and blankets.
(D) Leaving their camp and shelters clean and in good repair.
(E) Keeping their pets on a leash or otherwise restrained and properly vaccinated.

(Indiana State Department of Health; Reg HSE 29R, Sec 4; filed Aug 29, 1972, 11:00 a.m.: Rules and Regs. 1973, p. 388; filed Sep 29, 1989, 2:02 p.m.: 13 IR 276; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-9-5 Health or safety hazards; reporting communicable diseases

Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 5. (a) No conditions, situation, or installation shall be created, installed, or maintained which may cause or result in a health or safety hazard or which may cause or transmit disease.

(b) The camp operator shall notify the local health officer immediately of any suspected communicable or contagious disease within the camp.

(c) A roster of all camp residents, and the number of the shelter to which they are assigned, must be maintained by the camp operator. This roster shall contain the first and last names of all adult residents and the total number of residents in each shelter. The roster must be kept up-to-date whenever the camp is occupied and shall be maintained by the operator for at least thirty (30) days after the camp is closed.

(d) Any structure located within fifty (50) feet of a shelter, which by its condition is an imminent threat to health or safety as determined by the board, must be razed, or removed, or repaired in such a manner that it is no longer a threat to health or safety. *(Indiana State Department of Health; Reg HSE 29R, Sec 5; filed Aug 29, 1972, 11:00 a.m.: Rules and Regs. 1973, p. 389; filed Sep 29, 1989, 2:02 p.m.: 13 IR 277; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-9-5.5 Civil penalties schedule

Authority: IC 16-19-3-4; IC 16-41-26-8
Affected: IC 4-21.5-3-8; IC 16-41-26

Sec. 5.5. (a) The board may commence an action under IC 13-1-9 *[IC 13-1-9 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-26.]* and IC 4-21.5-3-8 to levy civil penalties against an agricultural labor camp operator who:

(1) fails to comply with IC 13-1-9 *[IC 13-1-9 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-26.]* or this rule; or

(2) interferes with or obstructs the state board or its designated agent in the performance of duties pursuant to IC 13-1-9 *[IC 13-1-9 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-26.]*.

(b) A civil penalty in an amount in the appropriate range specified in this section may be assessed for each day of each violation.

(c) In determining the seriousness of the violation and the specific amount of the civil penalty to be sought for each violation, the state board shall consider the following:

(1) The potential for harm or imminent threat to public health.

(2) The extent of deviation from statutory or regulatory requirements.

(3) Degree of willfulness or negligence.

(4) History of noncompliance.

The absence of direct harm shall not result in assessment of a lower penalty for a violation.

(d) Unless adjusted as provided for in subsection (e), all penalties shall be in accordance with the following schedule:

Violation		Range of Penalty
Construction notice; permit	410 IAC 6-9-2	$50 to $100
Camp facilities	410 IAC 6-9-3	$50 to $500
Operation and sanitation: safety requirements	410 IAC 6-9-4	$50 to $500
Health or safety hazards; reporting communicable diseases	410 IAC 6-9-5	$50 to $500
Interference with agent	410 IAC 6-9-5.5	$100 to $500

(e) After determining the appropriate penalty based on the schedule in this section, the state board may adjust the penalty to reflect a good faith effort to comply by the operator of an agricultural labor camp.

(f) Each individual penalty shall be multiplied by the number of days the particular violation occurred. Penalties for violations occurring in two (2) consecutive inspections by the board shall be assessed on the basis that the violations have remained uncorrected over the period of time between the two (2) inspections.

(g) Penalties for all violations shall be totaled and sought under one (1) cause of action.

(h) After filing an action pursuant to IC 4-21.5, and in an attempt to resolve violations of IC 13-1-9 *[IC 13-1-9 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-26.]* and this rule without resort to a hearing, the board may negotiate and enter into agreed orders. An agreed order may suspend all or part of the civil penalty calculated under the requirements and deadlines established in the agreed order. *(Indiana State Department of Health; 410 IAC 6-9-5.5; filed Dec 4, 1991, 9:30 a.m.: 15 IR 493; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-9-6 Severability
Authority: IC 16-19-3-5
Affected: IC 16-19-3-4; IC 16-20-1-19

Sec. 6. (Validity). If any section, paragraph, sentence, clause, phrase, or word of this regulation *[410 IAC 6-9]*, or any other part thereof, be declared invalid for any reason, the remainder of said regulation *[410 IAC 6-9]* shall not be affected thereby and shall remain in full force and effect. *(Indiana State Department of Health; Reg HSE 29R, Sec. 6; filed Aug 29, 1972, 11:00 am: Rules and Regs. 1973, p. 389; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 10. Commercial On-Site Wastewater Disposal

410 IAC 6-10-1 Purpose
Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-4-3

Sec. 1. 410 IAC 6-10 governs construction, installation and modification of commercial on-site wastewater disposal facilities. *(Indiana State Department of Health; 410 IAC 6-10-1; filed Dec 3, 1986, 4:00 p.m.: 10 IR 867; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-10-2 Definitions
Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 2. As used in 410 IAC 6-10 *[this rule]*:

"Absorption field" means a system of open-jointed tiles or perforated pipes laid in a series of trenches or a bed of sand, gravel, and soil, into which the effluent from a septic tank is pumped or flows by gravity for absorption into the soil.

"Board" means the state board of health.

"Commercial on-site wastewater disposal facility" means all equipment and devices necessary for proper conduction, collection, storage, treatment, and on-site disposal of wastewater from other than one- or two-family dwellings. Included within, but not limited to, the scope of this definition are building sewers, grease traps, septic tanks, dosing tanks, absorption fields, perimeter drains, vault privies, and temporary wastewater holding tanks serving such facilities as apartment buildings, campgrounds, churches, commercial establishments, condominiums, medical facilities, mobile home parks, motels, office buildings, restaurants, and schools.

"Commissioner" means the commissioner of the state board of health or his duly authorized representative.

"Conventional subsurface absorption field" means a system of open-jointed tiles or perforated pipes laid in a series of trenches, each line connected to a distribution box into which the effluent from a septic tank flows by gravity for absorption into the soil.

"Distribution box" means a watertight structure which distributes the effluent from a septic tank equally to the various trenches it serves in an absorption field.

"Local health department" means a local board of health created pursuant to IC 16-1 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, or its duly authorized representative.

"Person" means an individual, partnership, copartnership, corporation, firm, company, association, society, holding company, trustee, school corporation, school city, school town, school district, any unit of government, or any other legal entity, its or their successors or assigns, or agent of the aforesaid.

"Septic tank" means a watertight structure into which wastewater is discharged for settling and solids digestion.

"Wastewater" means waste derived from ordinary living processes. *(Indiana State Department of Health; 410 IAC 6-10-2; filed Dec 3, 1986, 4:00 p.m.: 10 IR 867; filed Oct 31, 1988, 2:50 p.m.: 12 IR 554; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-10-3 Prohibitions
Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 3. No person shall throw, run, drain, seep, or otherwise dispose into any of the surface waters or groundwaters of this state, or cause, permit, or suffer to be thrown, run, drained, allowed to seep, or otherwise disposed into such waters, any organic or inorganic matter that would cause or contribute to a polluted condition of such waters unless a permit for such disposal has been obtained as authorized by IC 13-1-3 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]* or IC 13-7 *[IC 13-7 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*. *(Indiana State Department of Health; 410 IAC 6-10-3; filed Dec 3, 1986, 4:00 p.m.: 10 IR 868; filed Oct 31, 1988, 2:50 p.m.: 12 IR 555; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-10-4 Right of entry

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 4. The board, the local health department, or their authorized representatives may enter upon public or private property at reasonable times and upon presentation of credentials to inspect facilities, equipment, or records, investigate allegations, determine soil characteristics, conduct tests, or collect samples for the purpose of obtaining information necessary to the issuance of a permit pursuant to 410 IAC 6-10 *[this rule]*, or to determine whether any person is subject to, or in violation of 410 IAC 6-10 *[this rule]* or any permit or order issued pursuant thereto. *(Indiana State Department of Health; 410 IAC 6-10-4; filed Dec 3, 1986, 4:00 p.m.: 10 IR 868; filed Oct 31, 1988, 2:50 p.m.: 12 IR 555; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-10-5 Permit requirement

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 5. (a) Except as allowed by subsection (b), (c), or (d), no person shall cause or allow the construction, installation, or modification of a commercial on-site wastewater disposal facility, or any facility to be served by a commercial on-site wastewater disposal facility, without having a valid construction permit issued in accordance with 410 IAC 6-10 *[this rule]*.

(b) Construction permits shall not be required for repair or replacement of commercial on-site wastewater disposal facility equipment with new units of similar design and capacity, none of which will cause a health hazard or adversely affect groundwater, facility operation, hydraulics, physiochemical treatment, biological treatment, solids removal, or the ultimate means of liquid disposal. This section shall not be construed as allowing the construction of replacement absorption fields or portions thereof without a valid construction permit issued in accordance with 410 IAC 6-10 *[this rule]*.

(c) Construction permits shall not be required for commercial on-site wastewater disposal facilities for which a construction permit has been issued pursuant to 327 IAC 3, and which serve two (2) or more premises, and which are owned, operated, or maintained by an incorporated city or town, a conservancy district established pursuant to IC 13-3-3 *[IC 13-3 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, or a regional sewer district established pursuant to IC 13-3-2 *[IC 13-3 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*. This section shall not be construed as an exemption from the requirement of subsection (a) for commercial on-site wastewater disposal facilities located on the premise of and serving only schools or municipal facilities.

(d) On a case by case basis the board may waive review of plans and issuance of a construction permit, in writing, if it determines that wastewater flow to a commercial on-site wastewater disposal facility on the peak day does not exceed two thousand (2,000) gallons, that the commercial on-site wastewater disposal facility can be constructed utilizing a conventional subsurface absorption field, and that such construction will be governed by a local sewage disposal ordinance and in accordance with Bulletin SE 13, "On-Site Water Supply and Wastewater Disposal for Public and Commercial Establishments," 1988 edition. *(Indiana State Department of Health; 410 IAC 6-10-5; filed Dec 3, 1986, 4:00 p.m.: 10 IR 868; filed Oct 31, 1988, 2:50 p.m.: 12 IR 555; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-10-6 Application for construction permit

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4; IC 25-31-1-2

Sec. 6. (a) Application for a permit to construct a commercial on-site wastewater disposal facility shall be made to the board

on forms provided by the board. Application for a construction permit shall be made at least ninety (90) days prior to the date construction of the commercial on-site wastewater disposal facility is to commence. An application shall be considered complete only when the form is completed in its entirety, including all supplemental information required or requested by the board. Unless waived by the board an application for permit shall include the following:

(1) The signature of the applicant or his designated agent.

(2) The name, business address, and business telephone number of the owner. For corporate owners, the name of the corporation, the name of its designated agent, and that agent's business address and business telephone number shall suffice.

(3) One (1) set of detailed construction plans and specifications certified and sealed by an engineer or architect currently registered in Indiana, said plans drawn to scale and having sufficient clarity to be reproduced to create legible microfilm. As provided in IC 25-31-1-2(h), registered land surveyors may only certify and seal plans for gravity sanitary sewers, storm sewers, and tile drains.

(4) A map or other documentation showing the location of the property involved.

(5) A plot plan, drawn to scale, showing the location of the proposed commercial on-site wastewater disposal facility with respect to property lines, existing and proposed structures, roads, and parking lots, and any drinking water supply facilities within three hundred (300) feet of the commercial on-site wastewater disposal facility. Said plot plans shall also show site topography, with contours established at intervals of two (2) feet or less.

(6) The name, business address, and business telephone number of the registered engineer or architect who certified and sealed the construction plans and specifications required by subdivision (a)(3) *[subdivision (3)]*, in writing.

(7) For those commercial on-site wastewater disposal facilities which will include an absorption field, a report prepared by a certified professional soil scientist, specialist, or classifier registered with the American Registry of Certified Professionals in Agronomy, Crops and Soils, or a soil scientist employed by the U.S. Soil Conservation Service, detailing his evaluation of soils observed in the area of the proposed absorption field. Said report shall name each soil type observed, map the approximate boundaries and specify slope for each soil type, and for each soil type observed provide a description of the soil textures, soil structure, soil color, and the depth to rock or seasonal high water table, in the upper five (5) feet of soil.

(8) For those commercial on-site wastewater disposal facilities which will include a temporary wastewater holding tank, documentation of sufficient clarity and conclusiveness to convince the board that:

(A) the wastewater will be collected from the holding tank and disposed of, in compliance with IC 13-7-8.8 *[IC 13-7 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*; and

(B) the temporary wastewater holding tank will be abandoned and a sewer connection will be made to another type of commercial on-site wastewater disposal facility, or to a municipal or private utility sewer, or to a regional sewer district or conservancy district sewer, within two (2) years from the date of permit issuance.

(9) Wastewater characteristics and calculations used to estimate wastewater flow on the peak day, in gallons, to be disposed of through each proposed commercial on-site wastewater disposal facility. If more than one (1) type of facility is to be connected to a proposed commercial on-site wastewater disposal facility, wastewater characteristics and calculations used to estimate wastewater flow, in gallons, from each facility on its peak day must be submitted.

(10) A summary delineating, for each diameter of pipe utilized, the estimated total length of sanitary sewer and sewage force main to be installed.

(11) All additional information requested by the board to substantiate that the proposed commercial wastewater disposal facility can reasonably be expected to treat and dispose of all wastewater received without causing a health hazard, nuisance, surface water pollution, or groundwater pollution.

(b) Requests for additional substantiating information made pursuant to subdivision (a)(11) *[subsection (a)(11)]* shall be addressed to the registered engineer or architect who certified and sealed the construction plans and specifications required by subdivision (a)(3) *[subsection (a)(3)]*. *(Indiana State Department of Health; 410 IAC 6-10-6; filed Dec 3, 1986, 4:00 p.m.: 10 IR 868; filed Oct 31, 1988, 2:50 p.m.: 12 IR 556; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-10-7 Official's signature; effective date

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 7. Commercial on-site wastewater disposal facility construction permits shall be signed by the commissioner on behalf of the board, and shall be considered issued as of the date of mailing. *(Indiana State Department of Health; 410 IAC 6-10-7; filed*

Dec 3, 1986, 4:00 pm: 10 IR 869; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-10-8 Construction permit for experimental facilities

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 8. In order to encourage development of new or more efficient treatment or disposal processes, the board may issue construction permits for experimental commercial on-site wastewater disposal facilities. Construction permits may be issued for installations, treatment or disposal equipment, processes or techniques for which extensive experience or records of use have not been developed in Indiana. However, the applicant must submit evidence of sufficient clarity and conclusiveness to convince the board that the proposal has a reasonable and substantial probability of satisfactory operation without causing a health hazard, nuisance, surface water pollution or groundwater pollution. The board may also require the applicant to satisfactorily document how and by whom the experimental facilities and any other portions of the commercial on-site wastewater disposal facility, which could be damaged due to a failure of the experimental installation, are to be replaced if it becomes necessary. *(Indiana State Department of Health; 410 IAC 6-10-8; filed Dec 3, 1986, 4:00 pm: 10 IR 869; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-10-9 Permit conditions

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 9. The board may specify in its construction permits any limitations, terms or conditions necessary to provide a functional, easily operated, enduring commercial on-site wastewater disposal facility in accordance with 410 IAC 6-10-10, or to prevent a health hazard, nuisance, surface water pollution or groundwater pollution. In addition, all commercial on-site wastewater disposal facility construction permits shall contain the following requirements, not necessarily verbatim:

(1) The permit shall expire on the last day of the twelfth month following the month of permit issuance, unless the applicant has started installation of equipment, piping or tankage which will comprise part of the commercial on-site wastewater disposal facility, on or before the date of permit expiration.

(2) That all necessary local permits and approvals be obtained before construction is begun.

(3) That any proposed changes, alterations or additions to the wastewater disposal facilities herein approved, be submitted to the board for review and approval prior to the start of construction to effect the proposed changes, alterations or additions.

(4) That no change in occupancy or use of the facility served be effected if it would result in wastewater flow on the peak day in excess of the capacity of the commercial on-site wastewater disposal facility as stated in the construction permit, or if it would result in wastewater being generated of a type incompatible with absorption field disposal. Any such change in occupancy or use may be made only after the board has issued a construction permit for modifications to the subject wastewater disposal facility that will allow it to accommodate increased wastewater flows.

(5) That if pollution, health hazards or nuisance conditions occur which are attributable to the commercial on-site wastewater disposal facility permitted herein, immediate corrective action be taken by the owner.

(6) That the permittee notify the board and the local health department at least seven days before construction of the approved commercial on-site wastewater disposal facilities is to commence.

(Indiana State Department of Health; 410 IAC 6-10-9; filed Dec 3, 1986, 4:00 pm: 10 IR 870; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-10-10 Standards for issuance

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 10. The board may reject an application for permit to construct a commercial on-site wastewater disposal facility unless the applicant has submitted:

(1) All documentation required by 410 IAC 6-10-6(a) *[section 6(a) of this rule]*.

(2) Evidence to fully justify the estimated wastewater flows and wastewater characteristics used as the basis of design for the subject wastewater disposal facilities.

(3) Evidence that the wastewater disposal facility can be constructed, modified or installed, and operated in such a manner that it will not violate any sanitation, health, siting, or pollution control rules or ordinances existing at the time of application.

(4) Evidence that the facility conforms to applicable design criteria contained in Bulletin SE 11, "The Sanitary Vault Privy," 1986 edition, or Bulletin SE 13, "On-Site Water Supply and Wastewater Disposal for Public and Commercial Establishments," 1988 edition, or such other criteria acceptable to the board which can reasonably be expected to result in a facility that will consistently treat and dispose of all wastewater received for the life of the facilities it serves, without causing a health hazard, nuisance, surface water pollution, or groundwater pollution.

(Indiana State Department of Health; 410 IAC 6-10-10; filed Dec 3, 1986, 4:00 p.m.: 10 IR 870; filed Oct 31, 1988, 2:50 p.m.: 12 IR 557; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-10-11 Construction permit; transferability

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 11. A commercial on-site wastewater disposal facility construction permit may only be transferred to another person by the current permit holder if:

(1) The commercial on-site wastewater disposal facility for which the permit was issued is designed to employ a vault privy or conventional subsurface absorption field.

(2) The current permit holder notifies the board and the local health department having jurisdiction, in writing, of the proposed transfer at least 30 days before the transfer is proposed to occur.

(3) The person to whom the permit is proposed to be transferred certifies to the board, in writing at least 30 days before the transfer is proposed to occur, any changes proposed in the occupancy or use of a facility to be served by the wastewater disposal facility for which the subject construction permit was issued.

(4) The board, within thirty (30) days of its having received notification in accordance with 410 IAC 6-10-11(2) and (3), does not notify the current permit holder of its intent to modify or revoke the subject construction permit.

(Indiana State Department of Health; 410 IAC 6-10-11; filed Dec 3, 1986, 4:00 pm: 10 IR 870; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-10-12 Construction permit; revocations and modifications

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 12. A commercial on-site wastewater disposal facility construction permit may be revoked or modified by the board for any of the following causes:

(1) violation of 410 IAC 6-10;

(2) violation of any limitation, term or condition contained in the construction permit;

(3) failure to disclose all facts relevant to construction and use of the commercial on-site wastewater disposal facility in a manner that it can consistently treat and dispose of all wastewater received for the life of the facilities it serves, without causing a health hazard, nuisance, surface water pollution or groundwater pollution;

(4) any misrepresentation made to obtain the construction permit; or

(5) any other change, situation or activity relating to use of the commercial on-site wastewater disposal facility which, in the judgment of the board, is not consistent with the purposes of 410 IAC 6-10.

(Indiana State Department of Health; 410 IAC 6-10-12; filed Dec 3, 1986, 4:00 pm: 10 IR 871; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-10-13 Denial of an application for construction permit

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 13. An application for commercial on-site wastewater disposal facility construction permit may be denied by the board for any of the following causes:

(1) any misrepresentation made in the application;
(2) failure of the owner, or the engineer or architect who certified and sealed the construction plans and specifications, to respond to a request for revised plans and specifications or additional information made pursuant to 410 IAC 6-10-6 *[section 6 of this rule]*, within six (6) months of receiving the request;
(3) a sanitary sewer of adequate capacity served by a sewage disposal facility owned by an incorporated city or town, conservancy district established pursuant to IC 13-3-3 *[IC 13-3 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, regional sewer district established pursuant to IC 13-3-2 *[IC 13-3 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*, or private utility, is located within three hundred (300) feet of the property line of the affected property, or is available for connection at a construction cost estimated by the board not to exceed one hundred fifty (150) percent of the cost estimated by the board for installing commercial on-site wastewater disposal facilities to serve the project were the commercial on-site wastewater disposal facilities otherwise acceptable to the board; or
(4) failure to show that the commercial on-site wastewater disposal facility can be constructed, operated, maintained, or abandoned in compliance with 410 IAC 6-10 *[this rule]*.

(Indiana State Department of Health; 410 IAC 6-10-13; filed Dec 3, 1986, 4:00 p.m.: 10 IR 871; filed Oct 31, 1988, 2:50 p.m.: 12 IR 557; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-10-14 Petitions for review

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 4-21.5; IC 16-19-3-4

Sec. 14. (a) Within fifteen (15) days following the date of receipt of an issued permit, permit modification, notice of permit denial, or notice of permit revocation, any person aggrieved by such action may file a petition for review concerning such action with the board.
(b) A petition for review shall:
(1) state the name and address of the person making the request;
(2) identify the interest of the petitioner which is affected by the permit issuance, denial, modification, or revocation;
(3) identify any persons whom the petitioner represents;
(4) state with particularity the reasons for the request;
(5) state with particularity the issues proposed to be considered; and
(6) include proposed terms or conditions which, in the judgment of the petitioner would be appropriate to carry out the requirements of law and 410 IAC 6-10 *[this rule]*, governing such permits.

(Indiana State Department of Health; 410 IAC 6-10-14; filed Dec 3, 1986, 4:00 p.m.: 10 IR 871; filed Oct 31, 1988, 2:50 p.m.: 12 IR 557; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-10-15 Incorporation by reference

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19-3-4

Sec. 15. Bulletin SE 11, "The Sanitary Vault Privy," 1986 edition, and Bulletin SE 13, "On-Site Water Supply and Wastewater Disposal for Public and Commercial Establishments," 1988 edition, are incorporated by reference as part of 410 IAC 6-10 *[this rule]*. They may be obtained free of charge by request mailed to the board at 1330 West Michigan Street, Indianapolis, Indiana 46206-1964. *(Indiana State Department of Health; 410 IAC 6-10-15; filed Dec 3, 1986, 4:00 p.m.: 10 IR 872; filed Oct 31, 1988, 2:50 p.m.: 12 IR 558; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 11. School-Age Child Care Facilities

410 IAC 6-11-1 Purpose

Authority: IC 16-19-3-4
Affected: IC 16-41

Sec. 1. This rule establishes minimum requirement for sanitation at school-age child care facilities. *(Indiana State Department*

of Health; 410 IAC 6-11-1; filed Jun 12, 1989, 9:45 a.m.: 12 IR 2046; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-11-2 Definitions

Authority: IC 16-19-3-4
Affected: IC 16-41

Sec. 2. As used in this rule:

(1) "Facility" means a school-age child care facility, except where clearly used in another context.

(2) "School-age child care facility" means that portion of a building used for school-age child care pursuant to IC 20-5-61 *[IC 20-5-61 was repealed by P.L.9-1991, SECTION 98, effective July 1, 1992.]*, including the property upon which the building rests.

(3) "Site" means the property upon which the school-age child care facility rests.

(4) "Student" means a child five (5) to fourteen (14) years of age who is served by a school-age child care facility.

(Indiana State Department of Health; 410 IAC 6-11-2; filed Jun 12, 1989, 9:45 a.m.: 12 IR 2046; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-11-3 General sanitation

Authority: IC 16-19-3-4
Affected: IC 16-41

Sec. 3. (a) Each site shall be maintained to protect the health of students and shall be free of any hazards or nuisances.

(b) No site shall be located nearer than five hundred (500) feet to any unhealthful condition.

(c) Each site shall be graded to prevent ponding and excessive inflow from surrounding areas.

(d) Each facility shall at all times be maintained in a clean, safe, and sanitary condition, and shall be in a good state of repair.

(Indiana State Department of Health; 410 IAC 6-11-3; filed Jun 12, 1989, 9:45 a.m.: 12 IR 2046; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-11-4 Facility sanitation

Authority: IC 16-19-3-4
Affected: IC 16-41

Sec. 4. (a) All interior surfaces of a facility shall be easily cleanable, and of nontoxic durable construction.

(b) All light fixtures in a facility shall be shielded to protect the students from injury due to bulb breakage.

(c) Each facility shall have ventilation sufficient to provide adequate oxygen, a character of freshness in the air, and to remove exhaled air and undesirable odors during periods of student occupancy.

(d) Each facility shall be equipped with a heating system capable of maintaining a temperature of not less than sixty-eight degrees Fahrenheit (68° F), in all student areas under the severest of weather conditions. Portable space heaters are prohibited.

(e) Pipes, ducts, and radiators containing steam or hot water and located in student areas shall be shielded to protect the students from injury.

(f) All electrical wiring accessible to students shall be protected to prevent accidental shock. All electrical receptacles and switches accessible to students shall be shielded to prevent accidental shock.

(g) All furniture and equipment accessible to students shall be durable and easily cleanable, with rounded corners and edges, and otherwise protected as necessary to ensure safety.

(h) Drinking water shall be provided on each floor of a facility that is accessible to students. Drinking water facilities shall have impervious, easily cleanable surfaces and shall be kept clean and in a good state of repair. Drinking fountains, where provided, shall have a sanitary type guarded angle-stream jet head and an adjustable flow regulator. The outlet shall not be below the flood rim of the fixture.

(i) Each facility shall be provided with restrooms and sanitary facilities. There shall be at least one (1) separate, readily accessible restroom for each sex including the following:

(1) Restrooms shall be equipped with lavatories or other satisfactory handwashing facilities or such equipment must be available in an adjacent room through which the students must pass upon egress from the restroom.

(2) Handwashing facilities shall be supplied with hot and cold water under pressure. Hot water provided for the handwashing facilities shall be maintained between one hundred five degrees Fahrenheit (105° F) and one hundred twenty degrees Fahrenheit (120° F). An adequate supply of soap, and individual sanitary towels in dispensers, or heating units for automatic hand drying shall be provided convenient to all handwashing facilities. Common towels are not acceptable. If individual sanitary towels are provided, a suitable container for used towels shall also be provided.

(3) Restroom toilet fixtures shall be of the water-flushed type. Multiple seat toilets or makeshift trough arrangements shall not be provided even though they may be equipped for water flushing. All water closets shall be partitioned as necessary to provide individual stalls. Partitions shall have impervious, smooth-surfaced, easily cleanable surfaces. Wood surfaces are not acceptable. An adequate supply of toilet paper shall be provided in a dispenser at each water closet.

(4) Covered disposal facilities shall be provided in restrooms available to junior high school age girls and above.

(5) Restroom floors shall have easily cleanable, nonporous surfaces. Restroom walls and ceilings shall have smooth nonabsorbent, easily cleanable surfaces.

(6) Restroom entrances shall be screened to prevent viewing the restroom interior from the exterior. Restroom exterior doors and operable windows shall be fly-proof and tight-fitting.

(Indiana State Department of Health; 410 IAC 6-11-4; filed Jun 12, 1989, 9:45 a.m.: 12 IR 2046; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-11-5 Food service

Authority: IC 16-19-3-4
Affected: IC 16-41

Sec. 5. All rooms, equipment, and utensils used for the storage, preparation, and serving of food, or for washing of food equipment and utensils at a facility, shall be constructed and operated in accordance with 410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]. (Indiana State Department of Health; 410 IAC 6-11-5; filed Jun 12, 1989, 9:45 a.m.: 12 IR 2047; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-11-6 Water supply

Authority: IC 16-19-3-4
Affected: IC 16-41

Sec. 6. A safe, potable supply of water under pressure, shall be provided at the facility at all times during periods of student occupancy. Where a public water supply is not available, a properly located and constructed private water supply shall be utilized. The potable water supply shall be maintained in a good state of repair. There shall be no direct physical connection, existing or potential, between a potable water supply system and an unsafe water supply system used for fire protection, lawn sprinkling, toilet flushing, or other nonpotable use. *(Indiana State Department of Health; 410 IAC 6-11-6; filed Jun 12, 1989, 9:45 a.m.: 12 IR 2047; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-11-7 Sewage disposal

Authority: IC 16-19-3-4
Affected: IC 16-41

Sec. 7. Facility sewers, sewage treatment and disposal systems shall be constructed, operated, and maintained to transmit and dispose of peak and average daily sewage flows without creating a health hazard, nuisance, surface water pollution, or groundwater pollution. Facility sewers, sewage treatment, and disposal systems shall also be located to prevent the possibility of contaminating the facility potable water supply. *(Indiana State Department of Health; 410 IAC 6-11-7; filed Jun 12, 1989, 9:45 a.m.: 12 IR 2047; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-11-8 Refuse disposal

Authority: IC 16-19-3-4
Affected: IC 16-41

Sec. 8. Refuse generated at a facility shall be properly collected pending disposal. Refuse shall be stored in fly-tight, water-tight containers. Refuse containers shall be kept in a sanitary condition, and shall be kept closed when not in use. Refuse containers shall be located on a concrete base, or else stored on racks with at least eight (8) inches clearance above the ground. Where service permits, approved hopper-type containers should be substituted for refuse cans. The area around refuse storage containers shall be kept clean and free of litter. *(Indiana State Department of Health; 410 IAC 6-11-8; filed Jun 12, 1989, 9:45 a.m.: 12 IR 2047; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 12. Plan Review, Construction Permits, and Fees for Services

410 IAC 6-12-1 "Absorption field" defined

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 1. As used in this rule, "absorption field" means a system of open-jointed tiles or perforated pipes laid in a series of trenches or a bed of sand, gravel, and soil into which the effluent from a septic tank is pumped or flows by gravity for absorption into the soil. *(Indiana State Department of Health; 410 IAC 6-12-1; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2219; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-2 "Board" defined

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 2. As used in this rule, "board" means the state board of health or its authorized representative. *(Indiana State Department of Health; 410 IAC 6-12-2; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2219; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-3 "Commissioner" defined

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 3. As used in this rule, "commissioner" means the commissioner of the state board of health or his duly authorized representative. *(Indiana State Department of Health; 410 IAC 6-12-3; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2219; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-4 "Person" defined

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 4. As used in this rule, "person" means an individual, partnership, copartnership, corporation, firm, company, association, society, holding company, trustee, school corporation, school city, school town, school district, any unit of government, or any other legal entity, its or their successors or assigns, or agent of the aforesaid. *(Indiana State Department of Health; 410 IAC 6-12-4; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2220; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-5 "Site evaluation" defined

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 5. As used in this rule, "site evaluation" means the evaluation of a site to determine the feasibility of installing a commercial on-site wastewater disposal system, and the limitations that must be applied to the design of a commercial on-site wastewater disposal system for the site in accordance with 410 IAC 6-10, based on the projected wastewater flow, topography and configuration of the site, and a soil profile analysis for the site. *(Indiana State Department of Health; 410 IAC 6-12-5; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2220; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-6 "Soil profile analysis" defined

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 6. As used in this rule, "soil profile analysis" means the observation and evaluation of the physical characteristics of the soil horizons or layers to a depth of at least five (5) feet or, if more shallow, to a layer which cannot be readily penetrated. *(Indiana State Department of Health; 410 IAC 6-12-6; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2220; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-7 Permit requirement

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 7. No person shall cause or allow the construction, installation, or modification of any facility described hereafter, without having a valid construction permit issued in accordance with this rule. Construction permits are required for the following:

(1) Agricultural labor camps subject to IC 13-1-9 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

(2) Child caring institutions, day nurseries, and children's group homes, subject to IC 12-3-2 *[IC 12-3 was repealed by P.L.2-1992, SECTION 897, effective July 1, 1992.]*.

(3) Mobile home parks subject to IC 13-1-7 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

(4) Motels subject to IC 13-1-8 *[IC 13-1 was repealed by P.L.1-1996, SECTION 99, effective July 1, 1996.]*.

(5) Organizational campgrounds subject to IC 16-1-3-13 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* and 410 IAC 6-7.

(6) Recreational campgrounds subject to IC 16-1-3-13 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* and 410 IAC 6-7.

(7) Schools subject to IC 16-1-24 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*.

(Indiana State Department of Health; 410 IAC 6-12-7; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2220; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-12-8 Application for construction permit

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19; IC 25-31-1-2

Sec. 8. (a) An application for a permit to construct any facility subject to section 7 of this rule shall be made to the board on forms provided by the board. Application for a construction permit shall be made at least ninety (90) days prior to the date construction of the facility is to commence. An application shall be considered complete only when the form is completed in its entirety, including all supplemental information required or requested by the board. An application for permit shall, at a minimum, include the following:

(1) The signature of the applicant or his designated agent.

(2) The name, business address, and business telephone number of the owner. For corporate owners, the name of the corporation, the name of its designated agent, and that agent's business address and business telephone number shall suffice.

(3) One (1) set of detailed construction plans and specifications certified and sealed by an engineer or architect currently registered in Indiana, drawn to scale, and having sufficient clarity to be reproduced to create legible microfilm. As provided in IC 25-31-1-2(h), registered land surveyors may only certify and seal plans for gravity sanitary sewers, storm sewers, and tile drains.

(4) A map or other documentation showing the location of the property involved.

(5) A plot plan, drawn to scale, showing the following:

(A) The location of the proposed facility with respect to property lines.

(B) The existing and proposed structures, roads, parking lots, sewers, sewage disposal systems, water wells, and water lines on the property.

For those facilities which will be served by a commercial on-site wastewater disposal system that includes an absorption field, the plot plan shall also show site topography, with contours established at intervals of two (2) feet or less.

(6) The fee for plan review required by section 16 *[410 IAC 6-12-16 was repealed filed Apr 16, 1996, 4:10 p.m.: 19 IR 2285.]* of this rule.

(7) The name, business address, and business telephone number of the registered engineer or architect who certified and sealed the construction plans and specifications required by subdivision (3), in writing.

(8) For those facilities which will be served by a commercial on-site wastewater disposal system that includes an absorption field, a soil profile analysis for the soils observed in the area of the proposed absorption field. Said analysis shall:

(A) include the name of each soil type observed;

(B) map the approximate boundaries and specify slope for each soil type; and

(C) provide a description of the soil textures, soil structure, soil color, and the depth to rock or seasonal high water table in the upper five (5) feet of soil for each soil type observed.

(9) Wastewater characteristics and calculations used to estimate wastewater flow on the peak day, in gallons, to be disposed of. If more than one (1) type of facility is involved in the project, wastewater characteristics and calculations used to estimate wastewater flow, in gallons, from each facility on the peak day must be submitted.

(10) A summary delineating, for each diameter of pipe utilized, the estimated total length of water line, sanitary sewer, and sewage force main to be installed.

(11) All additional information requested by the board to substantiate that the proposed facility can reasonably be expected to conform to the requirements of laws and rules applicable to the facility, without causing a health or safety hazard, nuisance, surface water pollution, or ground water pollution.

(b) Requests for additional substantiating information made pursuant to subsection (a)(11) shall be addressed to the registered engineer or architect who certified and sealed the construction plans and specifications in compliance with subsection (a)(3). *(Indiana State Department of Health; 410 IAC 6-12-8; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2220; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-9 Right of entry

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 9. The board or the local health department's authorized representative may enter upon public or private property at reasonable times and upon presentation of credentials to:

(1) inspect facilities, equipment, or records;

(2) investigate allegations;

(3) determine soil characteristics;

(4) conduct tests or collect samples for the purpose of obtaining information necessary to the issuance of a permit pursuant to this rule; or

(5) determine whether any person is subject to, or in violation of, this rule or any permit or order issued pursuant to this rule. *(Indiana State Department of Health; 410 IAC 6-12-9; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2221; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-10 Official's signature, effective date

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 10. Construction permits shall be signed by the commissioner on behalf of the board and shall be considered issued as of the date of mailing. *(Indiana State Department of Health; 410 IAC 6-12-10; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2221; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 6-12-11 Permit conditions

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 11. The board may specify in its construction permits any limitations, terms, or conditions necessary to provide a

functional, easily operated, enduring facility or to prevent a health or safety hazard, nuisance, surface water pollution, or ground water pollution. In addition, all construction permits shall contain the following requirements, not necessarily verbatim:

(1) The permit shall expire on the last day of the twelfth month following the month of permit issuance, unless the applicant has started construction of the facility on or before the date of permit expiration.

(2) That all necessary local permits and approvals shall be obtained before construction is begun.

(3) That any proposed changes, alterations, or additions to the approved facilities be submitted to the board for review and approval prior to the start of construction which will effect the proposed changes, alterations, or additions.

(4) That if pollution, health hazards, or nuisance conditions occur which are attributable to the facility permitted, immediate corrective action shall be taken by the owner.

(5) That the permittee notify the board and the local health department at least seven (7) days before construction of the approved facilities is to commence.

(Indiana State Department of Health; 410 IAC 6-12-11; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2221; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-12-12 Standards for issuance

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 12. The board may reject an application for permit to construct a facility unless the applicant has submitted the following:

(1) All documentation and fees required by sections 8(a) and 16 *[410 IAC 6-12-16 was repealed filed Apr 16, 1996, 4:10 p.m.: 19 IR 2285.]* of this rule.

(2) Evidence that the facility can be constructed, modified, or installed and operated in such a manner that it will not violate any law or rule applicable to the facility, or any other applicable sanitation, health, siting, or pollution control rules or ordinances existing at the time of application.

(Indiana State Department of Health; 410 IAC 6-12-12; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2222; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-12-13 Construction permit revocations and modifications

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 13. A facility construction permit may be revoked or modified by the board for any of the following causes:

(1) Violation of a law or rule applicable to the facility, or any other applicable sanitation, health, siting, or pollution control rules or ordinances existing at the time of application.

(2) Violation of any limitation, term, or condition contained in the construction permit.

(3) Failure to disclose all facts relevant to construction and use of the facility that might adversely impact health, surface water, or ground water.

(4) Any misrepresentation made to obtain the construction permit.

(5) Any other change, situation, or activity relating to use of the facility which, in the judgment of the board, is not consistent with the purposes of this rule or a law or rule applicable to the facility.

(Indiana State Department of Health; 410 IAC 6-12-13; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2222; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-12-14 Denial of an application for construction permit

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 14. An application for facility construction permit may be denied by the board for any of the following causes:

(1) Any misrepresentation made in the application.

(2) Failure of the owner, or the engineer or architect who certified and sealed the construction plans and specifications, to respond to a request for revised plans and specifications or additional information made pursuant to section 8 of this rule,

within six (6) months of receiving the request.

(3) Failure to show that the facility can be constructed, operated, maintained, or abandoned in compliance with any law or rule applicable to the facility.

(Indiana State Department of Health; 410 IAC 6-12-14; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2222; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-12-15 Petitions for review

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-19

Sec. 15. (a) Within fifteen (15) days following the date of receipt of an issued permit, permit modification, notice of permit denial, or notice of permit revocation, any person aggrieved by such action may file a petition for review concerning such action with the board.

(b) A petition for review shall:

(1) state the name and address of the person making the request;

(2) identify the interest of the petitioner which is affected by the permit issuance, denial, modification, or revocation;

(3) identify any persons whom the petitioner represents;

(4) state with particularity the reasons for the request;

(5) state with particularity the issues proposed to be considered; and

(6) include proposed terms or conditions which, in the judgment of the petitioner, would be appropriate to carry out the requirements of this rule.

(Indiana State Department of Health; 410 IAC 6-12-15; filed Jul 12, 1991, 5:00 p.m.: 14 IR 2222; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 6-12-16 Fees (Repealed)

Sec. 16. *(Repealed by Indiana State Department of Health; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2285)*

Rule 13. Tanning Facility Sanitation and Safety (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 6-13) to the State Board of Cosmetology Examiners (820 IAC 5-1) by P.L.142-1995, SECTION 33, effective July 1, 1995.

ARTICLE 6.1. PERMIT REQUIREMENTS (REPEALED)

(Repealed by Indiana State Department of Health; filed Sep 24, 1987, 3:00 pm: 11 IR 737)

ARTICLE 6.2. WATER SANITATION (REPEALED)

(Repealed by Indiana State Department of Health; filed Sep 24, 1987, 3:00 pm: 11 IR 737)

ARTICLE 7. FOOD AND DRUGS

Rule 1. False and Misleading Labeling

410 IAC 7-1-1 Misleading labeling (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 2. New Drugs; Determination

410 IAC 7-2-1 Newness of drug (Repealed)

Sec. 1. *(Repealed by Indiana State Department of Health; filed Jun 7, 1990, 11:20 a.m.: 13 IR 1855)*

410 IAC 7-2-2 Manufacturer, processor, repackager, or wholesale distributor of drugs, cosmetics, or medical devices registration fee (Repealed)

Sec. 2. *(Repealed by Indiana State Department of Health; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2285)*

Rule 3. Guaranty

410 IAC 7-3-1 Guaranty liability (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 4. Hearings

410 IAC 7-4-1 Informal hearings (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 5. Food Misbranding

410 IAC 7-5-1 Misbranding of food; what constitutes

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-42-1

Sec. 1. (A) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

Providing however, the labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(B) If a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "Manufactured for and Packed by _____", "Distributed by _____", or other similar phrase which expresses the facts.

(C) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(D) When a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(E) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

(F) (1) The statement of the quantity of the contents shall reveal the quantity of food in the package, exclusive of wrappers and other material packed with such food.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity.

(G) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon if 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and, except in case

of frozen food which is so consumed, shall express the volume at 68° Fahrenheit (20° Centigrade). A statement of dry measure shall be in terms of the United States bushel of 2150.42 cubic inches and peck, dry quart, and dry pint, subdivision thereof; or in terms of the United States standard barrel and its subdivisions of third, half, and three-quarters barrel. However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement weight or measure in the terms specified in subdivision (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the food as will give such information.

(H) Statements of quantity shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(I) (1) If the quantity of food in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (G) of this regulation, and which is applicable to such food under the provisions of paragraph (F) (2) of this regulation, the statement shall express (except as provided in subdivision (2) of this paragraph) the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one quart of food shall be "1 quart", and not "2 pints" or "32 fluid ounces"). Where such number is a whole number and a fraction, there may be substituted for the fraction, its equivalent in smaller units, if any smaller is specified in such paragraph (G) (for examples, 1 3/4 quarts may be expressed as "1 quart 1 1/2 pints" or "1 quart 1 pint 8 fluid ounces"; 1 1/4 pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit specified in such paragraph (G) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1 1/2 quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1 1/2 pounds" or "1 pound 8 ounces").

(2) In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(J) A food shall be exempt from compliance with the requirements of clause (2) of Section 13 (e) of the Act if–

(1) the quantity of the contents, as expressed in terms applicable to such food under the provisions of paragraph (F) (2) of this regulation, is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or (in case the units of the food can be easily counted without opening the package) less than six units; or

(2) the statement of the quantity of the contents of the package, together with all other words, statements, and information required by or under authority of the Act to appear on the label, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of Section 13 (f) of the Act and regulations promulgated thereunder.

(K) A word, statement, or other information required by or under authority of the Act to appear on the label may lack that prominence and conspicuousness required by Section 13 (f) of the Act by reason (among other reasons) of–

(1) the failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) the failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) the failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(5) insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs of vignettes, or crowding with other written, printed, or graphic matter.

(L) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under Section 13 (e) or (i) of the Act shall apply if such insufficiency is caused by–

(1) the use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;

(2) the use of label space to give greater conspicuousness to any word, statement, or other information than is required by Section 13 (f) of the Act; or

(3) the use of label space for any representation in a foreign language.

(M) (1) All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear on the labeling in the foreign language.

(N) If an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by regulations under Section 11 of the Acts, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(O) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance.

(P) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring as the case may be, unless such ingredient is designated by its specific name.

(Q) A label may be misleading by reason (among other reasons) of–

(1) the order in which the names of ingredients appear thereon, or the relative prominence otherwise given such names; or

(2) its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(R) (1) A food shall be exempt from the requirements of clause 2 of Section 13 (i) of the Act if all words, statements, and other information required by or under authority of the Act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of Section 13 (f) of the Act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by regulation (m) (2) under Section 13 (e) of the Act, and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) In the case of an assortment of different items of food, when variations in the items which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variation in the ingredients in different packages, such food shall be exempt from compliance with the requirements of clause (2) of Section 13 (i) of the Act with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement in terms which are as informative as practicable and which are not misleading, indicating that other ingredients may be present.

(S) (1) The term "artificial flavoring" means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(2) The term "artificial coloring" means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(3) The term "chemical preservative" means any chemical which, when added to food, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegars, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

(T) A food which is subject to the requirements of Section 13 (k) of the Act shall bear labeling, even though such food is not in package form.

(U) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary

individual under customary conditions of purchase and use of such food.

(V) A food shall be exempt from compliance with the requirements of Section 13 (k) of the Act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use. *(Indiana State Department of Health; Reg HFD 5; filed Oct 18, 1945, 10:30 am: Rules and Regs. 1947, p. 1313; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 6. Labeling Requirements; Exemptions in Case of Food

410 IAC 7-6-1 Shipments for processing; labeling exemptions

Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-42-1

Sec. 1. (A) Except as provided by paragraphs (B) and (C) of this regulation, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in commerce and the time of holding in such establishment, from compliance with the labeling requirements of Section 13 (c), (g), (h), (i), (j) and (k) of the Act if–

(1) the person who introduced such shipment or delivery into commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement signed by and containing the post-office address of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to the Secretary or his authorized agent who requests them.

(B) An exemption of a shipment or other delivery of a food under clause (1) of paragraph (A) of this regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.

(C) An exemption of a shipment or other delivery of a food under clause (2) of paragraph (A) of this regulation shall become void ab initio with respect to the person who introduced such shipment or delivery into commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(D) An exemption of a shipment or other delivery of a food under clause (2) of paragraph (A) of this regulation shall expire–

(1) at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or

(2) upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(Indiana State Department of Health; Reg HFD 6; filed Oct 18, 1945, 10:30 am: Rules and Regs. 1947, p. 1321; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 6.5. Wholesale Manufacturers, Processors, Repackagers, and Distributors of Food

410 IAC 7-6.5-1 Fee schedule (Repealed)

Sec. 1. *(Repealed by Indiana State Department of Health; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2285)*

Rule 7. Adulterated Drugs and Devices

410 IAC 7-7-1 Designation of drug (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 8. Misbranded Drugs and Devices

410 IAC 7-8-1 Misbranded drugs; what constitutes (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 9. Application for New Drugs; Delivery

410 IAC 7-9-1 Shipment of new drug; filing application for new drug (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 10. Coal-Tar Hair Dye

410 IAC 7-10-1 Definition of coal-tar hair dye (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 11. Misbranded Cosmetics

410 IAC 7-11-1 Misbranded cosmetics; what constitutes (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 12. Labeling Exemptions in Case of Cosmetics

410 IAC 7-12-1 Shipments for processing; labeling exemptions (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 13. Cold Storage Locker Plants

410 IAC 7-13-1 Application for license; facilities; hearing officer
Authority: IC 16-19-3-4; IC 16-19-3-5
Affected: IC 16-42-7

Sec. 1. (A) Application for License: Procedure. Application for renewal of a license to operate a cold storage locker plant or branch locker plant shall be made to the Board not less than two weeks before expiration of the current license. Application for a new license to operate a cold storage locker plant or branch locker plant shall be made to the Board at least two weeks before the plant is scheduled to be placed in operation.

(B) Locker Plant and Branch Locker Plant: Definition. “All rooms of a locker plant or branch locker plant” shall include all detached buildings or rooms, under the control of the operator of said locker plant or branch locker plant and used in any capacity in connection with the operation of said locker plant or branch locker plant.

(C) Dressing Rooms. All locker plants or branch locker plants where employees' street clothing is stored shall be provided with adequate lockers or dressing rooms, separate and apart from any rooms in which food is prepared, processed, chilled, frozen or stored.

(D) Temperature. A temperature of not to exceed zero degrees Fahrenheit shall be maintained in the locker room of all locker plants or branch locker plants at all times. Provided, however, that a variation of five degrees Fahrenheit higher, for short periods incidental to plant operation, shall not be prohibited.

(E) Recording Thermometer: Installation.

(1) The recording thermometer in use at all locker plants or branch locker plants shall continually record temperatures in such plants for a period of not less than seven days; shall be enclosed in a moisture proof case, permanently fastened to a substantial wall in the vestibule or waiting room, and shall be five feet from the floor so that the recording chart is visible at all times. The instrument must be kept locked at all times except when changing dials, inking or repairing. Charts shall be changed once each week, be properly dated so as to indicate the period for which temperatures were recorded, be signed by the operator and be made available for inspection for at least one year.

(2) The sensitive bulb used to determine temperatures shall be located in the locker room not less than eight feet from any door or blower, not less than ten inches from any plates or coils and at least ten inches from the ceiling. The bulb shall not be placed directly in front of any door or blower.

(3) When more than one room or one section of lockers is maintained in a locker plant or branch locker plant, which rooms or sections of lockers are refrigerated independently of each other, a sensitive bulb, properly connected to an accurate recording thermometer, shall be installed in each such room or section of lockers in such a manner as to give accurate recordings of temperatures in each such room or section of lockers.

(F) Defrosting. Whenever refrigeration coils or plates are located directly above patrons lockers, said coils or plates shall be defrosted in such a manner that contents of said patrons lockers are not contaminated.

(G) Hearing Officer. The Board is hereby authorized to designate an authorized agent or employee of the Indiana State Board of Health to act in its stead in giving notice and holding hearings and of establishing the time and date for such hearing prior to the revocation of a cold storage locker plant or branch plant license as provided for in Section 20 of the Act. Before the Board takes action to revoke a license, the person or persons designated to hold the hearing shall submit to the Board, a complete report of the results of the hearing. *(Indiana State Department of Health; Reg HFD 14; filed Nov 29, 1945, 10:30 am: Rules and Regs. 1947, p. 1347; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 14. Cold Storage Warehouses

410 IAC 7-14-1 Definition of cold storage warehouse; marking goods; inspection (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 15. Sanitation of Public Eating and Drinking Establishments (Repealed)

(Repealed by Indiana State Department of Health; filed Jul 6, 1983, 11:18 am: 6 IR 1394, eff one hundred twenty (120) days after filing with secretary of state)

Rule 15.1. Sanitation of Public Eating and Drinking Establishments (Repealed)

(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)

Rule 15.5. Sanitation of Bed and Breakfast Establishments

410 IAC 7-15.5-1 Applicability

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 7-15.5-1; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2572; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-2 "Bed and breakfast establishment" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 2. "Bed and breakfast establishment" means an operator occupied residence that:
(1) provides sleeping accommodations to the public for a fee;
(2) has no more than fourteen (14) guest rooms;
(3) provides breakfast to its guests as part of the fee; and
(4) provides sleeping accommodations for no more than thirty (30) consecutive days to a particular guest.
The term does not include hotels, motels, boarding houses, or food service establishments. *(Indiana State Department of Health; 410 IAC 7-15.5-2; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2572; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-3 "Corrosion-resistant materials" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 3. "Corrosion-resistant materials" means those materials that maintain their original surface characteristics under prolonged contact with food, the normal use of cleaning compounds and bactericidal solutions, and other conditions-of-use environment. *(Indiana State Department of Health; 410 IAC 7-15.5-3; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2572; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-4 "Department" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 4. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 7-15.5-4; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2572; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-5 "Easily cleanable" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 5. "Easily cleanable" means readily accessible and made of materials which allow for residue to be effectively removed by normal cleaning methods. *(Indiana State Department of Health; 410 IAC 7-15.5-5; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2572; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-6 "Employee" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 6. "Employee" means the operator permit holder, individuals having supervisory or management duties, and any other person working in a bed and breakfast establishment. *(Indiana State Department of Health; 410 IAC 7-15.5-6; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2572; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-7 "Equipment" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 7. "Equipment" means stoves, ovens, ranges, hoods, slicers, mixers, meat blocks, tables, counters, refrigerators, sinks, dishwashing machines, steam tables, and similar items other than utensils, used in the operation of a bed and breakfast establishment. *(Indiana State Department of Health; 410 IAC 7-15.5-7; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2572; readopted filed Jul 11, 2001,*

2:23 p.m.: 24 IR 4234)

410 IAC 7-15.5-8 "Food" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 8. "Food" means any raw, cooked, or processed edible substance, ice, beverage, drink, or ingredient used or intended for use or for sale in whole or in part for human consumption. *(Indiana State Department of Health; 410 IAC 7-15.5-8; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2572; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-9 "Food contact surface" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 9. "Food contact surface" means those surfaces of equipment and utensils with which food normally comes in contact, and those surfaces from which food may drain, drip, or splash back onto surfaces normally in contact with food. *(Indiana State Department of Health; 410 IAC 7-15.5-9; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-10 "Food processing establishment" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 10. "Food processing establishment" means a commercial establishment in which food is manufactured or packaged for human consumption. The term does not include a food service establishment, retail food store, bed and breakfast establishment, or commissary operation. *(Indiana State Department of Health; 410 IAC 7-15.5-10; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-11 "Guest" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 11. "Guest" means an individual who rents a guest room in a bed and breakfast establishment. *(Indiana State Department of Health; 410 IAC 7-15.5-11; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-12 "Guest room" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 12. "Guest room" means a sleeping room intended to accommodate not more than four (4) guests each night. *(Indiana State Department of Health; 410 IAC 7-15.5-12; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-13 "Hermetically sealed container" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 13. "Hermetically sealed container" means a container designed and intended to be secure against the entry of micro-organisms and to maintain the commercial sterility of its contents after processing. *(Indiana State Department of Health; 410 IAC 7-15.5-13; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-14 "Kitchenware" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 14. "Kitchenware" means all multiuse utensils, other than tableware. *(Indiana State Department of Health; 410 IAC 7-15.5-14; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-15 "Local board" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 15. "Local board" means the local board of health or its authorized representative. *(Indiana State Department of Health; 410 IAC 7-15.5-15; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-16 "Operator" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 16. "Operator" means an owner, or the owner's agent, of a bed and breakfast establishment who resides within the establishment or on contiguous property. *(Indiana State Department of Health; 410 IAC 7-15.5-16; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-17 "Packaged" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 17. "Packaged" means bottled, canned, cartoned, or securely wrapped. *(Indiana State Department of Health; 410 IAC 7-15.5-17; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-18 "Person" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 18. "Person" includes any individual, partnership, copartnership, firm, company, corporation, association, trust, estate, or other legal entity, and its or their successors, assigns, or agents. *(Indiana State Department of Health; 410 IAC 7-15.5-18; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-19 "Person in charge" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 19. "Person in charge" means the individual present in a bed and breakfast establishment who is the apparent supervisor of the bed and breakfast establishment at the time of inspection. If no individual is the apparent supervisor, then any employee present is the person in charge. *(Indiana State Department of Health; 410 IAC 7-15.5-19; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2573; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-20 "Potentially hazardous food" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 20. "Potentially hazardous food" means any food that consists in whole or in part of milk or milk products, eggs, meat,

poultry, fish, shellfish, edible crustacea, or other ingredients, including synthetic ingredients, in a form capable of supporting rapid and progressive growth of infectious or toxigenic micro-organisms. The term does not include foods which have a Ph level at or below four and six-tenths (4.6) or a water activity (Aw) value at or below eighty-five hundredths (0.85) under standard conditions or food products in hermetically sealed containers processed to prevent spoilage. *(Indiana State Department of Health; 410 IAC 7-15.5-20; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-21 "Reconstituted" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 21. "Reconstituted" means dehydrated food products recombined with water or other liquids. *(Indiana State Department of Health; 410 IAC 7-15.5-21; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-22 "Safe materials" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 22. "Safe materials" means articles manufactured from or composed of materials that may not reasonably be expected to become a component or otherwise affect the characteristics of any food. If materials used are food additives or color additives, they are "safe" only if they are used in conformity with requirements of IC 16-1-28 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* and IC 16-1-29 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*. *(Indiana State Department of Health; 410 IAC 7-15.5-22; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-23 "Sanitization" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 23. "Sanitization" means effective bactericidal treatment by a process that provides enough accumulative heat or concentration of chemicals for enough time to reduce the bacterial count, including pathogens, to a safe level on utensils and equipment. *(Indiana State Department of Health; 410 IAC 7-15.5-23; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-24 "Sealed" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 24. "Sealed" means free of cracks or other openings that permit the entry or passage of moisture. *(Indiana State Department of Health; 410 IAC 7-15.5-24; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-25 "Single-service articles" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 25. "Single-service articles" means cups, containers, lids, closures, plates, knives, forks, spoons, stirrers, paddles, straws, napkins, wrapping materials, toothpicks, and similar articles intended for one (1) time, one (1) person use. *(Indiana State Department of Health; 410 IAC 7-15.5-25; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-26 "Tableware" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 26. "Tableware" means multiuse eating and drinking utensils. *(Indiana State Department of Health; 410 IAC 7-15.5-26; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-27 "Utensils" defined

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 27. "Utensils" means any implement used in the storage, preparation, transportation, or service of food. *(Indiana State Department of Health; 410 IAC 7-15.5-27; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-28 Food supplies

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 28. (a) Food shall be in sound condition, free from spoilage, filth, or other contamination and shall be safe for human consumption. Food shall be obtained from sources that comply with requirements of IC 16-1-28 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* and IC 16-1-29 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* relating to food and food labeling. The use of food in hermetically sealed containers that was not prepared in a food processing establishment is prohibited except those jams and jellies which are not potentially hazardous foods.

(b) Fluid milk and fluid milk products used or served shall be pasteurized and shall meet the Grade A quality standards as established by law. Dry milk and dry milk products shall be made from pasteurized milk products.

(c) Only clean whole eggs, with shells intact and without cracks or checks, or pasteurized liquid, frozen, or dry eggs or pasteurized dry egg products shall be used, except that hard boiled, peeled eggs, commercially prepared and packaged, may be used. *(Indiana State Department of Health; 410 IAC 7-15.5-28; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2574; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-29 Food protection

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 29. (a) At all times, including while being stored, prepared, displayed, served, or transported, food shall be protected from potential contamination, including dust, insects, rodents, unclean equipment and utensils, unnecessary handling, coughs, and sneezes, flooding, drainage, and overhead leakage or overhead drippage from condensation. The temperature of potentially hazardous food shall be at or below forty-five degrees Fahrenheit (45°F) or at or above one hundred forty degrees Fahrenheit (140°F) at all times, except as otherwise provided in this rule.

(b) The person in charge of a bed and breakfast establishment that is affected by a fire, flood, extended power outage, or a similar significant occurrence that creates a reasonable probability that food in the establishment may have been contaminated, or that the temperature level of food which is in a potentially hazardous form may have caused that food to have become hazardous to health, shall take action necessary to protect the public health, and shall promptly notify the department and the local board of the emergency. *(Indiana State Department of Health; 410 IAC 7-15.5-29; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2575; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-30 Food storage

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 30. (a) Food, whether raw or prepared, if removed from the container or package in which it was obtained, shall be stored in a clean, covered container except during necessary periods of preparation or service. Container covers shall be impervious and nonabsorbent.

(b) Containers of food shall be stored above the floor in a manner that protects the food from splash and other contamination, and that permits easy cleaning of the storage area.

(c) Food and containers of food shall not be stored under exposed or unprotected sewers or waterlines, except for automatic fire protection sprinkler heads that may be required by law. The storage of food in toilet rooms or vestibules is prohibited.

(d) Food not subject to further washing or cooking before serving shall be stored in a way that protects it against cross-contamination from food requiring washing or cooking.

(e) Packaged food shall not be stored in contact with water or undrained ice. Wrapped sandwiches shall not be stored in direct contact with ice.

(f) Unless its identity is unmistakable, bulk food, such as cooking oil, syrup, salt, sugar, or flour, not stored in the product container or package in which it was obtained, shall be stored in a container identifying the food by common name.

(g) Enough conveniently located refrigeration facilities or effectively insulated facilities shall be provided to assure the maintenance of potentially hazardous food at required temperatures during storage.

(h) Each mechanically refrigerated facility storing potentially hazardous food shall be provided with a numerically scaled indicating thermometer or recording thermometer, accurate to plus or minus three degrees Fahrenheit (±3°F), which is:

(1) located to measure the air temperature in the warmest part of the facility; and

(2) located to be easily readable.

(i) Potentially hazardous food requiring refrigeration after preparation shall be rapidly cooled to an internal temperature of forty-five degrees Fahrenheit (45°F) or below.

(j) Potentially hazardous foods of large volume or prepared in large quantities which require refrigeration shall be rapidly cooled, utilizing such methods as shallow pans, agitation, quick chilling, or water circulation external to the food container so that the cooling period shall not exceed four (4) hours.

(k) Frozen food shall be kept frozen and should be stored at a temperature of zero degrees Fahrenheit (0°F) or below.

(l) Ice intended for human consumption shall not be used as a medium for cooling stored food, food containers, or food utensils.

(m) Enough conveniently located hot food storage facilities shall be provided to assure the maintenance of food at the required temperature during storage. Each hot food facility storing potentially hazardous food shall be provided with a numerically scaled indicating thermometer or recording thermometer, accurate to plus or minus three degrees Fahrenheit (±3°F), located to measure the air temperature in the coolest part of the facility and located to be easily readable. Where it is impractical to install thermometers on equipment, a product thermometer must be available and used to check internal food temperature.

(n) The internal temperature of potentially hazardous foods requiring hot storage shall be one hundred forty degrees Fahrenheit (140°F) or above except during necessary periods of preparation. Potentially hazardous food to be transported shall be held at a temperature of one hundred forty degrees Fahrenheit (140°F) or above unless maintained in accordance with subsection (i).

(o) Upon delivery, intact shell eggs shall be stored at an ambient temperature of forty-five degrees Fahrenheit (45°F) or below.
(Indiana State Department of Health; 410 IAC 7-15.5-30; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2575; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 7-15.5-31 Food preparation

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 31. (a) Food shall be prepared with the least possible manual contact, with suitable utensils and on surfaces that prior to use have been cleaned, rinsed, and sanitized to prevent cross-contamination.

(b) Raw fruits and raw vegetables shall be thoroughly washed with potable water before being cooked or served.

(c) Potentially hazardous foods being processed shall be cooked to heat all parts of the food to a temperature of at least one hundred forty degrees Fahrenheit (140°F), except that:

(1) poultry, poultry stuffings, stuffed meats, and stuffings containing meat shall be cooked to heat all parts of the food to at least one hundred sixty-five degrees Fahrenheit (165°F) with no interruption of the cooking process; and

(2) pork and pork products shall be cooked to heat all parts of the food to at least one hundred fifty degrees Fahrenheit

(150°F), or, if cooked in a microwave oven, to at least one hundred seventy degrees Fahrenheit (170°F).

(d) Reconstituted dry milk and dry milk products may be used in instant desserts and whipped products, or for cooking and baking purposes.

(e) Liquid, frozen, dry eggs, and egg products shall be used only for cooking and baking purposes.

(f) Potentially hazardous foods that have been cooked and then refrigerated, shall be reheated rapidly to one hundred sixty-five degrees Fahrenheit (165°F) or higher throughout before being served or before being placed in a hot food storage facility. Steam tables, bainmaries, warmers, and similar hot food holding facilities are prohibited for the rapid reheating of potentially hazardous foods.

(g) Nondairy creaming, whitening, or whipping agents may be reconstituted on the premises only when they will be stored in sanitized, covered containers not exceeding one (1) gallon in capacity and cooled to forty-five degrees Fahrenheit (45°F) or below within four (4) hours after preparation.

(h) Metal stem-type numerically scaled indicating thermometers, accurate to plus or minus two degrees Fahrenheit (±2°F), shall be provided and used to assure the attainment and maintenance of proper internal cooking, holding, or refrigeration temperatures of all potentially hazardous foods.

(i) Potentially hazardous foods shall be thawed:

(1) in refrigerated units at a temperature not to exceed forty-five degrees Fahrenheit (45°F);

(2) under potable, running water of a temperature of seventy degrees Fahrenheit (70°F) or below, with sufficient water velocity to agitate and float off loose food particles into the overflow;

(3) in a microwave oven only when the food will be immediately transferred to conventional cooking facilities as part of a continuous cooking process or when the entire, uninterrupted cooking process takes place in the microwave oven; or

(4) as part of the conventional cooking process.

(Indiana State Department of Health; 410 IAC 7-15.5-31; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2576; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 7-15.5-32 Food display and service

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 32. (a) Intact shell eggs shall be displayed at an ambient temperature of forty-five degrees Fahrenheit (45°F) or below. Other potentially hazardous food shall be kept at an internal temperature of forty-five degrees Fahrenheit (45°F) or below or at an internal temperature of one hundred forty degrees Fahrenheit (140°F) or above during display and service, except that rare roast beef shall be held for service at a temperature of at least one hundred thirty degrees Fahrenheit (130°F).

(b) Ice for consumer use shall be dispensed only by employees with scoops, tongs, or other ice dispensing utensils or through automatic self-service, ice dispensing equipment. Ice dispensing utensils shall be stored on a clean surface or in the ice with the dispensing utensil's handle extended out of the ice. Between uses, ice transfer receptacles shall be stored in a way that protects them from contamination. Ice storage bins shall be drained through an air gap or an air break.

(c) To avoid unnecessary manual contact with food, suitable dispensing utensils shall be used by employees or provided to consumers who serve themselves.

(d) Once served to a consumer, portions of leftover food shall not be served again except that packaged food, other than potentially hazardous food, that is still packaged and is still in sound condition, may be re-served.

(e) Food on display shall be protected from consumer contamination by the use of packaging or by the use of easily cleanable counter, serving line or salad bar protector devices, display cases, or by other effective means. Enough hot or cold food facilities shall be available to maintain the required temperature of potentially hazardous food on display.

(f) Reuse of soiled tableware by self-service consumers returning to the service area for additional food is prohibited. Beverage cups and glasses are exempt from this requirement. *(Indiana State Department of Health; 410 IAC 7-15.5-32; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2576; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-33 Personnel

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 33. (a) No person who has a communicable or infectious disease such as an open wound, an acute respiratory infection, or vomiting or diarrhea caused by an infection, shall work in a bed and breakfast establishment in any capacity in which epidemiological evidence indicates the person may spread the disease.

(b) Employees shall thoroughly wash their hands and the exposed portions of their arms with soap and warm water before starting work, during work, as often as is necessary to keep them clean, and after smoking, eating, drinking, or using the toilet. Employees shall keep their fingernails clean and trimmed.

(c) The outer clothing of all employees shall be clean.

(d) Employees shall consume food only in areas that will not result in contamination of other food, equipment, utensils, or other items needing protection.

(e) Employees shall not use tobacco in any form while engaged in food preparation or service, nor while in areas used for equipment or utensil washing or for food preparation. Employees shall use tobacco only in designated areas.

(f) Employees shall maintain a high degree of personal cleanliness and shall conform to good hygienic practices during all working periods in the bed and breakfast establishment. *(Indiana State Department of Health; 410 IAC 7-15.5-33; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2577; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-34 Equipment, utensils; materials

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 34. (a) Multiuse equipment and utensils shall be:

(1) constructed and repaired with safe materials, including finishing materials;

(2) corrosion-resistant and nonabsorbent; and

(3) smooth, easily cleanable, and durable under conditions of normal use.

Single-service articles shall be made from clean, sanitary, safe materials. Equipment, utensils, and single-service articles shall not impart odors, color, or taste, nor contribute to the contamination of food.

(b) If solder is used, it shall be composed of safe materials and be corrosion-resistant.

(c) Hard maple or other nonabsorbent material that meets the general requirements set forth in subsection (a) may be used for cutting blocks, cutting boards, salad bowls, and baker's tables. Wood may be used for single-service articles, such as chopsticks, stirrers, or ice cream spoons.

(d) Safe plastic or safe rubber or safe rubberlike materials that are resistant under normal conditions of use to scratching, scoring, decomposition, crazing, chipping, and distortion, that are of sufficient weight and thickness to permit cleaning and sanitizing by normal dishwashing methods, and which meet the general requirements set forth in subsection (a) are permitted for repeated use.

(e) Reuse of single-service articles is prohibited. *(Indiana State Department of Health; 410 IAC 7-15.5-34; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2577; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-35 Equipment, utensils; design and fabrication

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 35. (a) All equipment and utensils, including plasticware, shall be designed and fabricated for durability under conditions of normal use and shall be resistant to denting, buckling, pitting, chipping, and crazing.

(b) Food contact surfaces shall be easily cleanable, smooth, and free of breaks, open seams, cracks, chips, pits, and similar imperfections. Cast iron may be used as a food contact surface only if the surface is heated, such as in grills, griddle tops, and skillets.

(c) Indicating thermometers required for immersion into food or cooking media shall be of metal stem-type construction, numerically scaled, and accurate to plus or minus two degrees Fahrenheit (±2°F).

(d) Surfaces of equipment not intended for contact with food, but which are exposed to splash or food debris or which otherwise require frequent cleaning, shall be designed and fabricated to be smooth, washable, and readily accessible for cleaning, and shall be of such materials and in such repair as to be easily maintained in a clean and sanitary condition.

(e) Ventilation hoods and devices shall be designed to prevent grease or condensation from collecting on walls and ceilings, and from dripping into food or onto food contact surfaces. Filters or other grease extracting equipment shall be readily removable

for cleaning and replacement if not designed to be cleaned in place.

(f) Equipment that was installed in a bed and breakfast establishment prior to the effective date of this rule and does not fully meet all of the design and fabrication requirements of this section, shall be deemed acceptable in that establishment if it is in good repair, capable of being maintained in a sanitary condition, and the food contact surfaces are nontoxic. Replacement equipment and new equipment acquired after the effective date of this rule shall meet the requirements of this rule. *(Indiana State Department of Health; 410 IAC 7-15.5-35; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2577; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-36 Equipment, utensils; installation and location

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 36. (a) Equipment, including ice makers and ice storage equipment, shall not be located under exposed or unprotected sewers or waterlines, open stairwells, or other sources of contamination. This requirement does not apply to automatic fire protection sprinkler heads.

(b) Equipment shall be installed in a manner which will facilitate the cleaning of the equipment and adjacent areas. *(Indiana State Department of Health; 410 IAC 7-15.5-36; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2578; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-37 Equipment, utensils; cleaning and sanitizing

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 37. (a) Tableware shall be washed, rinsed, and sanitized after each use.

(b) To prevent cross-contamination, kitchenware and food contact surfaces of equipment shall be washed, rinsed, and sanitized after each use and following any interruption of operations during which time contamination may have occurred.

(c) Where equipment and utensils are used for the preparation of potentially hazardous foods, the food contact surfaces of equipment and utensils shall be washed, rinsed, and sanitized.

(d) The food contact surfaces of all cooking equipment shall be kept free of encrusted grease deposits and other accumulated soil.

(e) Nonfood contact surfaces of equipment shall be cleaned as often as is necessary to keep the equipment free of accumulation of dust, dirt, food particles, and other debris.

(f) Cloths used for wiping food spills on tableware, such as plates or bowls being served to the consumer, shall be clean, dry, and used for no other purpose.

(g) For manual washing, rinsing, and sanitizing of utensils and equipment, a sink with not fewer than two (2) compartments shall be provided and used. Sink compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable, running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed and sanitized manually.

(h) A method for the proper handling of soiled utensils prior to washing, and for cleaned utensils following sanitizing, shall be provided and located so as not to interfere with the proper use of the dishwashing facilities.

(i) Equipment and utensils shall be preflushed or prescraped and, when necessary, presoaked to remove food particles and soil.

(j) Sinks shall be cleaned prior to use.

(k) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing, and sanitizing shall be conducted in the following sequence for three (3) compartment sinks:

(1) Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.

(2) Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.

(3) Equipment and utensils shall be sanitized in the third compartment according to one (1) of the methods included in subsection (m)(1) through (m)(5).

(l) When a two (2) compartment sink is utilized for utensil and equipment washing, one (1) of the following two (2) methods shall be used:

(1) Equipment and utensils shall be thoroughly cleaned in the first compartment with a hot detergent solution that is kept clean and rinsed free of detergent with clean water in the second compartment, then the first compartment shall be drained and refilled for sanitization in accordance with subsection (m)(1) through (m)(5).

(2) Equipment and utensils shall be thoroughly cleaned in the first compartment with a detergent sanitizer solution that is kept clean and shall be sanitized in the second compartment in hot water in accordance with subsection (m)(1), or with a solution containing the same detergent sanitizer in accordance with subsection (m)(2) through (m)(5). Sanitizers or detergent sanitizers shall be of the type which do not require a freshwater rinse.

(m) The food contact surfaces of all equipment and utensils shall be sanitized by:

(1) immersion for at least one-half (1/2) minute in clean, hot water at a temperature of at least one hundred seventy degrees Fahrenheit (170°F);

(2) immersion for at least one (1) minute in a clean solution containing at least fifty (50) parts per million of available chlorine as a hypochlorite and at a temperature of at least seventy-five degrees Fahrenheit (75°F);

(3) immersion for at least one (1) minute in a clean solution containing at least twelve and five-tenths (12.5) parts per million of available iodine and at a pH at which the efficacy has been demonstrated to be effective by the manufacturer and at a temperature of at least seventy-five degrees Fahrenheit (75°F);

(4) immersion in quaternary ammonium compound solutions that are of a concentration indicated by the manufacturers' label instructions, and shall be used only in water with five hundred (500) parts per million hardness or less;

(5) immersion in a clean solution containing any other chemical sanitizing agent approved by the Indiana state department of health that will provide the equivalent bactericidal effect of a solution containing at least fifty (50) parts per million of available chlorine as a hypochlorite at a temperature of at least seventy-five degrees Fahrenheit (75°F) for one (1) minute; or

(6) rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under subdivisions (2), (3), and (5) in the case of equipment too large to sanitize by immersion.

(n) When hot water is used for sanitizing, the following facilities shall be provided and used:

(1) An integral heating device or fixture installed in or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least one hundred seventy degrees Fahrenheit (170°F).

(2) A numerically scaled indicating thermometer, accurate to plus or minus three degrees Fahrenheit (±3°F), convenient to the sink for frequent checks of water temperature.

(3) Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(o) When chemicals are used for sanitization, they shall not have concentrations higher than those specified by the manufacturer, and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(p) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils. These machines and devices shall be properly installed and maintained in good repair.

(q) Drain boards or dish tables shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and for cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities.

(r) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove food particles and soil prior to being washed in a dishwashing machine.

(s) Machines (single tank, stationary rack, door-type machines, and spray-type glass washers) using chemicals for sanitization may be used provided that:

(1) the temperature of the wash water shall not be less than one hundred twenty degrees Fahrenheit (120°F);

(2) the wash water shall be kept clean;

(3) chemicals added for sanitization purposes shall be automatically dispensed;

(4) utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration;

(5) the chemical sanitizing rinse water temperature shall not be less than seventy-five degrees Fahrenheit (75°F) nor less than the temperature specified by the machine's manufacturer;

(6) chemical sanitizers used shall meet requirements for safe usage; and

(7) a test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(t) Machines using hot water for sanitizing may be used provided that wash water and rinse water shall be kept clean, and water shall be maintained at a temperature of not less than one hundred sixty degrees Fahrenheit (160°F) as measured by a maximum registering thermometer, thermolabel (temperature-sensitive tape), or other accepted method on the utensil contact surface.

(u) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(v) After sanitization, all equipment and utensils shall be air dried. *(Indiana State Department of Health; 410 IAC 7-15.5-37; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2578; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-38 Equipment, utensils; storage and handling

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 38. (a) Cleaned and sanitized equipment and utensils shall be handled in a way that protects them from contamination. Spoons, knives, and forks shall be touched only by their handles. Cups, glasses, bowls, plates, and similar items shall be handled without contact with inside surfaces or surfaces that contact the user's mouth.

(b) Cleaned and sanitized utensils and equipment shall be stored above the floor in a clean, dry location in a way that protects them from contamination by splash, dust, and other means. The food contact surfaces of fixed equipment shall also be protected from contamination. Equipment and utensils shall not be placed under exposed sewers or waterlines, except for automatic fire protection sprinkler heads.

(c) Utensils shall be air dried before being stored or shall be stored in a self-draining position.

(d) Single-service articles shall be stored above the floor in closed cartons or containers which protect them from contamination and shall not be placed under exposed sewers or waterlines, except for automatic fire protection sprinkler heads.

(e) Single-service articles shall be handled and dispensed in a manner that prevents contamination of surfaces which may come in contact with food or with the mouth of the user.

(f) The storage of food equipment, utensils, or single-service articles in toilet rooms or vestibules is prohibited. *(Indiana State Department of Health; 410 IAC 7-15.5-38; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2580; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-39 Water supply

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 39. (a) A bed and breakfast establishment shall be provided with a safe, potable water supply through the use of a public water supply system if the water supply is reasonably available to the bed and breakfast establishment. If a public water supply system is not available, water shall be provided by a system approved by the local board.

(b) The water for a bed and breakfast establishment shall be supplied under pressure. The water supply and distribution system shall be sized and constructed to deliver water at twenty (20) pounds per square inch minimum pressure to all fixtures and appurtenances during periods of peak water demand.

(c) For bed and breakfast establishments which are not connected to public water supply and which have six (6) or fewer rooms for rent, the minimum distance between wells and buried pump suction lines and from sources of contamination shall be in accordance with the following:

Sewers and drains 50 feet

Exception: Sewers and drains of waterworks grade ductile iron pipe with mechanical joints or PVC pressure sewer pipe with an SDR rating of twenty-six (26) or less, having mechanical or compression joints, may be located within the fifty (50) foot distance. In no case, however, shall sewers be located closer than twenty (20) feet to dug and bored water supply wells nor closer than ten (10) feet to drilled and driven water supply wells or subsurface pump suction lines.

Septic tanks, soil absorption systems,
wastewater treatment facilities, and
privies 50 feet

Streams, lakes, ponds, and ditches	25 feet
Property lines	50 feet

Exception: The distances enumerated herein shall be doubled for soil absorption systems constructed where there exist horizons, layers, or strata within thirty-four (34) inches of the ground surface with a loading rate greater than seventy-five hundredths (0.75) gallons per day per square foot as determined from 410 IAC 6-8.1-49, Table V, unless that hazard can be overcome through system design.

(d) For bed and breakfast establishments which are not connected to public water supply and which have more than six (6) rooms for rent, the minimum distance between wells and buried pump suction lines and from sources of contamination shall be in accordance with the following:

Sewers and drains	100 feet

Exception: Sewers and drains of waterworks grade ductile iron pipe with mechanical joints or PVC pressure sewer pipe with an SDR rating of twenty-six (26) or less, having mechanical or compression joints, may be located within the one hundred (100) feet distance. In no case, however, shall sewers be located closer than thirty (30) feet to water supply wells or subsurface pump suction lines.

Septic tanks, soil absorption systems, wastewater treatment facilities, and privies	100 feet
Streams, lakes, ponds, and ditches	25 feet
Property lines	100 feet

Exception: The distances enumerated herein shall be doubled for soil absorption systems constructed where there exist horizons, layers, or strata within thirty-four (34) inches of the ground surface which are classified by the U.S. Department of Agriculture, Soil Conservation Service, as "severe due to poor filter" unless that hazard can be overcome through system design.

(e) Water supplies shall have no well head, well casing, pump, pumping machinery, or exposed pressure tanks or suction pumping located in any pit, room, or space which is walled in or otherwise enclosed so that it does not have free drainage by gravity to the surface of the ground at all times.

(f) All water supply wells shall be cased, and the annular space properly sealed, to a depth of at least twenty-five (25) feet below finished grade. The casing pipe of any well shall project not less than twelve (12) inches above flood level, finished grade, or the highest flood level of record, whichever is greater. No casing shall be cut off below grade except to install a pitless adapter.

(g) Well pumps, pressure tanks, storage tanks, etc., shall be sized to meet peak water demands and total daily demands. The minimum usable capacity of the pressure tank, in gallons, shall be three (3) times the installed well pump capacity, in gallons per minute. If the well or pump cannot meet peak demands, sufficient additional usable storage shall be provided to meet peak demands.

(h) Wells and potable water distribution systems shall be disinfected after construction and after each repair. Before releasing the potable system for use, the water shall be tested and shown to be bacteriologically acceptable in at least two (2) consecutive samples collected twenty-four (24) hours apart.

(i) The water supply of a bed and breakfast establishment may not be constructed or altered until the plans for construction or alteration have been submitted to and approved by the local board. *(Indiana State Department of Health; 410 IAC 7-15.5-39; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2580; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-40 Sewage disposal

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 40. (a) A water carriage system of collecting sewage shall be used. A bed and breakfast establishment shall dispose of sewage through the use of a public sewerage system if the sewerage system is available within a reasonable distance from the bed and breakfast establishment.

(b) If a public sewerage system is not available, all components of the sewage disposal collection and disposal system serving a bed and breakfast establishment with six (6) or fewer bedrooms shall be located in accordance with the provisions of 410 IAC 6-8.1-37(a).

(c) If a public sewerage system is not available, all components of the sewage disposal collection and disposal system serving a bed and breakfast establishment with more than six (6) bedrooms shall be located in accordance with the provisions of 410 IAC

6-10 or applicable rules of the water pollution control board.

(d) A sewage disposal system for a bed and breakfast establishment may not be constructed or altered until the following has been accomplished:

(1) Plans for construction or alteration of the septic tank soil absorption system for a bed and breakfast establishment with six (6) or fewer guest bedrooms have been forwarded to and approved by the local board in accordance with provisions of 410 IAC 6-8.1-33.

(2) Plans for construction or alteration of the septic tank soil absorption system for a bed and breakfast establishment with more than six (6) guest bedrooms have been forwarded to and approved by the department's division of sanitary engineering in accordance with the provisions of 410 IAC 6-10-5.

(3) Plans for construction or alteration of any sewage disposal system other than a septic tank soil absorption system have been forwarded to and approved by the commissioner of the department of environmental management under rules adopted by the water pollution control board.

(Indiana State Department of Health; 410 IAC 7-15.5-40; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2581; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 7-15.5-41 Plumbing

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 41. (a) Plumbing shall be sized, installed, and maintained in accordance with 675 IAC 16. There shall be no cross-connection between the potable water supply and any nonpotable or questionable water supply nor any source of pollution through which the potable water supply might become contaminated.

(b) A nonpotable water system is permitted only for purposes such as air conditioning and fire protection and only if the system is installed according to law, and the nonpotable water does not contact, directly or indirectly, food, potable water, equipment that contacts food, or utensils. The piping of any nonpotable water system shall be durably identified so that it is readily distinguishable from piping that carries potable water.

(c) The potable water system shall be installed to preclude the possibility of backflow. Devices shall be installed to protect against backflow and back siphonage at all fixtures and equipment where an air gap at least twice the diameter of the water supply inlet is not provided between the water supply inlet and the fixture's flood level rim. A hose shall not be attached to a faucet unless a backflow prevention device is installed.

(d) If used, grease traps shall be located to be easily accessible for cleaning.

(e) Drains shall be constructed in accordance with 675 IAC 16. *(Indiana State Department of Health; 410 IAC 7-15.5-41; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2582; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-42 Toilet facilities

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 42. (a) Toilet facilities shall be installed in accordance with 675 IAC 16, shall be conveniently located, and shall be accessible to employees at all times.

(b) Toilets and urinals shall be designed to be easily cleanable.

(c) Toilet rooms shall be completely enclosed and shall have tight fitting, solid doors, which shall be closed except during cleaning or maintenance.

(d) Toilet fixtures shall be kept clean and in good repair. A supply of toilet tissue shall be provided at each toilet at all times. Easily cleanable receptacles shall be provided for waste materials. *(Indiana State Department of Health; 410 IAC 7-15.5-42; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2582; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-43 Lavatory facilities

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 43. (a) Lavatories shall be located to permit convenient use by all employees in food preparation areas and utensil washing areas.

(b) Lavatories shall be accessible to employees at all times.

(c) Lavatories shall also be located in or immediately adjacent to toilet rooms or vestibules. Sinks used for food preparation or for washing equipment shall not be used for handwashing.

(d) Each lavatory shall be provided with hot and cold water tempered by means of a mixing valve or combination faucet. Any self-closing, slow-closing, or metering faucet used shall be designed to provide a flow of water for at least fifteen (15) seconds without the need to reactivate the faucet. Steam mixing valves are prohibited.

(e) A supply of hand cleansing soap or detergent shall be available at each lavatory. A supply of sanitary towels or a hand drying device providing heated air shall be conveniently located near each lavatory. Common towels are prohibited. If disposable towels are used, easily cleanable waste receptacles shall be conveniently located near the handwashing facilities.

(f) Lavatories, soap dispensers, hand drying devices, and all related fixtures shall be kept clean and in good repair. *(Indiana State Department of Health; 410 IAC 7-15.5-43; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2582; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-44 Solid waste collection and disposal

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 44. (a) Solid waste shall be kept in durable, easily cleanable, insect-proof, and rodent-proof containers that do not leak and do not absorb liquids. Plastic bags and wet-strength paper bags may be used to line these containers, and they may be used for storage inside the food service establishment.

(b) Containers used in food preparation and utensil washing areas shall be kept covered after they are filled.

(c) Containers stored outside the establishment, and dumpsters, compactors, and compactor systems shall be easily cleanable, shall be provided with tight fitting lids, doors, or covers, and shall be kept covered when not in actual use. In containers designed with drains, drain plugs shall be in place at all times, except during cleaning.

(d) There shall be a sufficient number of containers to hold all the solid waste that accumulates.

(e) Soiled containers shall be cleaned at a frequency to prevent insect and rodent attraction. Each container shall be thoroughly cleaned on the inside and outside in a way that does not contaminate food, equipment, utensils, or food preparation areas. Suitable facilities, including hot water and detergent or steam, shall be provided and used for washing containers. Liquid waste from compacting or cleaning operations shall be disposed of as sewage.

(f) Solid waste on the premises shall be stored in a manner to make it inaccessible to insects and rodents. Outside storage of unprotected plastic bags or wet-strength paper bags or baled units containing solid waste is prohibited. Cardboard or other packaging material not containing solid waste need not be stored in covered containers.

(g) Solid waste shall be disposed of often enough to prevent the development of odor and the attraction of insects and rodents. *(Indiana State Department of Health; 410 IAC 7-15.5-44; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2582; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-45 Insect and rodent control

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 45. (a) Effective measures intended to minimize the presence of rodents, flies, cockroaches, and other insects on the premises shall be utilized. The premises shall be kept in such condition as to prevent the harborage or feeding of insects or rodents.

(b) Openings to the outside shall be effectively protected against the entrance of rodents. Outside openings shall be protected against the entrance of insects by tight fitting, self-closing doors, closed windows, screening, controlled air currents, or other means. Screen doors shall be self-closing, and screens for windows, doors, skylights, transoms, intake and exhaust air ducts, and other openings to the outside shall be tight fitting and free of breaks. Screening material shall not be less than sixteen (16) mesh to the inch. *(Indiana State Department of Health; 410 IAC 7-15.5-45; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2583; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-46 Floors

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 46. (a) Floors and floor coverings of all food preparation, food storage, and utensil washing areas shall be constructed of a smooth durable material and shall be maintained in good repair.

(b) Carpeting, if used as floor covering, shall be of closely woven construction, properly installed, easily cleanable, and maintained in good repair.

(c) Mats and duckboards shall be of nonabsorbent, grease-resistant materials and of such size, design, and construction as to facilitate their being easily cleaned. *(Indiana State Department of Health; 410 IAC 7-15.5-46; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2583; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-47 Walls and ceilings

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 47. (a) Walls and ceilings, including doors, windows, skylights, and similar closures, shall be maintained in good repair.

(b) The walls, including nonsupporting partitions, wall coverings, and ceilings of food preparation areas, equipment washing areas, and utensil washing areas, shall be easily cleanable.

(c) Studs, joints, and rafters shall not be exposed in food preparation areas, equipment washing areas, utensil washing areas, toilet rooms, and vestibules. If exposed in other rooms or areas, they shall be finished to provide an easily cleanable surface.

(d) Exposed utility service lines and pipes shall be installed in a way that does not obstruct or prevent cleaning of the walls and ceilings.

(e) Light fixtures, vent covers, wall mounted fans, decorative materials, and similar equipment attached to walls and ceilings shall be easily cleanable and shall be maintained in good repair.

(f) Wall and ceiling covering materials shall be attached and sealed so as to be easily cleanable. *(Indiana State Department of Health; 410 IAC 7-15.5-47; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2583; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-48 Cleaning physical facilities

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 48. (a) Cleaning of floors and walls, except emergency cleaning of floors, shall be done during periods when the least amount of food is exposed. Floors, mats, duckboards, walls, ceilings, and attached equipment and decorative materials shall be kept clean.

(b) In new or extensively remodeled establishments, at least one (1) utility sink shall be provided and used for the cleaning of mops and similar wet floor cleaning tools and for the disposal of mop water or similar liquid wastes. The use of lavatories, utensil washing or equipment washing, or food preparation sinks for this purpose is prohibited. *(Indiana State Department of Health; 410 IAC 7-15.5-48; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2584; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-49 Lighting

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 49. (a) Artificial light sources shall be installed to provide at least twenty (20) foot-candles of light on all food preparation surfaces and at equipment or utensil washing work levels.

(b) Artificial light sources shall be installed to provide, at a distance of thirty (30) inches from the floor, at least ten (10) foot-candles of light in all other areas. This shall also include dining areas during cleaning operations. *(Indiana State Department of Health; 410 IAC 7-15.5-49; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2584; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-50 Ventilation

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 50. All rooms shall have sufficient ventilation to keep them free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes. Ventilation systems shall be installed and operated in accordance with 675 IAC 18, and, when vented to the outside, shall not create an unsightly, harmful, or unlawful discharge. *(Indiana State Department of Health; 410 IAC 7-15.5-50; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2584; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-51 Poisonous or toxic materials

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-31

Sec. 51. (a) There shall be present in bed and breakfast establishments only those poisonous or toxic materials necessary for maintaining the establishment, cleaning and sanitizing equipment and utensils, and controlling insects and rodents.

(b) Containers of poisonous or toxic materials shall be prominently and distinctly labeled according to law for easy identification of contents.

(c) Poisonous or toxic materials consist of the following categories:

(1) Insecticides and rodenticides.

(2) Detergents, sanitizers, and related cleaning or drying agents, and caustics, acids, polishes, and other chemicals.

(d) Each of the preceding two (2) categories of poisonous or toxic materials shall be stored and physically located separate from each other. All poisonous or toxic materials shall be stored in cabinets or in a similar physically separate place used for no other purpose. To preclude contamination, poisonous or toxic materials shall not be stored above food, food equipment, utensils, or single-service articles, except that this requirement does not prohibit the convenient availability of detergents or sanitizers at utensil or dishwashing stations.

(e) Bactericides, cleaning compounds, or other compounds intended for use on food contact surfaces shall not be used in a way that leaves a toxic residue on such surfaces or that constitutes a hazard to employees or other persons.

(f) Poisonous or toxic materials shall not be used in a way that contaminates food, equipment, or utensils, nor in a way that constitutes a hazard to employees or other persons, nor in a way other than in full compliance with the manufacturer's labeling.

(g) Personal medications shall not be stored in food storage, preparation, or service areas.

(h) First aid supplies shall be stored in a way that prevents them from contaminating food and food contact surfaces. *(Indiana State Department of Health; 410 IAC 7-15.5-51; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2584; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-52 Premises

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-30; IC 16-41-31

Sec. 52. (a) Bed and breakfast establishments and all parts of property used in connection with their operations shall be kept clean and free of litter.

(b) Clean, laundered bed sheets and pillowcases shall be provided on each bed and shall be replaced by clean, freshly laundered sheets and pillowcases after the departure of each guest or lodger and prior to occupancy by the next guest.

(c) Clean clothes and linens shall be stored in a clean place and protected from contamination until used.

(d) Soiled clothes and linens shall be stored in nonabsorbent containers or washable laundry bags until removed for laundering.

(e) Maintenance and cleaning tools such as brooms, mops, vacuum cleaners, and similar equipment shall be maintained and stored in a way that does not contaminate food, utensils, equipment, or linens and shall be stored in an orderly manner for the cleaning of that storage location.

(f) Live animals, including birds and turtles, shall be excluded from within the food service, preparation, and food storage areas. This exclusion does not apply to edible fish, crustacea, shellfish, or to fish in aquariums. Patrol dogs accompanying security or police officers, or guide dogs accompanying blind persons, partially blind persons, physically disabled persons, guide dog trainers,

or persons with impaired hearing shall be permitted in dining areas. *(Indiana State Department of Health; 410 IAC 7-15.5-52; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2584; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-53 Occupancy register

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-29; IC 16-41-31

Sec. 53. (a) The operator of each bed and breakfast establishment shall keep a register, entry book, or card filing system containing the names and addresses, including the street number, town or city, and state, of every individual occupying the premises or any part thereof, and the dates and time when occupied.

(b) The register, entry book, or card filing system shall be kept open for inspection by the department, local board, or any law enforcement officer. It shall be maintained for every calendar year and may not be discarded or destroyed until the expiration of one (1) year after the calendar year for which it was maintained. *(Indiana State Department of Health; 410 IAC 7-15.5-53; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2585; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 7-15.5-54 Fresh bedding

Authority: IC 16-19-3-4; IC 16-41-31-5
Affected: IC 16-41-29; IC 16-41-31

Sec. 54. An owner, lessee, superintendent, or manager of a bed and breakfast establishment who furnishes beds and bedding for guests or lodgers shall provide each bed with the following:

(1) Undersheets sufficiently large to cover completely the mattress on each bed.

(2) Top sheets that are not less than ninety-nine (99) inches long and eighty-one (81) inches wide that may be folded over the blankets or other bed covering not less than two (2) feet.

(Indiana State Department of Health; 410 IAC 7-15.5-54; filed Jul 29, 1992, 10:00 a.m.: 15 IR 2585; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 16. Sanitation of Retail Food Markets (Repealed)

(Repealed by Indiana State Department of Health; filed Jun 4, 1985, 2:33 pm: 8 IR 1297)

Rule 16.1. Sanitation in Retail Food Stores

410 IAC 7-16.1-1 Definitions (Repealed)

Sec. 1. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-2 Food supplies (Repealed)

Sec. 2. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-3 Food protection (Repealed)

Sec. 3. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-4 Food storage (Repealed)

Sec. 4. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-5 Food preparation (Repealed)

Sec. 5. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-6 Food display (Repealed)

Sec. 6. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-7 Food transportation by retail food store (Repealed)

Sec. 7. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-8 Personnel (Repealed)

Sec. 8. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-9 Equipment and utensils; materials (Repealed)

Sec. 9. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-10 Equipment and utensils; design, fabrication (Repealed)

Sec. 10. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-11 Equipment and utensils; installation, location (Repealed)

Sec. 11. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-12 Equipment and utensils; cleaning, sanitizing (Repealed)

Sec. 12. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-13 Equipment and utensils; storage, handling (Repealed)

Sec. 13. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-14 Water supply (Repealed)

Sec. 14. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-15 Sewage disposal (Repealed)

Sec. 15. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-16 Plumbing (Repealed)

Sec. 16. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-17 Toilet facilities (Repealed)

Sec. 17. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-18 Handwashing facilities (Repealed)

Sec. 18. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-19 Garbage and refuse disposal (Repealed)

Sec. 19. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-20 Insect and rodent control (Repealed)

Sec. 20. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-21 Floors (Repealed)

Sec. 21. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-22 Walls; ceilings (Repealed)

Sec. 22. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-23 Cleaning physical facilities (Repealed)

Sec. 23. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-24 Lighting (Repealed)

Sec. 24. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-25 Ventilation (Repealed)

Sec. 25. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-26 Employee dressing rooms; locker areas (Repealed)

Sec. 26. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-27 Poisonous or toxic materials (Repealed)

Sec. 27. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-28 Premises (Repealed)

Sec. 28. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-29 Exemptions for existing facilities (Repealed)

Sec. 29. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-16.1-30 Fee schedule (Repealed)

Sec. 30. *(Repealed by Indiana State Department of Health; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2285)*

Rule 17. Sanitation of Vending of Foods and Beverages

410 IAC 7-17-1 Definitions (Repealed)

Sec. 1. *(Repealed by Indiana State Department of Health; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-17-2 Sanitation requirements (Expired)

Sec. 2. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

410 IAC 7-17-3 Communicable disease control (Expired)

Sec. 3. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 18. Adoption by Reference from Code of Federal Regulations, Title 21, Chapter 1; Definitions and Standards

410 IAC 7-18-1 Definitions and standards; adoption of federal regulations (Expired)

Sec. 1. *(Expired under IC 4-22-2.5, effective January 1, 2002.)*

Rule 19. Retail and Manufactured Food Production and Processing

410 IAC 7-19-1 Schedule of civil penalties

Authority: IC 16-19-3-4; IC 16-42-1-17
Affected: IC 4-21.5-3-8; IC 16-42

Sec. 1. (a) The Indiana state board of health may commence an action under IC 4-21.5-3-8 to levy civil penalties against a person who:

(1) fails to comply with IC 16-1-20 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, IC 16-1-28 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, IC 16-1-29 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, 410 IAC 7-15.1, 410 IAC 7-16.1, or 410 IAC 7-17; or

(2) interferes with or obstructs the Indiana state board of health or its designated agent in the performance of duties pursuant to IC 16-1-20 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, IC 16-1-28 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, IC 16-1-29 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, 410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*, 410 IAC 7-16.1, or 410 IAC 7-17.

(b) A civil penalty in an amount in the appropriate range specified in subsection (d) may be sought for each day of each violation.

(c) In determining the seriousness of the violation and the specific amount of the civil penalty to be sought for each violation, the Indiana state board of health will consider, but is not limited to, the following:

(1) The potential for harm or imminent threat to public health.
(2) The extent of deviation from statutory or regulatory requirements.
(3) Degree of willfulness or negligence.
(4) History of noncompliance.

The absence of direct harm will not result in assessment of a lower penalty for a violation.

(d) Unless adjusted by administrative procedure, all penalties shall be in accordance with the following schedule:

VIOLATION	CODE	RANGE OF PENALTY
Conditions of health and comfort	IC 16-1-20-8 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000

Cleanliness and sanitation of premises and vehicles	IC 16-1-20-9 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $500
Construction to facilitate cleaning	IC 16-1-20-10 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $100
Walls and ceilings; construction; washing	IC 16-1-20-11 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $100
Floors; construction; washing	IC 16-1-20-12 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $100
Animals; rodents; flies or other insects	IC 16-1-20-13 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Garbage removal	IC 16-1-20-14 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $500
Toilets	IC 16-1-20-15 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $500
Washrooms	IC 16-1-20-16 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $500
Food handling rooms	IC 16-1-20-17 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $500
Dressing rooms	IC 16-1-20-18 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $100
Spitting	IC 16-1-20-19 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $100
Sleeping in food handling rooms	IC 16-1-20-20 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $500
Diseases; employees	IC 16-1-20-21 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Wearing apparel; employees	IC 16-1-20-22 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $500
Washing hands and arms; employees	IC 16-1-20-23 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Sitting or lying on food handling equipment	IC 16-1-20-24 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $100
Prohibited acts; misdemeanor or felony	IC 16-1-28-4 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Advertisements, curative or therapeutic effect for certain diseases	IC 16-1-28-7 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Samples; investigation and examination	IC 16-1-28-10 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Access to and copying of records, evidence	IC 16-1-28-12 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Inspection of factories, etc., and vehicles	IC 16-1-28-13 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Solid waste hauling in food transports	IC 16-1-28-13.5 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000

Embargoes; adulterated or misbranded merchandise	IC 16-1-28-22 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Destruction; adulterated or misbranded products expense	IC 16-1-28-35 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Perishable articles unfit for human consumption; contamination or destruction	IC 16-1-28-36 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Adulteration; poisonous or deleterious substance	IC 16-1-29-2 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Adulteration; omitting or concealing quality of product	IC 16-1-29-3 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Adulteration; coal-tar color	IC 16-1-29-4 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Adulteration; confectionary	IC 16-1-29-5 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Adulteration; standards of purity or quality	IC 16-1-29-6 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Misbranding; imitation products containers	IC 16-1-29-7 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Misbranding; package, label requirements	IC 16-1-29-8 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Misbranding; insufficient prominence to required information	IC 16-1-29-9 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Misbranding; nonconformity to definition and standard of identity	IC 16-1-29-10 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Misbranding; nonconformity of standard of quality or fill of container	IC 16-1-29-11 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Misbranding common name or ingredients	IC 16-1-29-12 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Misbranding; special dietary information	IC 16-1-29-13 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Misbranding; artificial flavoring or coloring; chemical preservative	IC 16-1-29-14 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Registration of business	IC 16-1-29-15 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $500
Poisonous or deleterious substance; regulations	IC 16-1-29-17 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*	$0 to $1,000
Food supplies	410 IAC 7-15.1-2 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-2 *[410 IAC 7-16.1-2 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Food protection	410 IAC 7-15.1-3 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-3 *[410 IAC 7-16.1-3 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	

Food storage	410 IAC 7-15.1-4 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-4 *[410 IAC 7-16.1-4 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Food preparation	410 IAC 7-15.1-5 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-5 *[410 IAC 7-16.1-5 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Food display and service	410 IAC 7-15.1-6 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-6 *[410 IAC 7-16.1-6 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Food transportation	410 IAC 7-15.1-7 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-7 *[410 IAC 7-16.1-7 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Personnel	410 IAC 7-15.1-8 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-8 *[410 IAC 7-16.1-8 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Equipment and utensils-materials	410 IAC 7-15.1-9 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-9 *[410 IAC 7-16.1-9 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Equipment and utensils design and fabrication	410 IAC 7-15.1-10 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-10 *[410 IAC 7-16.1-10 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Equipment and utensils installation and location	410 IAC 7-15.1-11 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-11 *[410 IAC 7-16.1-11 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Equipment and utensils cleaning and sanitizing	410 IAC 7-15.1-12 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-12 *[410 IAC 7-16.1-12 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Equipment and utensils storage and handling	410 IAC 7-15.1-13 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-13 *[410 IAC 7-16.1-13 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Water supply	410 IAC 7-15.1-14 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-14 *[410 IAC 7-16.1-14 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	

Sewage disposal	410 IAC 7-15.1-15 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-15 *[410 IAC 7-16.1-15 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Plumbing	410 IAC 7-15.1-16 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-16 *[410 IAC 7-16.1-16 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Toilet facilities	410 IAC 7-15.1-17 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-17 *[410 IAC 7-16.1-17 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Handwashing facilities	410 IAC 7-15.1-18 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-18 *[410 IAC 7-16.1-18 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Garbage and refuse	410 IAC 7-15.1-19 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-19 *[410 IAC 7-16.1-19 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Insect and rodent control	410 IAC 7-15.1-20 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
	410 IAC 7-16.1-20 *[410 IAC 7-16.1-20 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Floors	410 IAC 7-15.1-21 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $100
	410 IAC 7-16.1-21 *[410 IAC 7-16.1-21 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Walls and ceilings	410 IAC 7-15.1-22 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $100
	410 IAC 7-16.1-22 *[410 IAC 7-16.1-22 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Cleaning physical facilities	410 IAC 7-15.1-23 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-23 *[410 IAC 7-16.1-23 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Lighting	410 IAC 7-15.1-24 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-24 *[410 IAC 7-16.1-24 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	
Ventilation	410 IAC 7-15.1-25 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
	410 IAC 7-16.1-25 *[410 IAC 7-16.1-25 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	

Dressing rooms and locker areas	410 IAC 7-15.1-26 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]* 410 IAC 7-16.1-26 *[410 IAC 7-16.1-26 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $100
Poisonous or toxic materials	410 IAC 7-15.1-27 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]* 410 IAC 7-16.1-27 *[410 IAC 7-16.1-27 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
Premises	410 IAC 7-15.1-28 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]* 410 IAC 7-16.1-28 *[410 IAC 7-16.1-28 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $500
Mobile food units or pushcarts	410 IAC 7-15.1-29 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
Mobile food service commissary	410 IAC 7-15.1-30 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
Mobile food service servicing and operations	410 IAC 7-15.1-31 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
Temporary food service establishments	410 IAC 7-15.1-32 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*	$0 to $1,000
Sanitation requirements; food containers; equipment maintenance and operation; water supply; waste disposal; delivery of food; cleanliness of employees	410 IAC 7-17-2	$0 to $1,000
Disease control; employees	410 IAC 7-17-3	$0 to $1,000

(e) After reinspection and determining the appropriate penalty based on the schedule in subsection (d), the Indiana state board of health may adjust the penalty to reflect a good faith effort to comply as follows:

(1) Each individual penalty will be multiplied by the number of days the particular violation has been documented by the Indiana state board of health. Penalties for violations documented in two (2) consecutive inspections by the Indiana state board of health shall be assessed on the basis that the violations have remained uncorrected over the period of time between the two (2) inspections. However, if the person found in violation has requested reinspection and has produced substantive evidence that the violation(s) have been corrected, the penalties shall be assessed for the period between initial discovery of violation and the receipt of request for reinspection.

(2) Penalties for all violations documented in an inspection or series of inspections at a firm will be totaled and sought under one (1) cause of action.

(f) After filing an action pursuant to IC 4-21.5, and in an attempt to resolve violations of said Indiana codes and rules and this rule without resort to a hearing, the Indiana state board of health may negotiate and enter into agreed orders. An agreed order may suspend all or part of the civil penalty calculated under the requirements and deadlines established in the agreed order. *(Indiana State Department of Health; 410 IAC 7-19-1; filed Jun 18, 1991, 10:10 a.m.: 14 IR 1955; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 20. Retail Food Establishment Sanitation

410 IAC 7-20-1 Applicability

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 7-20-1; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918)*

410 IAC 7-20-2 "Adulterated" defined

Authority: IC 16-42-5-5
Affected: IC 16-42

Sec. 2. "Adulterated" has the meaning set forth in IC 16-42-1 through IC 16-42-4. *(Indiana State Department of Health; 410 IAC 7-20-2; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918)*

410 IAC 7-20-3 "Approved" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 3. "Approved" means acceptable to the regulatory authority based on a determination of conformity with principles, practices, and generally recognized standards that protect public health. *(Indiana State Department of Health; 410 IAC 7-20-3; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918)*

410 IAC 7-20-4 "aw" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 4. "aw" means water activity that is:

(1) a measure of the free moisture in a food;

(2) the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature; and

(3) indicated by the symbol aw.

(Indiana State Department of Health; 410 IAC 7-20-4; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)

410 IAC 7-20-5 "Beverage" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 5. "Beverage" means a liquid for drinking, including water. *(Indiana State Department of Health; 410 IAC 7-20-5; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918)*

410 IAC 7-20-6 "Bottled drinking water" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 6. "Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water. *(Indiana State Department of Health; 410 IAC 7-20-6; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918)*

410 IAC 7-20-7 "Certification number" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 7. "Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program. *(Indiana State Department*

of Health; 410 IAC 7-20-7; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918)

410 IAC 7-20-8 "CFR" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 8. "CFR" means the Code of Federal Regulations. *(Indiana State Department of Health; 410 IAC 7-20-8; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918)*

410 IAC 7-20-9 "CIP" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 9. "CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine. The term does not include the cleaning of equipment, such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system. *(Indiana State Department of Health; 410 IAC 7-20-9; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1918)*

410 IAC 7-20-10 "Color additive" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 10. "Color additive" has the meaning set forth in the federal Food, Drug, and Cosmetic Act, Section 201(t) and 21 CFR 70. *(Indiana State Department of Health; 410 IAC 7-20-10; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)*

410 IAC 7-20-11 "Comminuted" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 11. "Comminuted" means reduced in size by methods, including chopping, flaking, grinding, or mincing. The term includes:

(1) fish or meat products that are reduced in size and restructured or reformulated, such as gefilte fish, gyros, ground beef, and sausage; and

(2) a mixture of two (2) or more types of meat that have been reduced in size and combined, such as sausages made from two (2) or more meats.

(Indiana State Department of Health; 410 IAC 7-20-11; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)

410 IAC 7-20-12 "Confirmed disease outbreak" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 12. "Confirmed disease outbreak" means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative agent and epidemiological analysis implicates the food as the source of the illness. *(Indiana State Department of Health; 410 IAC 7-20-12; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)*

410 IAC 7-20-13 "Consumer" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 13. "Consumer" means a person who is a member of the public who:

(1) takes possession of food;
(2) is not functioning in the capacity of an operator of a retail food establishment or food processing plant; and
(3) does not offer the food for resale.
(Indiana State Department of Health; 410 IAC 7-20-13; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)

410 IAC 7-20-14 "Corrosion-resistant material" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 14. "Corrosion-resistant material" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment. *(Indiana State Department of Health; 410 IAC 7-20-14; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)*

410 IAC 7-20-15 "Critical control point" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 15. "Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk. *(Indiana State Department of Health; 410 IAC 7-20-15; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)*

410 IAC 7-20-16 "Critical item" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 16. (a) "Critical item" means a provision of this rule that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard.
(b) "Critical item" is an item that is denoted in this rule with an asterisk. *(Indiana State Department of Health; 410 IAC 7-20-16; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)*

410 IAC 7-20-17 "Critical limit" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 17. "Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur. *(Indiana State Department of Health; 410 IAC 7-20-17; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)*

410 IAC 7-20-18 "Department" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 18. "Department" means the Indiana state department of health or its authorized representative. *(Indiana State Department of Health; 410 IAC 7-20-18; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919)*

410 IAC 7-20-19 "Drinking water" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 19. (a) "Drinking water" means water that meets the requirements of 327 IAC 8.
(b) The term is traditionally known as potable water.
(c) The term includes "water", except where the term used connotes that the water is not potable, such as boiler water,

mopwater, rainwater, wastewater, and nondrinking water. *(Indiana State Department of Health; 410 IAC 7-20-19; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1919; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-20 "Dry storage area" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 20. "Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous and dry goods such as single-service items. *(Indiana State Department of Health; 410 IAC 7-20-20; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1920)*

410 IAC 7-20-21 "Easily cleanable" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 21. (a) "Easily cleanable" means a characteristic of a surface that:

(1) allows effective removal of soil by normal cleaning methods;

(2) is dependent on the material, design, construction, and installation of the surface; and

(3) varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

(b) The term includes a tiered application of the criteria that qualify the surface as easily cleanable as specified under subsection (a) to different situations in which varying degrees of cleanability are required, such as:

(1) the appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or

(2) the need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

(Indiana State Department of Health; 410 IAC 7-20-21; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1920)

410 IAC 7-20-22 "Easily movable" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 22. "Easily movable" means the following:

(1) Portable;

(2) Mounted on casters, gliders, or rollers; or

(3) Provided with a mechanical means to safely tilt a unit of equipment for cleaning; and

(4) Having no utility connection;

(5) Having a utility connection that disconnects quickly; or

(6) Having a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

(Indiana State Department of Health; 410 IAC 7-20-22; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1920)

410 IAC 7-20-23 "Employee" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 23. "Employee" means:

(1) the person-in-charge;

(2) the person having supervisory or management duties;

(3) the person on the payroll;

(4) a family member;

(5) a volunteer;
(6) a person performing work under contractual agreement; or
(7) other person working in a retail food establishment.
(Indiana State Department of Health; 410 IAC 7-20-23; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1920)

410 IAC 7-20-24 "EPA" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 24. "EPA" means the United States Environmental Protection Agency. *(Indiana State Department of Health; 410 IAC 7-20-24; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1920)*

410 IAC 7-20-25 "Equipment" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 25. (a) "Equipment" means an article that is used in the operation of a retail food establishment, such as:
(1) a freezer;
(2) a grinder;
(3) a hood;
(4) an ice maker;
(5) a meat block;
(6) a mixer;
(7) an oven;
(8) a reach-in refrigerator;
(9) a scale;
(10) a sink;
(11) a slicer;
(12) a stove;
(13) a table;
(14) a temperature measuring device for ambient air;
(15) a vending machine; or
(16) a warewashing machine.
(b) The term does not include items used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as:
(1) hand trucks;
(2) forklifts;
(3) dollies;
(4) pallets;
(5) racks; and
(6) skids.
(Indiana State Department of Health; 410 IAC 7-20-25; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1920)

410 IAC 7-20-26 "Fish" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 26. (a) "Fish" means fresh or saltwater finfish, crustaceans, all mollusks, and all other forms of aquatic life, such as:
(1) alligator;
(2) frog;
(3) aquatic turtle;

(4) jellyfish;
(5) sea cucumber;
(6) sea urchin; and
(7) the roe of such animals;
other than birds or mammals, if such animal life is intended for human consumption.

(b) The term includes an edible human food product derived in whole or in part from fish, including fish that have been processed in any manner. *(Indiana State Department of Health; 410 IAC 7-20-26; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1921)*

410 IAC 7-20-27 "Food" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 27. "Food" means the following:
(1) All articles used for food, drink, confectionery, or condiment whether simple, mixed, or compound.
(2) All substances or ingredients used in the preparation of the items described in subdivision (1).
(Indiana State Department of Health; 410 IAC 7-20-27; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1921)

410 IAC 7-20-28 "Food additive" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 28. "Food additive" has the meaning stated in the federal Food, Drug, and Cosmetic Act, Section 201(s) and 21 CFR 170. *(Indiana State Department of Health; 410 IAC 7-20-28; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1921)*

410 IAC 7-20-29 "Food-contact surface" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 29. "Food-contact surface" means a surface of equipment or a utensil:
(1) with which food normally comes into contact; or
(2) from which food may drain, drip, or splash into a food, or onto a surface normally in contact with food.
(Indiana State Department of Health; 410 IAC 7-20-29; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1921)

410 IAC 7-20-30 "Food employee" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 30. "Food employee" means an individual working with food, food equipment or utensils, or food-contact surfaces. *(Indiana State Department of Health; 410 IAC 7-20-30; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1921)*

410 IAC 7-20-31 "Food processing plant" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 31. (a) "Food processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption and does not provide food directly to a consumer.

(b) The term does not include a retail food establishment as defined under section 70 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-31; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1921)*

410 IAC 7-20-32 "Foodborne disease outbreak" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 32. (a) "Foodborne disease outbreak" means an incident, except as specified under subsection (b) of this section, in which:

(1) there is an occurrence of two (2) or more cases of a similar illness resulting from the ingestion of a common food; and

(2) epidemiological analysis implicates the food as the source of the illness.

(b) The term includes a single case of illness from botulism or chemical poisoning. *(Indiana State Department of Health; 410 IAC 7-20-32; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1921; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-33 "Game animal" defined

Authority: IC 16-42-5-5
Affected: IC 15-2.1-24; IC 16-42-5

Sec. 33. "Game animal" means an animal, the products of which are food, that is not:

(1) regulated under IC 15-2.1-24;

(2) fish as defined under section 26 of this rule; and

(3) possessed or raised in violation of state or federal law.

(Indiana State Department of Health; 410 IAC 7-20-33; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1921)

410 IAC 7-20-34 "General use pesticide" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 34. "General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175. *(Indiana State Department of Health; 410 IAC 7-20-34; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)*

410 IAC 7-20-35 "Grade A standards" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 35. "Grade A standards" means the requirements of the United States Public Health Service/FDA Grade A Pasteurized Milk Ordinance and Grade A Condensed and Dry Milk Ordinance with which certain fluid and dry milk and milk products comply. *(Indiana State Department of Health; 410 IAC 7-20-35; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)*

410 IAC 7-20-36 "Group residence" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 36. (a) "Group residence" means a private or public housing corporation or institutional facility that provides living quarters and meals.

(b) The term includes a domicile for unrelated persons, such as a retirement home or long term health care facility. *(Indiana State Department of Health; 410 IAC 7-20-36; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)*

410 IAC 7-20-37 "HACCP plan" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 37. "HACCP plan" means a written document that delineates the formal procedures for following the Hazard Analysis/Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods.

(Indiana State Department of Health; 410 IAC 7-20-37; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)

410 IAC 7-20-38 "Hazard" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 38. "Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk. *(Indiana State Department of Health; 410 IAC 7-20-38; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)*

410 IAC 7-20-39 "Hermetically sealed container" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 39. "Hermetically sealed container" means a container that is designed and intended to be secure against the entry of micro-organisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing. *(Indiana State Department of Health; 410 IAC 7-20-39; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)*

410 IAC 7-20-40 "Highly susceptible population" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 40. "Highly susceptible population" means a group of persons who are more likely than other populations to experience foodborne disease because they are:

(1) immunocompromised or adults who are sixty-five (65) years of age or older and in a hospital; or

(2) preschool age children in a facility that provides custodial care, such as a child care center.

(Indiana State Department of Health; 410 IAC 7-20-40; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)

410 IAC 7-20-41 "Imminent health hazard" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 41. "Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury or illness based on:

(1) the number of potential injuries or illnesses; and

(2) the nature, severity, and duration of the anticipated injury or illness.

(Indiana State Department of Health; 410 IAC 7-20-41; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)

410 IAC 7-20-42 "Injected" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 42. "Injected" means manipulating a meat so that infectious or toxigenic micro-organisms may be introduced from its surface to its interior through tenderizing with deep penetration or injecting the meat, such as by processes that may be referred to as injecting, pinning, or stitch pumping. *(Indiana State Department of Health; 410 IAC 7-20-42; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)*

410 IAC 7-20-43 "Juice" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 43. "Juice" means the aqueous liquid expressed or extracted from:
(1) one (1) or more fruits or vegetables;
(2) purees of the edible portions of one (1) or more fruits or vegetables; or
(3) any concentrate of such liquid or puree.
The term does not apply to standards of identity. *(Indiana State Department of Health; 410 IAC 7-20-43; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1922)*

410 IAC 7-20-44 "Kitchenware" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 44. "Kitchenware" means food preparation and storage utensils. *(Indiana State Department of Health; 410 IAC 7-20-44; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)*

410 IAC 7-20-45 "Law" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 45. "Law" means applicable state and federal statutes, regulations, and local ordinances. *(Indiana State Department of Health; 410 IAC 7-20-45; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)*

410 IAC 7-20-46 "Linens" defined
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 46. "Linens" means fabric items, such as:
(1) cloth hampers;
(2) cloth napkins;
(3) table cloths;
(4) wiping cloths; and
(5) work garments, including cloth gloves.
(Indiana State Department of Health; 410 IAC 7-20-46; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)

410 IAC 7-20-47 "Meat" defined
Authority: IC 16-42-5-5
Affected: IC 15-2.1-24; IC 16-42-5

Sec. 47. (a) "Meat" means the food products of animals, such as:
(1) pork;
(2) beef;
(3) lamb; and
(4) ratite;
included under IC 15-2.1-24.
(b) The term does not include fish, poultry, and game animals. *(Indiana State Department of Health; 410 IAC 7-20-47; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)*

410 IAC 7-20-48 "Misbranded" defined
Authority: IC 16-42-5-5
Affected: IC 16-42

Sec. 48. "Misbranded" has the meaning stated in IC 16-42-1 through IC 16-42-4 and 410 IAC 7-5. *(Indiana State Department*

of Health; 410 IAC 7-20-48; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)

410 IAC 7-20-49 "Molluscan shellfish" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 49. "Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle. *(Indiana State Department of Health; 410 IAC 7-20-49; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)*

410 IAC 7-20-50 "Packaged" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 50. (a) "Packaged" means:
(1) bottled;
(2) canned;
(3) cartoned;
(4) securely bagged; or
(5) securely wrapped;
whether packaged in a retail food establishment or a food processing plant.

(b) The term does not include a wrapper, carry-out box, or other nondurable container used to containerize food with the purpose of facilitating food protection during service and receipt of the food by the consumer. *(Indiana State Department of Health; 410 IAC 7-20-50; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)*

410 IAC 7-20-51 "Person" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 51. "Person" means:
(1) an association;
(2) a corporation;
(3) an individual;
(4) partnership; or
(5) other legal entity, government, or governmental subdivision or agency.
(Indiana State Department of Health; 410 IAC 7-20-51; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)

410 IAC 7-20-52 "Person-in-charge" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 52. "Person-in-charge" means the individual present at a retail food establishment who is responsible for the operation at the time of inspection. *(Indiana State Department of Health; 410 IAC 7-20-52; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)*

410 IAC 7-20-53 "Personal care items" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 53. (a) "Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance.

(b) The term includes items, such as:

(1) medicines;
(2) first aid supplies;
(3) cosmetics; and
(4) toiletries.

(Indiana State Department of Health; 410 IAC 7-20-53; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1923)

410 IAC 7-20-54 "pH" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 54. "pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between zero (0) and seven (7) indicate acidity, and values between seven (7) and fourteen (14) indicate alkalinity. The value for pure distilled water is seven (7), which is considered neutral. *(Indiana State Department of Health; 410 IAC 7-20-54; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1924)*

410 IAC 7-20-55 "Physical facilities" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 55. "Physical facilities" means the structure and interior surfaces of a retail food establishment, including floors, walls, ceilings, and accessories, such as:
(1) soap and towel dispensers; and
(2) attachments, such as light fixtures and heating or air conditioning system vents.

(Indiana State Department of Health; 410 IAC 7-20-55; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1924)

410 IAC 7-20-56 "Plumbing fixture" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 56. "Plumbing fixture" means a receptacle or device that:
(1) is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system; or
(2) discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

(Indiana State Department of Health; 410 IAC 7-20-56; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1924)

410 IAC 7-20-57 "Plumbing system" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 57. "Plumbing system" means:
(1) the water supply and distribution pipes;
(2) plumbing fixtures and traps;
(3) soil, waste, and vent pipes;
(4) sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and
(5) water-treating equipment.

(Indiana State Department of Health; 410 IAC 7-20-57; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1924)

410 IAC 7-20-58 "Poisonous or toxic materials" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 58. "Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four (4) categories, as follows:

(1) Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals.

(2) Pesticides except sanitizers, which include substances such as insecticides and rodenticides.

(3) Substances necessary for the operation and maintenance of the establishment, such as nonfood grade lubricants and personal care items that may be deleterious to health; and

(4) Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

(Indiana State Department of Health; 410 IAC 7-20-58; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1924)

410 IAC 7-20-59 "Potentially hazardous food" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 59. (a) "Potentially hazardous food" means a food that is natural or synthetic and requires temperature control because it is in a form capable of supporting the following:

(1) the rapid and progressive growth of infectious or toxigenic micro-organisms;

(2) the growth and toxin production of Clostridium botulinum; or

(3) in raw shell eggs, the growth of Salmonella enteritidis.

(b) The term includes:

(1) a food of animal origin that is raw or heat-treated;

(2) a food of plant origin that is heat-treated or consists of raw seed sprouts;

(3) cut melons; and

(4) garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under subsection (a).

(c) The term does not include any of the following:

(1) An air-cooled hard-boiled egg with shell intact.

(2) A food with an aw value of eighty-five hundredths (0.85) or less.

(3) A food with a pH level of four and six-tenths (4.6) or below when measured at seventy-five degrees (75oF) Fahrenheit.

(4) A food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution.

(5) A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic micro-organisms or the growth of S. enteritidis in eggs or C. botulinum cannot occur, such as a food that:

(A) has an aw and a pH that are above the levels specified under subdivisions (2) and (3); and

(B) may contain a preservative, other barrier to the growth of micro-organisms, or a combination of barriers that inhibit the growth of micro-organisms.

(6) A food that may contain an infectious or toxigenic micro-organism or chemical or physical contaminant at a level sufficient to cause illness, but that does not support the growth of micro-organisms as specified under subsection (a).

(Indiana State Department of Health; 410 IAC 7-20-59; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1924)

410 IAC 7-20-60 "Poultry" defined

Authority: IC 16-42-5-5
Affected: IC 15-2.1-24; IC 16-42-5

Sec. 60. "Poultry" means:

(1) a domesticated bird included under IC 15-2.1-24 and is not meat; or

(2) a game animal.

(Indiana State Department of Health; 410 IAC 7-20-60; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1925)

410 IAC 7-20-61 "Ppm" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 61. "Ppm" means parts per million, which is equivalent to milligrams per liter. *(Indiana State Department of Health; 410 IAC 7-20-61; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1925)*

410 IAC 7-20-62 "Premises" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 62. "Premises" means:

(1) the physical facility, its contents, and the contiguous land or property under the control of the retail food establishment; or

(2) the physical facility, its contents, and the land or property not described under subdivision (1) if its facilities and contents are under the control of the retail food establishment and may impact personnel, facilities, or operations, if a retail food establishment is only one (1) component of a larger operation, such as a health care facility, hotel, motel, school, recreational camp, or prison.

(Indiana State Department of Health; 410 IAC 7-20-62; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1925; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)

410 IAC 7-20-63 "Primal cut" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 63. "Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as:

(1) a beef round;
(2) a pork loin;
(3) a lamb flank; or
(4) a veal breast.

(Indiana State Department of Health; 410 IAC 7-20-63; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1925)

410 IAC 7-20-64 "Public water system" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 64. "Public water system" has the meaning set forth in 327 IAC 8. *(Indiana State Department of Health; 410 IAC 7-20-64; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1925)*

410 IAC 7-20-65 "Ready-to-eat food" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 65. "Ready-to-eat food" means food that is in a form that is edible without washing, cooking, or additional preparation by the retail food establishment or the consumer and that is reasonably expected to be consumed in that form. The term includes the following:

(1) Potentially hazardous food that is unpackaged and cooked to the temperature and time required for the specific food under sections 161 through 163 of this rule.

(2) Raw, washed cut fruits and vegetables.

(3) Whole, raw fruits and vegetables that are presented for consumption without the need for further washing, such as at a buffet.

(4) Other food presented for consumption for which further washing or cooking is not required and from which rinds, peels, husks, or shells are removed.

(Indiana State Department of Health; 410 IAC 7-20-65; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1925)

410 IAC 7-20-66 "Reduced oxygen packaging" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 66. (a) "Reduced oxygen packaging" means the following:

(1) The reduction of the amount of oxygen in a package by:

(A) removing oxygen;

(B) displacing oxygen and replacing it with another gas or combination of gases; or

(C) otherwise controlling the oxygen content to a level below that normally found in the surrounding twenty-one percent (21%) oxygen atmosphere.

(2) A process as specified in subdivision (1) that involves a food for which Clostridium botulinum is identified as a microbiological hazard in the final packaged form.

(b) The term includes the following:

(1) Vacuum packaging in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package, such as sous vide.

(2) Modified atmosphere packaging in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes any of the following:

(A) Reduction in the proportion of oxygen.

(B) Total replacement of oxygen.

(C) An increase in the proportion of other gases, such as carbon dioxide or nitrogen.

(3) Controlled atmosphere packaging in which the atmosphere of a package of food is modified so that until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained, such as by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(Indiana State Department of Health; 410 IAC 7-20-66; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1925)

410 IAC 7-20-67 "Refuse" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 67. "Refuse" means solid waste not carried by water through the sewage system. *(Indiana State Department of Health; 410 IAC 7-20-67; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1926)*

410 IAC 7-20-68 "Regulatory authority" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 68. "Regulatory authority" means the local, state, or federal enforcement body or authorized representative having jurisdiction over a retail food establishment. *(Indiana State Department of Health; 410 IAC 7-20-68; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1926)*

410 IAC 7-20-69 "Restricted use pesticide" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 69. "Restricted use pesticide" has the same meaning as when defined in law and rules of the office of the Indiana state chemist. *(Indiana State Department of Health; 410 IAC 7-20-69; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1926)*

410 IAC 7-20-70 "Retail food establishment" defined

Authority: IC 16-42-5-5
Affected: IC 12-13-5; IC 16-41-31; IC 16-42-5-4

Sec. 70. (a) "Retail food establishment" means an operation that:

(1) stores, prepares, packages, serves, vends, or otherwise provides food for human consumption, such as:

(A) a restaurant;
(B) satellite or catered feeding location;
(C) a catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people;
(D) a market;
(E) a grocery store;
(F) a convenience store;
(G) a vending location;
(H) a conveyance used to transport people;
(I) an institution; or
(J) a food bank; and

(2) that relinquishes possession of food to a consumer directly or indirectly through a delivery service, such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

(b) The term includes the following:

(1) An element of the operation, such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority.
(2) An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location, where consumption is on or off the premises, and regardless of whether there is a charge for the food.

(c) The term does not include the following:

(1) An establishment that offers only prepackaged foods that are not potentially hazardous.
(2) A produce stand that only offers whole, uncut fresh fruits and vegetables.
(3) A food processing plant operated under IC 16-42-5.
(4) A private home where food is prepared by a member of an organization that is operating under IC 16-42-5-4.
(5) An area where food that is prepared as specified in subdivision (4) is sold or offered for human consumption.
(6) A bed and breakfast establishment as defined and regulated under IC 16-41-31 and 410 IAC 7-15.5.
(7) A private home that receives catered or home-delivered food.
(8) A private home which provides childcare and is not subject to IC 12-13-5.
(9) A private home.

(Indiana State Department of Health; 410 IAC 7-20-70; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1926)

410 IAC 7-20-71 "Safe material" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 71. "Safe material" means:

(1) an article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food;
(2) an additive that is used as specified in Section 409 or 706 of the federal Food, Drug, and Cosmetic Act; or
(3) other materials that are not food or color additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

(Indiana State Department of Health; 410 IAC 7-20-71; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)

410 IAC 7-20-72 "Sanitization" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 72. "Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five (5) logs, which is equal to a ninety-nine and nine hundred ninety-nine thousandths percent (99.999%) reduction, of representative disease micro-organisms of public health importance. *(Indiana State Department of Health; 410 IAC 7-20-72; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)*

410 IAC 7-20-73 "Sealed" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 73. "Sealed" means free of cracks or other openings that allow the entry or passage of moisture. *(Indiana State Department of Health; 410 IAC 7-20-73; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)*

410 IAC 7-20-74 "Service animal" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 74. "Service animal" means a professionally trained animal, such as a guide dog, signal dog, or other animal that provides assistance to an individual with a disability. *(Indiana State Department of Health; 410 IAC 7-20-74; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)*

410 IAC 7-20-75 "Servicing area" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 75. "Servicing area" means an operating base location to which a mobile retail food establishment or transportation vehicle returns at least once each day for such functions as:

(1) vehicle and equipment cleaning;
(2) discharging liquid or solid wastes;
(3) refilling water tanks and ice bins; and
(4) boarding food.

(Indiana State Department of Health; 410 IAC 7-20-75; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)

410 IAC 7-20-76 "Sewage" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 76. "Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution. *(Indiana State Department of Health; 410 IAC 7-20-76; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)*

410 IAC 7-20-77 "Shellfish control authority" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 77. "Shellfish control authority" means a state, federal, foreign, tribal, or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce. *(Indiana State Department of Health; 410 IAC 7-20-77; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)*

410 IAC 7-20-78 "Shellstock" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 78. "Shellstock" means raw, in-shell molluscan shellfish. *(Indiana State Department of Health; 410 IAC 7-20-78; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)*

410 IAC 7-20-79 "Shucked shellfish" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 79. "Shucked shellfish" means molluscan shellfish that have one (1) or both shells removed. *(Indiana State Department of Health; 410 IAC 7-20-79; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)*

410 IAC 7-20-80 "Single-service articles" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 80. "Single-service articles" means tableware, carry-out utensils, and other items, such as:
(1) bags;
(2) containers;
(3) placemats;
(4) stirrers;
(5) straws;
(6) toothpicks; and
(7) wrappers;
that are designed and constructed for one (1) time, one (1) person use after which they are intended for discard. *(Indiana State Department of Health; 410 IAC 7-20-80; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1927)*

410 IAC 7-20-81 "Single-use articles" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 81. (a) "Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded.
(b) The term includes items, such as:
(1) wax paper;
(2) butcher paper;
(3) plastic wrap;
(4) formed aluminum food containers;
(5) jars;
(6) plastic tubs or buckets;
(7) bread wrappers;
(8) pickle barrels;
(9) ketchup bottles; and
(10) number ten (10) cans;
that do not meet the materials, durability, strength, and cleanability specifications under sections 184, 196, and 198 of this rule for multi-use utensils. *(Indiana State Department of Health; 410 IAC 7-20-81; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1928)*

410 IAC 7-20-82 "Slacking" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 82. "Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of minus ten (10) degrees Fahrenheit to twenty-five (25) degrees Fahrenheit in preparation for deep-fat frying

or to facilitate even heat penetration during the cooking of previously block-frozen food, such as kale. *(Indiana State Department of Health; 410 IAC 7-20-82; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1928)*

410 IAC 7-20-83 "Smooth" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 83. "Smooth" means the following:

(1) A food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of one hundred (100) grit number three (3) stainless steel.

(2) A nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale.

(3) A floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

(Indiana State Department of Health; 410 IAC 7-20-83; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1928)

410 IAC 7-20-84 "Table-mounted equipment" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 84. "Table-mounted equipment" means equipment that is not portable and is designed to be mounted off the floor on a table, counter, or shelf. *(Indiana State Department of Health; 410 IAC 7-20-84; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1928)*

410 IAC 7-20-85 "Tableware" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 85. "Tableware" means:

(1) eating, drinking, and serving utensils for table use, such as flatware, including:
  (A) forks;
  (B) knives; and
  (C) spoons;

(2) hollowware, including:
  (A) bowls;
  (B) cups;
  (C) serving dishes; and
  (D) tumblers; and

(3) plates.

(Indiana State Department of Health; 410 IAC 7-20-85; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1928)

410 IAC 7-20-86 "Temperature measuring device" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 86. "Temperature measuring device" means:

(1) a thermometer;

(2) a thermocouple;

(3) a thermistor; or

(4) other device that indicates the temperature of food, air, or water.

(Indiana State Department of Health; 410 IAC 7-20-86; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1928)

410 IAC 7-20-87 "Temporary food establishment" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 87. "Temporary food establishment" means a retail food establishment that operates for a period of no more than fourteen (14) consecutive days in conjunction with a single event or celebration. *(Indiana State Department of Health; 410 IAC 7-20-87; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1928)*

410 IAC 7-20-88 "USDA" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 88. "USDA" means the United States Department of Agriculture. *(Indiana State Department of Health; 410 IAC 7-20-88; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1929)*

410 IAC 7-20-89 "Utensil" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 89. "Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as:

(1) kitchenware or tableware that is multi-use, single-service, or single-use;
(2) gloves used in contact with food;
(3) food temperature measuring devices; and
(4) probe-type price or identification tags used in contact with food.

(Indiana State Department of Health; 410 IAC 7-20-89; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1929)

410 IAC 7-20-90 "Vending machine" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 90. "Vending machine" means a self-service device that, upon activation, such as through the insertion of a coin, paper currency, token, card, key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation. *(Indiana State Department of Health; 410 IAC 7-20-90; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1929)*

410 IAC 7-20-91 "Vending machine location" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 91. "Vending machine location" means the room, enclosure, space, or area where one (1) or more vending machines are installed and operated and includes the storage areas and areas on the premises that are used to service and maintain the vending machines. *(Indiana State Department of Health; 410 IAC 7-20-91; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1929)*

410 IAC 7-20-92 "Warewashing" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 92. "Warewashing" means the cleaning and sanitizing of food-contact surfaces of equipment and utensils. *(Indiana State Department of Health; 410 IAC 7-20-92; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1929)*

410 IAC 7-20-93 "Whole-muscle, intact beef" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 93. "Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut. *(Indiana State Department of Health; 410 IAC 7-20-93; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1929)*

410 IAC 7-20-94 Assignment of supervision responsibility

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 94. The retail food establishment shall have a person-in-charge present at the retail food establishment during all hours of operation. *(Indiana State Department of Health; 410 IAC 7-20-94; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1929)*

410 IAC 7-20-95 Foodborne illness prevention training

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 95. (a) Each retail food establishment shall provide foodborne illness prevention training to at least one (1) employee who has a primary oversight responsibility for food safety at the establishment.

(b) The foodborne illness prevention training shall include at least the following areas of knowledge as those are applicable to the operations conducted at the establishment:

(1) The relationship between the prevention of foodborne disease and the personal hygiene of a food employee.

(2) Responsibility of the person-in-charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease.

(3) Symptoms associated with the diseases that are transmissible through food.

(4) The significance of the relationship between maintaining the time and temperature of potentially hazardous food and the prevention of foodborne illness.

(5) Hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish.

(6) Required food temperatures and times for safe cooking of potentially hazardous food, including meat, poultry, eggs, and fish.

(7) Required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food.

(8) The relationship between the prevention of foodborne illness and the management and control of the following:

(A) Cross contamination.

(B) Hand contact with ready-to-eat foods.

(C) Handwashing.

(D) Maintaining the retail food establishment in a clean condition and in good repair.

(9) The relationship between food safety and providing equipment that is:

(A) sufficient in number and capacity; and

(B) properly designed, constructed, located, installed, operated, maintained, and cleaned.

(10) The correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment.

(11) Water source identification and measures taken to ensure that it remains protected from contamination, such as providing protection from backflow and precluding the creation of cross connections.

(12) Poisonous or toxic materials identification in the retail food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law.

(13) Critical control points in the operation from purchasing through sale or service that when not controlled may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this rule.

(14) Details of how the person-in-charge and food employees comply with the HACCP plan if a plan is required by law, this

rule, or an agreement between the regulatory authority and the establishment.

(15) Responsibilities, rights, and authorities assigned by this rule to the following:

(A) Food employee.

(B) Person-in-charge.

(C) Regulatory authority.

(c) From one (1) year beyond the effective date of this rule, the retail food establishment shall maintain at least one (1) copy of this rule on the premises at all times. Immediate electronic access to this rule shall be considered acceptable in meeting this requirement. *(Indiana State Department of Health; 410 IAC 7-20-95; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1929)*

410 IAC 7-20-96 Duties of the person-in-charge

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 96. When applicable, the person-in-charge of the retail food establishment shall ensure the following:

(1) Retail food establishment operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under section 382 of this rule.

(2) Persons unnecessary to the retail food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person-in-charge if steps are taken to ensure that:

(A) exposed food;

(B) clean equipment, utensils, and linens; and

(C) unwrapped single-service and single-use articles;

are protected from contamination.

(3) Employees and other persons, such as delivery and maintenance persons and pesticide applicators, entering the food preparation, food storage, and warewashing areas comply with this rule.

(4) Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing.

(5) Employees are visibly observing foods as they are received to determine that they are:

(A) from approved sources;

(B) delivered at the required temperatures;

(C) protected from contamination;

(D) unadulterated; and

(E) accurately presented;

by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt.

(6) Employees are properly cooking potentially hazardous food, being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under sections 206 and 260 of this rule.

(7) Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within four (4) hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling.

(8) Consumers who order raw or partially cooked ready-to-eat foods of animal origin are informed as specified under section 181 of this rule that the food is not cooked sufficiently to ensure its safety.

(9) Employees are properly sanitizing cleaned multi-use equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing.

(10) Consumers are notified that clean tableware is to be used when they return to self-service areas, such as salad bars and buffets as specified under section 150 of this rule.

(11) Employees are preventing cross-contamination of ready-to-eat food from unwashed hands and are properly using suitable utensils, such as:

(A) deli tissue;

(B) spatulas;

(C) tongs;
(D) single-use gloves; or
(E) dispensing equipment;
when such items can be used.
(12) Employees are properly trained in food safety as it relates to their assigned duties.
(Indiana State Department of Health; 410 IAC 7-20-96; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1930)

410 IAC 7-20-97 Responsibility to require reporting by food employees and applicants
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 97. The retail food establishment shall require food employee applicants to whom a conditional offer of employment is made and food employees to report to the person-in-charge, information about their health and activities as they relate to diseases that are transmissible through food. A food employee or applicant shall report the information in a manner that allows the person-in-charge to prevent the likelihood of foodborne disease transmission, including the date of onset of jaundice or of an illness specified under subdivision (3), if the food employee or applicant:
(1) is diagnosed with an illness due to:
(A) Salmonella typhi;
(B) Salmonella spp.;
(C) Shigella spp.;
(D) Escherichia coli O157:H7; or
(E) hepatitis A virus;
(2) has a symptom caused by illness, infection, or other source that is:
(A) associated with an acute gastrointestinal illness, such as:
(i) diarrhea;
(ii) fever;
(iii) vomiting;
(iv) jaundice; or
(v) sore throat with fever;
(B) a lesion containing pus, such as a boil or infected wound that is open or draining and is:
(i) on the hands or wrists unless an impermeable cover, such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;
(ii) on exposed portions of the arms unless the lesion is protected by an impermeable cover; or
(iii) on other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;
(3) had a past illness from an infectious agent specified under subdivision (1); or
(4) meets one (1) or more of the following high-risk conditions, such as:
(A) is suspected of causing, or being exposed to, a confirmed disease outbreak caused by S. typhi, Salmonella spp., Shigella spp., E. coli O157:H7, or hepatitis A virus because the food employee or applicant:
(i) prepared food implicated in the outbreak;
(ii) consumed food implicated in the outbreak; or
(iii) consumed food at the event prepared by a person who is infected or ill with the infectious agent that caused the outbreak or who is suspected of being a shedder of the infectious agent; or
(B) lives in the same household as a person who is diagnosed with a disease caused by S. typhi, Salmonella spp., Shigella spp., E. coli O157:H7, or hepatitis A virus.
(Indiana State Department of Health; 410 IAC 7-20-97; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1931)

410 IAC 7-20-98 Exclusions and restrictions
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 98. The person-in-charge shall do the following:

(1) Exclude a food employee from a retail food establishment if the food employee is diagnosed with an infectious agent specified under section 97(1) of this rule.

(2) Except as specified under subdivisions (3) or (4), restrict a food employee from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles; in a retail food establishment if the food employee is:

(A) suffering from a symptom specified under section 97(2) of this rule; or

(B) not experiencing a symptom of acute gastroenteritis specified under section 97(2)(A) of this rule but has a stool that yields a specimen culture that is positive for S. typhi, Salmonella spp., Shigella spp., or E. coli O157:H7.

(3) If the population served is a highly susceptible population, exclude a food employee who:

(A) is experiencing a symptom of acute gastrointestinal illness specified under section 97(2)(A) of this rule and meets a high-risk condition specified under section 97(4) of this rule;

(B) is not experiencing a symptom of acute gastroenteritis specified under section 97(2)(A) of this rule but has a stool that yields a specimen culture that is positive for S. typhi, Salmonella spp., Shigella spp., or E. coli O157:H7;

(C) had a past illness from S. typhi without three (3) successive negative stool cultures; or

(D) had a past illness from Salmonella spp., Shigella spp., or E. coli O157:H7 without two (2) successive negative stool cultures.

(4) For a food employee who is jaundiced, if the onset of jaundice occurred within the last seven (7) calendar days, exclude the food employee from the food establishment.

(Indiana State Department of Health; 410 IAC 7-20-98; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1931)

410 IAC 7-20-99 Removal of exclusions and restrictions

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 99. (a) The person-in-charge may remove an exclusion specified under section 98(1) of this rule if:

(1) the person-in-charge obtains approval from the regulatory authority; and

(2) the person excluded as specified under section 98(1) of this rule provides to the person-in-charge written medical documentation from a physician licensed to practice medicine, a nurse practitioner, or a physician assistant that specifies that the excluded person may work in an unrestricted capacity in a retail food establishment, including an establishment that serves a highly susceptible population, because the person is free of the infectious agent of concern as specified in section 104 of this rule.

(b) The person-in-charge may remove a restriction specified under:

(1) section 98(2)(A) of this rule if the restricted person:

(A) is free of the symptoms specified under section 98(2) of this rule and no foodborne illness occurs that may have been caused by the restricted person;

(B) is suspected of causing foodborne illness but:

(i) is free of the symptoms specified under section 98(2) of this rule; and

(ii) provides written medical documentation from a physician licensed to practice medicine, a nurse practitioner, or a physician assistant stating that the restricted person is free of the infectious agent that is suspected of causing the person's symptoms or causing foodborne illness as specified in section 104 of this rule; or

(C) provides written medical documentation from a physician licensed to practice medicine, a nurse practitioner, or physician assistant stating that the symptoms experienced result from a chronic noninfectious condition, such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis; or

(2) section 98(2)(B) of this rule if the restricted person provides written medical documentation from a physician licensed to practice medicine, a nurse practitioner, or physician assistant according to the criteria specified in section 104 of this rule that indicates the stools are free of Salmonella typhi, Salmonella spp., Shigella spp., or E. coli O157:H7, whichever is the infectious agent of concern.

(c) The person-in-charge may remove an exclusion specified under section 98(3) of this rule if the excluded person provides written medical documentation from a physician licensed to practice medicine, a nurse practitioner, or physician assistant:

(1) who specifies that the person is free of:

(A) the infectious agent of concern as specified in section 104 of this rule; or

(B) jaundice as specified under subsection (d) of this rule if hepatitis A virus is the infectious agent of concern; or

(2) if the person is excluded under section 98(3)(A) of this rule, stating that the symptoms experienced result from a chronic noninfectious condition, such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis.

(d) The person-in-charge may remove an exclusion specified under section 98(4)(A) of this rule if:

(1) at least seven (7) days have passed since the onset of jaundice; or

(2) at least fourteen (14) days have passed since the onset of symptoms if no jaundice occurred.

(Indiana State Department of Health; 410 IAC 7-20-99; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1931)

410 IAC 7-20-100 Responsibility of a food employee or an applicant to report to the person-in-charge

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 100. A food employee or a person who applies for a job as a food employee shall do the following:

(1) In a manner specified under section 97 of this rule, report to the person-in-charge the information specified under section 97 of this rule.

(2) Comply with exclusions and restrictions that are specified under section 98 of this rule.

(Indiana State Department of Health; 410 IAC 7-20-100; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1932)

410 IAC 7-20-101 Obtaining information: personal history of illness, medical examination, and specimen analysis

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 101. (a) The regulatory authority shall act when it has reasonable cause to believe that a food employee:

(1) has possibly transmitted disease;

(2) may be infected with a disease in a communicable form that is transmissible through food;

(3) may be a carrier of infectious agents that cause a disease that is transmissible through food; or

(4) is affected with:

(A) a boil;

(B) an infected wound; or

(C) an acute respiratory infection.

(b) The regulatory authority shall act to secure a confidential medical history of the food employee suspected of transmitting disease or making other investigations as deemed appropriate. The regulatory authority shall also require appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected food employee and other employees. *(Indiana State Department of Health; 410 IAC 7-20-101; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1932)*

410 IAC 7-20-102 Regulatory authority restriction or exclusion of food employee

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 102. Based on the findings of an investigation related to a food employee who is suspected of being infected or diseased, the regulatory authority may issue an order to the suspected employee or retail food establishment instituting one (1) or more of the following control measures:

(1) Restricting the employee's services to specific areas and tasks in a retail food establishment that present no risk of transmitting the disease.

(2) Excluding the employee from a retail food establishment.

(3) Closing the retail food establishment in accordance with law.

(Indiana State Department of Health; 410 IAC 7-20-102; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1933)

410 IAC 7-20-103 Restriction or exclusion order

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 103. Based on the findings of the investigation as specified in section 101 of this rule and to control disease transmission, the regulatory authority may issue an order of restriction or exclusion to a suspected food employee or the retail food establishment without prior warning, notice of a hearing, or a hearing if the order states the following:

(1) The reasons for the restriction or exclusion that is ordered.

(2) The evidence that the food employee or retail food establishment shall provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated.

(3) That the suspected food employee or the retail food establishment may request an appeal hearing by submitting a timely request as provided in law.

(4) The name and address of the regulatory authority representative to whom a request for an appeal hearing may be made.

(Indiana State Department of Health; 410 IAC 7-20-103; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1933)

410 IAC 7-20-104 Release of a food employee from restriction or exclusion

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 104. The regulatory authority shall release a food employee from restriction or exclusion according to following conditions:

(1) If the employee's stools are negative for S. typhi based on testing of at least three (3) consecutive stool specimen cultures that are taken:

(A) not earlier than one (1) month after onset;

(B) at least forty-eight (48) hours after discontinuance of antibiotics; and

(C) at least twenty-four (24) hours apart.

(2) If one (1) of the cultures taken as specified in subdivision (1) is positive, repeat cultures are taken at intervals of one (1) month until at least three (3) consecutive negative stool specimen cultures are obtained.

(3) If the employee's stools are negative for Salmonella spp., Shigella spp. or E. coli O157:H7 based on testing of two (2) consecutive stool specimen cultures that are taken:

(A) not earlier than forty-eight (48) hours after discontinuance of antibiotics; and

(B) at least twenty-four (24) hours apart.

(4) For a food employee who was infected with hepatitis A virus if:

(A) at least seven (7) days have passed since the onset of jaundice;

(B) at least fourteen (14) days have passed since the onset of symptoms, if no jaundice occurred; or

(C) at least two (2) blood tests show falling liver enzymes.

(Indiana State Department of Health; 410 IAC 7-20-104; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1933)

410 IAC 7-20-105 Personal cleanliness

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 105. Food employees shall keep their hands and exposed portions of their arms clean. *(Indiana State Department of Health; 410 IAC 7-20-105; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1933)*

410 IAC 7-20-106 Hand cleaning and drying procedure

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 106. (a) Food employees shall clean their hands and exposed portions of their arms with a cleaning compound in a lavatory that is equipped as specified under section 303(a) of this rule by vigorously rubbing together the surfaces of their lathered hands and arms for at least twenty (20) seconds and thoroughly rinsing with clean water. Employees shall pay particular attention to the areas underneath the fingernails and between the fingers. A nail brush shall be used when provided.

(b) If approved and capable of removing the types of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands.

(c) Food employees, when drying their hands, shall utilize the provisions under section 385 of this rule. The use of a common towel is prohibited. *(Indiana State Department of Health; 410 IAC 7-20-106; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1933)*

410 IAC 7-20-107 When to wash hands

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 107. Food employees shall clean their hands and exposed portions of their arms as specified under section 106 immediately before engaging in food preparation, including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles and the following:

(1) After touching bare human body parts other than clean hands and clean, exposed portions of arms.
(2) After using the toilet room.
(3) After caring for or handling service animals or aquatic animals as specified in section 116(b) of this rule.
(4) After coughing, sneezing, using a handkerchief or disposable tissue.
(5) After drinking, other than as specified in section 113(b) of this rule, using tobacco, or eating.
(6) After handling soiled surfaces, equipment, or utensils.
(7) During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks.
(8) When switching between working with raw food and working with ready-to-eat food.
(9) Directly before touching ready-to-eat food or food-contact surfaces.
(10) After engaging in other activities that contaminate the hands.

(Indiana State Department of Health; 410 IAC 7-20-107; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1934)

410 IAC 7-20-108 Where to wash hands

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 108. Food employees shall clean their hands in a handwashing lavatory or approved automatic handwashing facility and may not clean their hands in a sink used for food preparation, or in a service sink or a curbed cleaning facility used for the disposal of mop water and similar liquid waste. *(Indiana State Department of Health; 410 IAC 7-20-108; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1934)*

410 IAC 7-20-109 Hand sanitizers

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 109. (a) A hand sanitizer and a chemical hand sanitizing solution used as a hand dip shall:

(1) have active antimicrobial ingredients that are safe and effective for application to human skin;
(2) have components that are:
    (A) regulated for the intended use as food additives as specified in 21 CFR 178;
    (B) generally recognized as safe (GRAS) for the intended use in contact with food within the meaning of Section 201(s) of the federal Food, Drug, and Cosmetic Act; or
    (C) exempted from the requirement of being listed in the federal food additive regulations as specified in 21 CFR 170.39; and
(3) be applied only to hands that are cleaned as specified under section 106 of this rule.

(b) If a hand sanitizer or a chemical hand sanitizing solution used as a hand dip does not meet the criteria specified under subsection (a)(2), use shall be:

(1) followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; or
(2) limited to situations that involve no direct contact with food by the bare hands.

(c) A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to at least one hundred (100) ppm chlorine. *(Indiana State Department of Health; 410 IAC 7-20-109; filed Mar 30, 2000, 3:51 p.m.: 23 IR*

1934)

410 IAC 7-20-110 Fingernail maintenance

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 110. (a) Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough.

(b) Unless wearing intact gloves in good repair, a food employee may not wear fingernail polish or artificial fingernails while working with exposed food. *(Indiana State Department of Health; 410 IAC 7-20-110; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1934)*

410 IAC 7-20-111 Jewelry prohibition

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 111. While preparing food, employees may not wear jewelry on their arms and hands. This section does not apply to a plain ring, such as a wedding band. *(Indiana State Department of Health; 410 IAC 7-20-111; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1934)*

410 IAC 7-20-112 Clean condition of outer clothing

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 112. Food employees shall wear clean outer clothing to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles. *(Indiana State Department of Health; 410 IAC 7-20-112; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1934)*

410 IAC 7-20-113 Eating, drinking, or using tobacco

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 113. (a) Except as specified in subsection (b), an employee shall eat, drink, or use any form of tobacco only in designated areas where the contamination of:

(1) exposed food;
(2) clean equipment, utensils, and linens;
(3) unwrapped single-service and single-use articles; or
(4) other items needing protection;

cannot result.

(b) A food employee may drink from a closed beverage container if the container is handled in a manner that prevents contamination of the following:

(1) The employee's hands.
(2) The container.
(3) Exposed food.
(4) Clean equipment, utensils, and linens.
(5) Unwrapped single-service and single-use articles.

(Indiana State Department of Health; 410 IAC 7-20-113; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1934)

410 IAC 7-20-114 Discharges from the eyes, nose, and mouth

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 114. Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with the following:

(1) Exposed food.

(2) Clean equipment, utensils, and linens.

(3) Unwrapped single-service or single-use articles.

(Indiana State Department of Health; 410 IAC 7-20-114; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1935)

410 IAC 7-20-115 Effectiveness of hair restraint

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 115. (a) Except as provided in subsection (b), food employees shall wear hair restraints, such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that are designed and worn to effectively keep their hair from contacting:

(1) exposed food;

(2) clean equipment, utensils, and linens; and

(3) unwrapped single-service and single-use articles.

(b) This section does not apply to food employees, such as counter staff who only serve beverages and wrapped or packaged foods, hostesses, and wait staff if they present a minimal risk of contaminating:

(1) exposed food;

(2) clean equipment, utensils, and linens; and

(3) unwrapped single-service and single-use articles.

(Indiana State Department of Health; 410 IAC 7-20-115; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1935)

410 IAC 7-20-116 Animal handling prohibited

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 116. (a) Except as specified in subsection (b), food employees may not care for or handle animals that may be present, such as patrol dogs, service animals, or pets that are allowed as specified in section 406(b)(2) through 406(b)(5) of this rule.

(b) Food employees with service animals may handle or care for their service animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified under sections 106 and 107(3) of this rule. *(Indiana State Department of Health; 410 IAC 7-20-116; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1935)*

410 IAC 7-20-117 Food condition

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 117. (a) Food shall be safe, unadulterated, and, as specified under section 179 of this rule, honestly presented.

(b) Food shall not be misbranded. *(Indiana State Department of Health; 410 IAC 7-20-117; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1935)*

410 IAC 7-20-118 Food sources

Authority: IC 16-42-5-5

Affected: IC 16-41-2; IC 16-42-1

Sec. 118. (a) Food shall be obtained from sources that comply with law.

(b) Food prepared in a private home may not be used or offered for human consumption in a retail food establishment.

(c) Packaged food shall be labeled as specified:

(1) in law, including IC 16-42-1, IC 16-41-2, 21 CFR 101, 9 CFR 317, 9 CFR 381, Subpart N; and

(2) under sections 131 and 132 of this rule.

(d) Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified in section

161(d)(1) of this rule may be offered for sale or service if they are:

(1) obtained from a supplier that freezes the fish as specified under section 164 of this rule; or

(2) frozen on the premises as specified under section 164 of this rule; and

records are retained as specified under section 165 of this rule.

(e) Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in section 161(c) of this rule shall be:

(1) obtained from a food processing plant that packages the steaks and labels them to indicate that they meet the definition of whole-muscle, intact beef; or

(2) if individually cut in a retail food establishment:

(A) cut from whole-muscle, intact beef that is labeled by a food processing plant to indicate that the beef meets the definition of whole-muscle, intact beef;

(B) prepared so they remain intact; and

(C) if packaged for undercooking in a retail food establishment, labeled to indicate that they meet the definition of whole-muscle, intact beef.

(f) Meat and poultry that is not a ready-to-eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b). *(Indiana State Department of Health; 410 IAC 7-20-118; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1935; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-119 Food in a hermetically sealed container

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 119. Food in a hermetically sealed container shall be obtained:

(1) from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant; or

(2) from a retail food establishment which meets all applicable state or federal requirements for food processing.

(Indiana State Department of Health; 410 IAC 7-20-119; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1936)

410 IAC 7-20-120 Fluid milk and milk products

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 120. Fluid milk and milk products shall be obtained from sources that comply with Grade A standards as specified in law. *(Indiana State Department of Health; 410 IAC 7-20-120; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1936)*

410 IAC 7-20-121 Fish

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 121. Fish that are received for sale or service shall be:

(1) commercially and legally produced, caught, or harvested; or

(2) approved by the department for sale or service.

(Indiana State Department of Health; 410 IAC 7-20-121; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1936)

410 IAC 7-20-122 Molluscan shellfish

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 122. (a) Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

(b) Molluscan shellfish received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

(c) Molluscan shellfish that are recreationally caught may not be received for sale or service. *(Indiana State Department of Health; 410 IAC 7-20-122; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1936)*

410 IAC 7-20-123 Wild mushrooms

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 123. (a) Except as specified in subsection (b), mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by a mushroom identification expert.

(b) This section does not apply to the following:

(1) Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation.

(2) Wild mushroom species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

(Indiana State Department of Health; 410 IAC 7-20-123; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1936; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)

410 IAC 7-20-124 Game animals

Authority: IC 16-42-5-5
Affected: IC 15-2.1-24; IC 16-42-5

Sec. 124. If game animals are received for sale or service, they shall be slaughtered and processed under a state or federal inspection program with requirements that are at least equal to IC 15-2.1-24. *(Indiana State Department of Health; 410 IAC 7-20-124; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1936)*

410 IAC 7-20-125 Specifications for receiving temperatures of food

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 125. (a) Except as specified in subsection (b), refrigerated, potentially hazardous food shall be at a temperature of forty-one (41) degrees Fahrenheit or below when received.

(b) If a temperature other than forty-one (41) degrees Fahrenheit for a potentially hazardous food is specified in law governing its distribution, such as laws governing milk, molluscan shellfish, and shell eggs, the food may be received at the specified temperature.

(c) Potentially hazardous food that is cooked to a temperature and for a time specified under sections 161 through 163 of this rule and received hot shall be at a temperature of one hundred forty (140) degrees Fahrenheit or above.

(d) A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen.

(e) Upon receipt, potentially hazardous food shall be free of evidence of previous temperature abuse. *(Indiana State Department of Health; 410 IAC 7-20-125; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1936)*

410 IAC 7-20-126 Food additives

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 126. Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170 through 21 CFR 180 relating to food additives, generally recognized as safe or prior sanctioned substances that exceed amounts specified in 21 CFR 181 through 21 CFR 186, substances that exceed amounts specified in 9 CFR 318.7, or pesticide residues that exceed provisions specified in 40 CFR 185. *(Indiana State Department of Health; 410 IAC 7-20-126; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1937)*

410 IAC 7-20-127 Shell eggs

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 127. Shell eggs shall be received clean and sound and may not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in 7 CFR 56, 9 CFR 590, U.S. Standards, Grades, and Weight classes for Shell Eggs (AMS 56.200 et seq.), and 370 IAC. *(Indiana State Department of Health; 410 IAC 7-20-127; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1937)*

410 IAC 7-20-128 Eggs and milk products; pasteurized

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 128. (a) Liquid, frozen, and dry eggs and egg products shall be pasteurized.

(b) Fluid and dry milk and milk products complying with Grade A standards as specified in law shall be obtained pasteurized.

(c) Frozen milk products, such as ice cream, shall be pasteurized as specified in 21 CFR 135.

(d) Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are specified in 21 CFR 133. *(Indiana State Department of Health; 410 IAC 7-20-128; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1937)*

410 IAC 7-20-129 Packaging integrity

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 129. Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants. *(Indiana State Department of Health; 410 IAC 7-20-129; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1937)*

410 IAC 7-20-130 Ice

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 130. Ice for use as a food or a cooling medium shall be made from drinking water. *(Indiana State Department of Health; 410 IAC 7-20-130; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1937)*

410 IAC 7-20-131 Shucked shellfish; packaging and identification

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 131. Raw shucked shellfish shall be obtained in nonreturnable packages that bear a legible label that identifies the:

(1) name, address, and certification number of the shucker-packer or repacker of the molluscan shellfish; and

(2) the "sell by" date for packages with a capacity of less than one-half (½) gallon or the date shucked for packages with a capacity of one-half (½) gallon or more.

(Indiana State Department of Health; 410 IAC 7-20-131; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1937)

410 IAC 7-20-132 Shellstock identification

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 132. (a) Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, and that list the following:

(1) Except as specified under subsection (b), on the harvester's tag or label, the following information in the following order:

(A) The harvester's identification number that is assigned by the shellfish control authority.

(B) The date of harvesting.

(C) The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested.

(D) The type and quantity of shellfish.

(E) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days.".

(2) Except as specified in subsection (c), on each dealer's tag or label, the following information in the following order:

(A) The dealer's name and address, and the certification number assigned by the shellfish control authority.

(B) The original shipper's certification number, including the abbreviation of the name of the state or country in which the shellfish are harvested.

(C) The same information as specified for a harvester's tag under subdivision 132(a)(1)(B) through (1)(D) *[subdivision (1)(B) through (1)(D)]*.

(D) The following statement in bold, capitalized type: "This tag is required to be attached until container is empty and thereafter kept on file for 90 days.".

(b) If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first.

(c) If the harvester's tag or label is designed to accommodate each dealer's identification as specified under subsections (a)(2)(A) and (a)(2)(B) *[subsection (a)(2)]*, individual dealer tags or labels need not be provided. *(Indiana State Department of Health; 410 IAC 7-20-132; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1937)*

410 IAC 7-20-133 Shellstock condition

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 133. When received by a retail food establishment, shellstock shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells shall be discarded. *(Indiana State Department of Health; 410 IAC 7-20-133; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1938)*

410 IAC 7-20-134 Molluscan shellfish original container

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 134. (a) Except as specified in subsections (b) and (c), molluscan shellfish shall not be removed from the container in which they are received other than immediately before sale or preparation for service.

(b) Shellstock may be removed from the container in which they are received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:

(1) the source of the shellstock on display is identified as specified under section 132 of this rule and recorded as specified under section 135 of this rule; and

(2) the shellstock are protected from contamination.

(c) Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

(1) the labeling information for the shellfish on display as specified under section 131 of this rule is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and

(2) the shellfish are protected from contamination.

(Indiana State Department of Health; 410 IAC 7-20-134; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1938)

410 IAC 7-20-135 Shellstock; maintaining identification

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 135. (a) Except as specified under subsection (b)(2), shellstock tags shall remain attached to the container in which the shellstock are received until the container is empty.

(b) The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for ninety (90) calendar days from the date the container is emptied by:

(1) using a record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the shellstock are sold or served; and

(2) using only one (1) tagged or labeled container at a time if shellstock are removed from their tagged or labeled container.

(Indiana State Department of Health; 410 IAC 7-20-135; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1938)

410 IAC 7-20-136 Preventing contamination from hands

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 136. (a) Food employees shall wash their hands as specified under section 106 of this rule.

(b) Food employees shall not contact exposed, ready-to-eat food with hands that have not been washed as specified in sections 107 and 108 of this rule and shall use suitable utensils, such as:

(1) deli tissue;
(2) spatulas;
(3) tongs;
(4) single-use gloves; or
(5) dispensing equipment;

when utensils can be used.

(c) Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form. *(Indiana State Department of Health; 410 IAC 7-20-136; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1938)*

410 IAC 7-20-137 Preventing contamination when tasting

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 137. A food employee may not reuse a utensil once it has been used to taste food that is to be sold or served. *(Indiana State Department of Health; 410 IAC 7-20-137; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1939)*

410 IAC 7-20-138 Packaged and unpackaged food; separation, packaging, and segregation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 138. (a) Food shall be protected from cross contamination by the following:

(1) Separating raw animal foods during storage, preparation, holding, and display from:
  (A) raw ready-to-eat food, including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as vegetables; and
  (B) cooked ready-to-eat food.

(2) Except when combined as ingredients, separating types of raw animal foods from each other, such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:
  (A) using separate equipment for each type, or arranging each type of food in equipment so that cross contamination of one (1) type with another is prevented; and
  (B) preparing each type of food at different times or in separate areas.

(3) Cleaning equipment and utensils as specified under section 265(a) of this rule and sanitizing as specified under section

276 of this rule.
(4) Except as specified in subsection (b), storing the food in packages, covered containers, or wrappings.
(5) Cleaning hermetically sealed containers of food of visible soil before opening.
(6) Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened.
(7) Storing damaged, spoiled, or recalled food being held in the retail food establishment as specified under section 394 of this rule.
(8) Separating fruits and vegetables, before they are washed as specified under section 142 of this rule from ready-to-eat food.
(b) Subsection (a)(4) does not apply to:
(1) whole, uncut raw fruits and vegetables and nuts in the shell that require peeling or hulling before consumption;
(2) primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;
(3) whole, uncut, processed meats, such as country hams and smoked or cured sausages that are placed on clean, sanitized racks;
(4) food being cooled as specified under section 172(b)(2) of this rule; or
(5) shellstock.
(Indiana State Department of Health; 410 IAC 7-20-138; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1939)

410 IAC 7-20-139 Food storage containers identified with common name of food

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 139. Working containers holding food or food ingredients that are removed from their original packages for use in the retail food establishment, such as:
(1) cooking oils;
(2) flour;
(3) herbs;
(4) potato flakes;
(5) salt;
(6) spices; and
(7) sugar;
shall be identified with the common name of the food, except that containers holding food that can be readily and unmistakably recognized, such as dry pasta need not be identified. *(Indiana State Department of Health; 410 IAC 7-20-139; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1939)*

410 IAC 7-20-140 Pasteurized eggs; substitute for raw shell eggs for certain recipes

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 140. Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods, such as caesar salad, hollandaise or béarnaise sauce, mayonnaise, and egg-fortified beverages that are not:
(1) cooked as specified under section 161(a)(1) or 161(a)(2) of this rule; or
(2) included in section 161(d)(1) of this rule.
(Indiana State Department of Health; 410 IAC 7-20-140; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1939)

410 IAC 7-20-141 Protection from unapproved food or color additives

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 141. (a) Food shall be protected from contamination that may result from the addition of:
(1) unsafe or unapproved food or color additives; and

(2) unsafe or unapproved levels of approved food and color additives.

(b) A food employee may not:

(1) apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B1; or

(2) serve or sell food specified under subdivision (1) that is treated with sulfiting agents before receipt by the retail food establishment, except that grapes need not meet this subdivision.

(Indiana State Department of Health; 410 IAC 7-20-141; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1940)

410 IAC 7-20-142 Washing fruits and vegetables

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 142. (a) Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form, except:

(1) as specified in subsection (b);

(2) that whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.

(b) Fruits and vegetables may be washed by using chemicals as specified under section 414 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-142; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1940)*

410 IAC 7-20-143 Ice used as exterior coolant; prohibited as ingredient

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 143. After use as a medium for cooling the exterior surfaces of:

(1) food, such as melons or fish;

(2) packaged foods, such as canned beverages; or

(3) cooling coils and tubes of equipment;

ice may not be used as food. *(Indiana State Department of Health; 410 IAC 7-20-143; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1940)*

410 IAC 7-20-144 Storage or display of food in contact with water or ice

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 144. (a) Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.

(b) Except as specified in subsections (c) and (d), unpackaged food may not be stored in direct contact with undrained ice.

(c) Whole, raw fruits or vegetables; cut, raw vegetables, such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.

(d) Raw chicken and raw fish that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale. *(Indiana State Department of Health; 410 IAC 7-20-144; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1940)*

410 IAC 7-20-145 Food contact with equipment and utensils

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 145. Food shall only contact surfaces of equipment and utensils that are cleaned as specified under sections 264 through 274 of this rule and sanitized as specified under sections 275 and 276 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-145; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1940)*

410 IAC 7-20-146 In-use utensils; between-use storage

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 146. During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

(1) except as specified under subdivision (2), in the food with their handles above the top of the food and the container;

(2) in food that is not potentially hazardous with their handles above the top of the food within containers or equipment that can be closed, such as bins of ice, sugar, flour, or cinnamon;

(3) on a clean portion of the food preparation table or cooking equipment if both the in-use utensil and food-contact surfaces of food preparation tables or cooking equipment are cleaned and sanitized at a frequency specified under sections 265 and 275 of this rule;

(4) in running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes;

(5) in a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not potentially hazardous; or

(6) in water maintained clean and at a temperature of at least one hundred forty (140) degrees Fahrenheit.

(Indiana State Department of Health; 410 IAC 7-20-146; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1940)

410 IAC 7-20-147 Linens and napkins; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 147. Linens and napkins may not be used in contact with food unless they are used temporarily to line a container for the service of foods and the linens and napkins are replaced each time the container is refilled for a new consumer. *(Indiana State Department of Health; 410 IAC 7-20-147; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1941)*

410 IAC 7-20-148 Wiping cloths; used for one purpose

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 148. (a) Cloths that are in use for wiping food spills shall be used for no other purpose.

(b) Cloths used for wiping food spills shall be:

(1) dry and used for wiping food spills from tableware and carry-out containers; or

(2) wet and cleaned as specified under section 278(d) of this rule, stored in a chemical sanitizer as specified under section 257 of this rule, and used for wiping spills from food-contact and nonfood-contact surfaces of equipment.

(c) Wet or dry cloths that are used with raw animal foods shall be kept separate from cloths used for other purposes, and wet cloths used with raw animal foods shall be kept in a separate sanitizing solution.

(d) Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths shall be free of food debris and visible soil. *(Indiana State Department of Health; 410 IAC 7-20-148; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1941)*

410 IAC 7-20-149 Gloves; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 149. (a) If used, single-use gloves shall be used for only one (1) task, such as working with ready-to-eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.

(b) Except as specified in subsection (c), slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under sections 161 through 163 of this rule, such as frozen food or a primal cut of meat.

(c) Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves:

(1) have a smooth, durable, and nonabsorbent outer surface; or

(2) are covered with a smooth, durable, nonabsorbent glove, or a single-use glove.

(d) Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required under sections 161 through 163 of this rule such as frozen food or a primal cut of meat. *(Indiana State Department of Health; 410 IAC 7-20-149; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1941)*

410 IAC 7-20-150 Using clean tableware for second portions and refills

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 150. (a) Except for refilling a consumer's drinking cup or container without contact between the pouring utensil and the lip-contact area of the drinking cup or container, food employees may not use tableware, including single-service articles, soiled by the consumer to provide second portions or refills.

(b) Except as specified in subsection (c), self-service consumers may not be allowed to use soiled tableware, including single-service articles, to obtain additional food from the display and serving equipment.

(c) Drinking cups and containers may be reused by self-service consumers if refilling is a contamination-free process as specified under section 211(1), 211(2), and 211(4) of this rule. *(Indiana State Department of Health; 410 IAC 7-20-150; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1941; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-151 Refilling returnables

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 151. (a) A take-home food container returned to a retail food establishment may not be refilled at a retail food establishment with a potentially hazardous food.

(b) Except as specified in subsection (c), a take-home food container refilled with food that is not potentially hazardous shall be cleaned as specified under section 274 of this rule.

(c) Personal take-out beverage containers, such as thermally insulated bottles, nonspill coffee cups, and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under section 211(1), 211(2), and 211(4) of this rule. *(Indiana State Department of Health; 410 IAC 7-20-151; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1941)*

410 IAC 7-20-152 Food storage

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 152. (a) Except as specified in subsections (b) and (c), food shall be protected from contamination by storing the food:

(1) in a clean, dry location;

(2) where it is not exposed to splash, dust, or other contamination; and

(3) at least six (6) inches above the floor.

(b) Food in packages and working containers may be stored less than six (6) inches above the floor on case lot handling equipment.

(c) Pressurized beverage containers, cased food in waterproof containers, such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture. *(Indiana State Department of Health; 410 IAC 7-20-152; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1942)*

410 IAC 7-20-153 Food storage; prohibited areas

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 153. Food may not be stored:

(1) in locker rooms;

(2) in toilet rooms;

(3) in dressing rooms;
(4) in garbage rooms;
(5) in mechanical rooms, when contamination is likely to occur;
(6) under sewer lines that are not shielded to intercept potential drips;
(7) under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
(8) under open stairwells; or
(9) under other sources of contamination.
(Indiana State Department of Health; 410 IAC 7-20-153; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1942)

410 IAC 7-20-154 Vended potentially hazardous food; original container
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 154. Potentially hazardous food dispensed through a vending machine shall be in the package in which it was placed at the retail food establishment or food processing plant at which it was prepared. *(Indiana State Department of Health; 410 IAC 7-20-154; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1942)*

410 IAC 7-20-155 Food preparation
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 155. During preparation, unpackaged food shall be protected from environmental sources of contamination. *(Indiana State Department of Health; 410 IAC 7-20-155; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1942)*

410 IAC 7-20-156 Food display
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 156. Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of:
(1) packaging;
(2) counter, service line, or salad bar food guards;
(3) display cases; or
(4) other effective means.
(Indiana State Department of Health; 410 IAC 7-20-156; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1942)

410 IAC 7-20-157 Condiments; protection
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 157. (a) Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.

(b) Condiments at a vending machine location shall be in individual packages or provided in dispensers that are filled at an approved location, such as the retail food establishment that provides food to the vending machine location, a food processing plant that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the vending machine location. *(Indiana State Department of Health; 410 IAC 7-20-157; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1942)*

410 IAC 7-20-158 Consumer self-service operations
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 158. (a) Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish, may not be offered for consumer self-service. This section does not apply to:

(1) consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods, such as sushi or raw shellfish; or

(2) ready-to-cook individual portions for immediate cooking and consumption on the premises.

(b) Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination.

(c) Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures. *(Indiana State Department of Health; 410 IAC 7-20-158; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1942)*

410 IAC 7-20-159 Returned food; reservice or sale

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 159. (a) Except as specified in subsection (b), after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption.

(b) Except as specified under section 183(d) of this rule, a container of food that is not potentially hazardous may be transferred from one (1) consumer to another if:

(1) the food is dispensed so that it is protected from contamination and the container is closed between uses, such as a narrow-neck bottle containing catsup, steak sauce, or wine; or

(2) the food, such as crackers, salt, or pepper, is in an unopened original package and is maintained in sound condition.

(Indiana State Department of Health; 410 IAC 7-20-159; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1943; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)

410 IAC 7-20-160 Miscellaneous sources of contamination

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 160. Food shall be protected from contamination that may result from a factor or source not specified under sections 136 through 159 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-160; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1943)*

410 IAC 7-20-161 Cooking of raw animal foods

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 161. (a) Except as specified under subsections (b), (c), and (d), raw animal foods, such as eggs, fish, meat, poultry, and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one (1) of the following methods based on the food that is being cooked:

(1) One hundred forty-five (145) degrees Fahrenheit or above for fifteen (15) seconds for the following:

(A) Raw shell eggs that are broken and prepared in response to a consumer's order and for immediate service.

(B) Except as specified under subdivisions (2) and (3) and subsection (b), fish and meat, including pork.

(2) One hundred fifty-five (155) degrees Fahrenheit for fifteen (15) seconds or the temperature specified in the chart in subsection (b) that corresponds to the holding time for:

(A) injected meats;

(B) raw eggs that are not prepared as specified under subdivision (1); and

(C) comminuted meat or fish.

(3) One hundred sixty-five (165) degrees Fahrenheit or above for fifteen (15) seconds for poultry, game animals, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, or stuffing containing fish, meat, or poultry.

(b) Whole beef roasts, corned beef roasts, pork roasts, and cured pork roasts, such as ham, shall be cooked as follows:

(1) In an oven that is preheated to the temperature specified for the roast's weight in the chart in subdivision (3) and that is held at that temperature.

(2) As specified in the chart in subdivision (3), to heat all parts of the food to a temperature and for the holding time that

corresponds to that temperature.

(3) The minimum cooking temperatures and holding times at a specified temperature are as follows:

<table>
<tr><th colspan="4">MINIMUM COOKING TEMPERATURES AND HOLDING TIME AT SPECIFIED TEMPERATURE</th></tr>
<tr><td>165ºF for 15 seconds</td><td colspan="3">Poultry and foods containing poultry; stuffed meat, fish, or pasta; and stuffing containing fish or meat; game animals and foods containing game animals.</td></tr>
<tr><td>165ºF for 2 minutes</td><td colspan="3">Microwave cooking for raw animal foods: covered, rotated, or stirred throughout or midway through the cooking process, and held for 2 minutes covered.</td></tr>
<tr><td>158ºF for 1 second
155ºF for 15 seconds
or
150ºF for 1 minute
145ºF for 3 minutes</td><td colspan="3">Injected meats; comminuted raw meat or fish; and raw shell eggs that are not prepared for immediate service (pooled or hot held).</td></tr>
<tr><td>145ºF for 15 seconds</td><td colspan="3">Raw shell eggs prepared for immediate service; meat and fish not otherwise specified in this chart.</td></tr>
<tr><td rowspan="5">145ºF for 3 minutes
or 144ºF for 5 minutes
142ºF for 8 minutes
140ºF for 12 minutes
138ºF for 19 minutes
136ºF for 32 minutes
134ºF for 47 minutes
132ºF for 77 minutes
130ºF for 121 minutes</td><td colspan="3">Roasts of beef, corned beef, pork, and cured pork: Note: holding time may include post cooking heat rise.</td></tr>
<tr><td>Oven Type</td><td>Roast Weight Less than 10 lbs.</td><td>Roast Weight More than 10 lbs.</td></tr>
<tr><td>Still Dry</td><td>Oven temperature ≥ 350ºF</td><td>Oven temperature ≥ 250ºF</td></tr>
<tr><td>Convection</td><td>Oven temperature ≥325ºF</td><td>Oven temperature ≥ 250ºF</td></tr>
<tr><td>High Humidity [1]</td><td>Oven temperature ≤ 250ºF</td><td>Oven temperature ≤ 250ºF</td></tr>
<tr><td>140ºF</td><td colspan="3">Potentially hazardous food cooked for hot holding: fruits, vegetables, and potentially hazardous foods not otherwise listed that will be hot held.</td></tr>
</table>

[1]Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

(c) A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:

(1) the food establishment serves a population that is not a highly susceptible population;

(2) the steak is labeled to indicate that it meets the definition of whole-muscle, intact beef as specified under section 118(e) of this rule; and

(3) the steak is cooked on both the top and bottom to a surface temperature of one hundred forty-five (145) degrees Fahrenheit or above and a cooked color change is achieved on all external surfaces.

(d) A raw animal food, such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare or a partially cooked food, such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in subsection (c) may be served or offered for sale in a ready-to-eat form if the retail food establishment serves a population that is not a highly susceptible population and the consumer is informed as specified under section 181 of this rule that to ensure its safety, the food should be cooked as specified under subsection (a) or (b). *(Indiana State Department of Health; 410 IAC 7-20-161; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1943)*

410 IAC 7-20-162 Microwave cooking

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 162. Raw animal foods cooked in a microwave oven shall be:

(1) rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;

(2) covered to retain surface moisture;

(3) heated to a temperature of at least one hundred sixty-five (165) degrees Fahrenheit in all parts of the food; and

(4) allowed to stand covered for two (2) minutes after cooking to obtain temperature equilibrium.
(Indiana State Department of Health; 410 IAC 7-20-162; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1944)

410 IAC 7-20-163 Potentially hazardous food cooking for hot holding

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 163. Fruits, vegetables, and any potentially hazardous foods not covered under sections 161 and 162 of this rule that are cooked for hot holding shall be cooked to an internal temperature of one hundred forty (140) degrees Fahrenheit. *(Indiana State Department of Health; 410 IAC 7-20-163; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1944)*

410 IAC 7-20-164 Parasite destruction

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 164. (a) Except as specified in subsection (b), before service or sale in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish other than molluscan shellfish shall be frozen throughout to a temperature of:

(1) minus four (4) degrees Fahrenheit or below for one hundred sixty-eight (168) hours (seven (7) days) in a freezer; or

(2) minus thirty-one (31) degrees Fahrenheit or below for fifteen (15) hours in a blast freezer.

(b) If the fish are tuna of the species:

(1) Thunnus alalunga;

(2) Thunnus albacares (yellowfin tuna);

(3) Thunnus atlanticus;

(4) Thunnus maccoyii (bluefin tuna, Southern);

(5) Thunnus obesus (bigeye tuna); or

(6) Thunnus thynnus (bluefin tuna, northern);

the fish may be served or sold in a raw, raw-marinated, or partially cooked ready-to-eat form without freezing as specified under subsection (a). *(Indiana State Department of Health; 410 IAC 7-20-164; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1944)*

410 IAC 7-20-165 Records; creation and retention

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 165. (a) Except as specified in section 164(b) of this rule and subsection (b), if raw, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person-in-charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the retail food establishment for ninety (90) calendar days beyond the time of service or sale of the fish.

(b) If the fish are frozen by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under section 164 of this rule may substitute for the records specified under subsection (a). *(Indiana State Department of Health; 410 IAC 7-20-165; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1944)*

410 IAC 7-20-166 Preparation for immediate service

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 166. Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature. *(Indiana State Department of Health; 410 IAC 7-20-166; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1944)*

410 IAC 7-20-167 Reheating for hot holding

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 167. (a) Except as specified under subsections (b), (c), and (e), potentially hazardous food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach a temperature of at least one hundred sixty-five (165) degrees Fahrenheit for fifteen (15) seconds.

(b) Except as specified under subsection (c), potentially hazardous food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least one hundred sixty-five (165) degrees Fahrenheit and the food is rotated or stirred, covered, and allowed to stand covered for two (2) minutes after reheating.

(c) Ready-to-eat food taken from a commercially processed, hermetically sealed container, or from an intact package from a food processing plant that is inspected by the food regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least one hundred forty (140) degrees Fahrenheit for hot holding.

(d) Reheating for hot holding shall be done rapidly, and the time the food is between the temperature specified under section 173(2) or 173(3) of this rule and one hundred sixty-five (165) degrees Fahrenheit may not exceed two (2) hours.

(e) Remaining unsliced portions of roasts of beef that are cooked as specified under section 161(b) of this rule may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under section 161(b) of this rule. *(Indiana State Department of Health; 410 IAC 7-20-167; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1944)*

410 IAC 7-20-168 Time and temperature control of frozen food

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 168. Stored frozen foods shall be maintained frozen and should be stored at zero (0) degrees Fahrenheit. *(Indiana State Department of Health; 410 IAC 7-20-168; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1945)*

410 IAC 7-20-169 Potentially hazardous food; slacking

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 169. Frozen potentially hazardous food that is slacked to moderate the temperature shall be held:

(1) under refrigeration that maintains the food temperature at forty-one (41) degrees Fahrenheit or less, or at forty-five (45) degrees Fahrenheit or less as specified under section 173(3) of this rule; or

(2) at any temperature if the food remains frozen.

(Indiana State Department of Health; 410 IAC 7-20-169; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1945)

410 IAC 7-20-170 Thawing of food

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 170. Except as specified in subdivision (4), potentially hazardous food shall be thawed:

(1) under refrigeration that maintains the food temperature at forty-one (41) degrees Fahrenheit or less, or at forty-five (45) degrees Fahrenheit or less as specified under section 173(3) of this rule;

(2) completely submerged under running water:

(A) at a water temperature of seventy (70) degrees Fahrenheit or below;

(B) with sufficient water velocity to agitate and float off loose particles in an overflow;

(C) for a period of time that does not allow thawed portions of ready-to-eat food to rise above forty-one (41) degrees Fahrenheit, or forty-five (45) degrees Fahrenheit as specified under section 173(3) of this rule; or

(D) for a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under sections *[sic., section]* 161(a) or 161(b) of this rule to be above forty-one (41) degrees Fahrenheit, or forty-five (45) degrees Fahrenheit as specified under section 173(3) of this rule, for more than four (4) hours, including:

(i) the time the food is exposed to the running water and the time needed for preparation for cooking; or
(ii) the time it takes under refrigeration to lower the food temperature to forty-one (41) degrees Fahrenheit, or forty-five (45) degrees Fahrenheit as specified under section 173(3) of this rule;

(3) as part of a cooking process if the food that is frozen is:
(A) cooked as specified under section 161(a) or 161(b), or 162 of this rule; or
(B) thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or

(4) using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

(Indiana State Department of Health; 410 IAC 7-20-170; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1945; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)

410 IAC 7-20-171 Potentially hazardous food; cooling

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 171. (a) Cooked potentially hazardous food shall be cooled:
(1) within two (2) hours, from one hundred forty (140) degrees Fahrenheit to seventy (70) degrees Fahrenheit; and
(2) within four (4) hours, from seventy (70) degrees Fahrenheit to forty-one (41) degrees Fahrenheit or less, or to forty-five (45) degrees Fahrenheit as specified under section 173(3) of this rule.

(b) Potentially hazardous food shall be cooled within four (4) hours to forty-one (41) degrees Fahrenheit or less, or to forty-five (45) degrees Fahrenheit as specified under section 173(3) of this rule if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.

(c) Except as specified in subsection (d), a potentially hazardous food received in compliance with laws allowing a temperature above forty-one (41) degrees Fahrenheit during shipment from the supplier as specified in section 125(b) of this rule, shall be cooled within four (4) hours to forty-one (41) degrees Fahrenheit or less, or forty-five (45) degrees Fahrenheit or less as specified under section 173(3) of this rule.

(d) Shell eggs need not comply with subsection (c) if the eggs are placed immediately, upon their receipt, in refrigerated equipment that is capable of maintaining food at forty-one (41) degrees Fahrenheit or less, or forty-five (45) degrees Fahrenheit or less as specified under section 173(3) of this rule. *(Indiana State Department of Health; 410 IAC 7-20-171; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1945; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-172 Cooling methods

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 172. (a) Cooling shall be accomplished in accordance with the time and temperature criteria specified under section 171 of this rule by using one (1) or more of the following methods based on the type of food being cooled:
(1) Placing the food in shallow pans.
(2) Separating the food into smaller or thinner portions.
(3) Using rapid cooling equipment.
(4) Stirring the food in a container placed in an ice water bath.
(5) Using containers that facilitate heat transfer.
(6) Adding ice as an ingredient.
(7) Other effective methods.

(b) When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:
(1) arranged in the equipment to provide maximum heat transfer through the container walls; and
(2) loosely covered, or uncovered if protected from overhead contamination as specified under section 152(a)(2) of this rule, during the cooling period to facilitate heat transfer from the surface of the food.

(Indiana State Department of Health; 410 IAC 7-20-172; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1946)

410 IAC 7-20-173 Potentially hazardous food; hot and cold holding

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 173. Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under section 175 of this rule, potentially hazardous food shall be maintained as follows:

(1) At one hundred forty (140) degrees Fahrenheit or above, except that roasts cooked to a temperature and for a time specified under section 161(b) of this rule or reheated as specified in section 167(e) of this rule may be held at a temperature of one hundred thirty (130) degrees Fahrenheit.

(2) At forty-one (41) degrees Fahrenheit or less, except as specified under subdivision (3) and section 219 of this rule.

(3) At forty-five (45) degrees Fahrenheit or between forty-five (45) degrees Fahrenheit and forty-one (41) degrees Fahrenheit in existing refrigeration equipment that is not capable of maintaining the food at forty-one (41) degrees Fahrenheit or less if:

(A) the equipment is in place and in use in the retail food establishment; and

(B) not more than ten (10) years beyond the effective date of this rule, the equipment is upgraded or replaced to maintain food at a temperature of forty-one (41) degrees Fahrenheit or less.

(Indiana State Department of Health; 410 IAC 7-20-173; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1946; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)

410 IAC 7-20-174 Ready-to-eat, potentially hazardous food; date marking

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 174. (a) Except as in subsection (c), ready-to-eat, potentially hazardous food prepared and held refrigerated or frozen more than twenty-four (24) hours in a retail food establishment shall be clearly marked to indicate the date of consumption, which reflects:

(1) four (4) days of cumulative refrigeration storage time when held at forty-five (45) degrees Fahrenheit; or

(2) seven (7) days of cumulative refrigeration storage time when held at forty-one (41) degrees Fahrenheit.

(b) Food mentioned in subsection (a), which is being stored or displayed beyond the date of consumption, shall be discarded.

(c) Subsection (a) does not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request, or to whole, unsliced portions of a cured and processed product with original casing maintained on the remaining portion, such as aged hard cheeses, bologna, salami, or other sausage in a cellulose casing. *(Indiana State Department of Health; 410 IAC 7-20-174; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1946)*

410 IAC 7-20-175 Time as a public health control

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 175. (a) Except as specified under subsection (b), if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption:

(1) the food shall be clearly marked or otherwise identified to indicate the time that is four (4) hours past the point in time when the food is removed from temperature control;

(2) the food shall be cooked and served, served if ready-to-eat, or discarded, within four (4) hours from the point in time when the food is removed from temperature control;

(3) the food in unmarked containers or packages or marked to exceed a four (4) hour limit shall be discarded; and

(4) written procedures shall be maintained in the retail food establishment and made available to the regulatory authority, upon request, that ensure compliance with:

(A) this section; and

(B) section 171 of this rule for food that is prepared, cooked, and refrigerated before time is used as a public health control.

(b) In a retail food establishment that serves a highly susceptible population, time alone shall not be used as the public health

control for raw eggs. *(Indiana State Department of Health; 410 IAC 7-20-175; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1946)*

410 IAC 7-20-176 Confidentiality of trade secrets

Authority: IC 16-42-5-5
Affected: IC 5-14-3; IC 16-42-5; IC 24-2-3

Sec. 176. The regulatory authority shall treat as confidential in accordance with IC 24-2-3 and IC 5-14-3:

(1) the information contained in plans and specifications listed in section 431 of this rule;

(2) an HACCP plan; or

(3) inspection report forms which meets the criteria of a trade secret.

(Indiana State Department of Health; 410 IAC 7-20-176; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1947)

410 IAC 7-20-177 Reduced oxygen packing; criteria

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 177. (a) A retail food establishment that packages food using a reduced oxygen packaging method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall ensure that there are at least two (2) barriers in place to control the growth and toxin formation of C. botulinum.

(b) A retail food establishment that packages food using a reduced oxygen packaging method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall have a HACCP plan that does the following:

(1) Contains a flow diagram by specific food or category type identifying critical control points and providing information on the following:

(A) Ingredients, materials, and equipment used in the preparation of that food.

(B) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

(2) Contains a statement of standard operating procedures for the plan which clearly identifies the following:

(A) Each critical control point.

(B) The critical limits for each critical control point.

(C) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person-in-charge.

(D) The method and frequency for the person-in-charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points.

(E) Action to be taken by the person-in-charge if the critical limits for each critical control point are not met.

(F) Records to be maintained by the person-in-charge to demonstrate that the HACCP plan is properly operated and managed.

(3) Identifies the food to be packaged.

(4) Limits the food packaged to a food that does not support the growth of Clostridium botulinum because it complies with one (1) of the following:

(A) Has a aw of ninety-one hundredths (0.91) or less.

(B) Has a pH of four and six-tenths (4.6) or less.

(C) Is a meat or poultry product cured at a food processing plant regulated by the USDA using substances specified in 9 CFR 318.7 and 9 CFR 381.147 and is received in an intact package.

(D) Is a food with a high level of competing organisms, such as raw meat or raw poultry.

(5) Specifies methods for maintaining food at forty-one (41) degrees Fahrenheit or below.

(6) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(A) maintain the food at forty-one (41) degrees Fahrenheit or below; and

(B) discard the food if within fourteen (14) calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption.

(7) Limits the shelf life to no more than fourteen (14) calendar days from packaging to consumption or the original

manufacturer's "sell by" or "use by" date, whichever occurs first.

(8) Includes operational procedures that:

(A) prohibit contacting food with bare hands;

(B) identify a designated area and the method by which:

(i) physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination; and

(ii) access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation; and

(C) delineate cleaning and sanitization procedures for food-contact surfaces.

(9) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(A) concepts required for a safe operation;

(B) equipment and facilities; and

(C) procedures specified under subdivisions (b)(2) and (b)(8) *[subdivisions (2) and (8)]*.

(c) Except for fish that is frozen before, during, and after packaging, a retail food establishment may not package fish using a reduced oxygen packaging method. *(Indiana State Department of Health; 410 IAC 7-20-177; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1947)*

410 IAC 7-20-178 Accurate representation of packaged food using standards of identity

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 178. Packaged food shall comply with standard of identity requirements in 21 CFR 131 through 21 CFR 169, 9 CFR 319, and the general requirements in 21 CFR 130 and 9 CFR 319, Subpart A. *(Indiana State Department of Health; 410 IAC 7-20-178; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1948)*

410 IAC 7-20-179 Honest presentation of food

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 179. (a) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

(b) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of a food. *(Indiana State Department of Health; 410 IAC 7-20-179; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1948)*

410 IAC 7-20-180 Food labels

Authority: IC 16-42-5-5
Affected: IC 16-42-1; IC 16-42-2

Sec. 180. (a) Food packaged in a retail food establishment shall be labeled as specified in law, including the following:

(1) IC 16-42-1.

(2) IC 16-42-2.

(3) 410 IAC 7-5.

(4) 21 CFR 101.

(5) 9 CFR 317.

(b) Label information shall include the following:

(1) The common name of the food or, absent a common name, an adequately descriptive identity statement.

(2) If made from two (2) or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives if contained in the food.

(3) An accurate declaration of the quantity of contents.

(4) The name and place of business of the manufacturer, packer, or distributor.

(c) Except as specified in subsection (d), bulk, unpackaged food not intended for immediate consumption that is available

for consumer self-dispensing or that is portioned to consumer specifications shall be prominently labeled with either of the following information in plain view of the consumer:

(1) The manufacturer's or processor's label that was provided with the food.

(2) A card, sign, or other method of notification that includes the information specified under subsection (b)(1), (b)(2), and (b)(4).

(d) Bulk unpackaged food need not be labeled if:

(1) a health, nutrient content, or other claim is not made; or

(2) the food is manufactured or prepared on the premises of the retail food establishment.

(e) Retail food establishment or manufacturers' dating information on foods may not be concealed or altered. *(Indiana State Department of Health; 410 IAC 7-20-180; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1948)*

410 IAC 7-20-181 Consumption of raw or undercooked foods of animal origin

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 181. (a) Except as specified in section 161(c) of this rule, if food of animal origin, such as meat, fish, poultry, eggs, or shellfish that is:

(1) raw, undercooked, or not otherwise processed to eliminate pathogens is offered in a ready-to-eat form as a deli, menu, vended, or other item; or

(2) as a raw ingredient in another ready-to-eat food;

the retail food establishment shall inform consumers by brochures, deli case or menu advisories, label statements, table tents, placards, or other effective means of the significantly increased risk associated with certain especially vulnerable consumers eating such foods in raw or undercooked form.

(b) Long term care health facilities and other institutional facilities, that provide meals to residents who are sixty-five (65) years or older, shall provide written information to resident consumers informing them of the risks associated with consuming food described in subsection (a). The facility shall have a record of the notice on file as long as residency is maintained at the facility by the consumer. *(Indiana State Department of Health; 410 IAC 7-20-181; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1948)*

410 IAC 7-20-182 Discarding or reconditioning of unsafe, misbranded, adulterated, or contaminated food

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 182. (a) A food that is unsafe, adulterated, misbranded, or not honestly presented as specified under section 117 of this rule shall be reconditioned according to an approved procedure or discarded.

(b) Food that is not from an approved source as specified under sections 118 through 124 of this rule shall be discarded.

(c) Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under section 98 of this rule shall be discarded.

(d) Food that is contaminated by food employees, consumers, or other persons through contact with soiled hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded. *(Indiana State Department of Health; 410 IAC 7-20-182; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1949)*

410 IAC 7-20-183 Pasteurized food; prohibited re-service; prohibited food

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 183. (a) This section applies in a retail food establishment that serves a highly susceptible population.

(b) Prepackaged juice or a prepackaged beverage containing juice that bears a warning label as specified in 21 CFR 101.17(g) may not be served or offered for sale.

(c) Pasteurized shell eggs or pasteurized liquid, frozen, or dry eggs or egg products shall be substituted for raw shell eggs in the preparation of:

(1) foods, such as caesar salad, hollandaise or béarnaise sauce, mayonnaise, and egg-fortified beverages; and

(2) except as specified in subsection (f), recipes in which more than one (1) egg is broken and the eggs are combined.

(d) Food in an unopened original package may not be re-served.

(e) The following foods may not be served or offered for sale in a ready-to-eat form:

(1) Raw animal foods, such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare.

(2) A partially cooked animal food, such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw shell eggs, and meringue.

(3) Raw seed sprouts.

(f) Subsection (c) does not apply if:

(1) the raw eggs are combined immediately before cooking for one (1) consumer's serving at a single meal, cooked as specified under section 161(a)(1) of this rule, and served immediately, such as an omelet, soufflé, or scrambled eggs; or

(2) the raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread.

(Indiana State Department of Health; 410 IAC 7-20-183; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1949)

410 IAC 7-20-184 Characteristics of materials for utensils and food-contact surfaces

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 184. Materials that are used in the construction of utensils and food-contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be:

(1) safe;

(2) durable, corrosion-resistant, and nonabsorbent;

(3) sufficient in weight and thickness to withstand repeated warewashing;

(4) finished to have a smooth, easily cleanable surface; and

(5) resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition.

(Indiana State Department of Health; 410 IAC 7-20-184; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1949)

410 IAC 7-20-185 Cast iron; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 185. (a) Except as specified in this section, cast iron may not be used for utensils or food-contact surfaces of equipment.

(b) Cast iron may be used as a surface for cooking.

(c) Cast iron may be used in utensils for serving food if the utensils are used only as part of an uninterrupted process from cooking through service. *(Indiana State Department of Health; 410 IAC 7-20-185; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1949)*

410 IAC 7-20-186 Lead in ceramic, china, and crystal utensils; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 186. Ceramic, china, crystal utensils, and decorative utensils, such as hand painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories:

Utensil Category	Description	Maximum Lead ppm
Hot Beverage Mugs	Coffee Mugs	0.5
Large Hollowware	Bowls ≥ 1.16 Quart	1
Small Hollowware	Bowls < 1.16 Quart	2.0
Flat Utensils	Plates, Saucers	3.0

(Indiana State Department of Health; 410 IAC 7-20-186; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1950)

410 IAC 7-20-187 Copper; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 187. (a) Except as specified in subsection (b), copper and copper alloys, such as brass, may not be used in contact with:

(1) a food that has a pH below six (6), such as vinegar, fruit juice, or wine; or

(2) for a fitting or tubing installed between a backflow prevention device and a carbonator.

(b) Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below six (6) in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery. *(Indiana State Department of Health; 410 IAC 7-20-187; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1950)*

410 IAC 7-20-188 Galvanized metal; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 188. Galvanized metal may not be used for utensils or food-contact surfaces of equipment that are used in contact with moist or acidic food. *(Indiana State Department of Health; 410 IAC 7-20-188; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1950)*

410 IAC 7-20-189 Sponges; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 189. Sponges may not be used in contact with cleaned and sanitized or in-use food-contact surfaces. *(Indiana State Department of Health; 410 IAC 7-20-189; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1950)*

410 IAC 7-20-190 Lead in pewter alloys; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 190. Pewter alloys containing lead in excess of five-hundredths percent (0.05%) may not be used as a food-contact surface. *(Indiana State Department of Health; 410 IAC 7-20-190; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1950)*

410 IAC 7-20-191 Lead in solder and flux; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 191. Solder and flux containing lead in excess of two-tenths percent (0.2%) may not be used as a food-contact surface. *(Indiana State Department of Health; 410 IAC 7-20-191; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1950)*

410 IAC 7-20-192 Wood; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 192. (a) Except as specified in this section, wood and wood wicker may not be used as a food-contact surface.

(b) Hard maple or an equivalently hard, close-grained wood may be used for:

(1) cutting boards, cutting blocks, bakers' tables, and utensils, such as:

(A) rolling pins;

(B) doughnut dowels;

(C) salad bowls; and

(D) chopsticks; and

(2) wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at

a temperature of two hundred thirty (230) degrees Fahrenheit or above.

(c) Whole, uncut raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.

(d) If the nature of the food requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw food may be kept in:

(1) untreated wood containers; or

(2) treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800.

(Indiana State Department of Health; 410 IAC 7-20-192; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1950)

410 IAC 7-20-193 Nonstick coatings; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 193. Multi-use kitchenware, such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers, that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching utensils and cleaning aids. *(Indiana State Department of Health; 410 IAC 7-20-193; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-194 Nonfood-contact surfaces

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 194. Nonfood-contact surfaces of equipment that are exposed to splash, spillage, or other food soiling or that require frequent cleaning shall be constructed of a corrosion-resistant, nonabsorbent, and smooth material. *(Indiana State Department of Health; 410 IAC 7-20-194; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-195 Characteristics of materials used in single-service and single-use articles

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 195. (a) Materials that are used to make single-service and single-use articles may not:

(1) allow the migration of deleterious substances; or

(2) impart colors, odors, or tastes to food.

(b) These materials shall be safe and clean. *(Indiana State Department of Health; 410 IAC 7-20-195; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-196 Durability and strength of equipment and utensils

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 196. Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions. *(Indiana State Department of Health; 410 IAC 7-20-196; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-197 Durability and strength of food temperature measuring devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 197. Food temperature measuring devices may not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used. *(Indiana State Department of Health; 410 IAC 7-20-197; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-198 Cleanability of food-contact surfaces

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 198. (a) Multiuse food-contact surfaces shall be:

(1) smooth;

(2) free of breaks, open seams, cracks, chips, inclusions, pits, and similar imperfections;

(3) free of sharp internal angles, corners, and crevices;

(4) finished to have smooth welds and joints; and

(5) except as specified in subsection (b), accessible for cleaning and inspection either:

(A) without being disassembled;

(B) disassembling without the use of tools; or

(C) easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and allen wrenches.

(b) Subsection (a)(5) does not apply to cooking oil storage tanks, distribution lines for cooking oils, or beverage syrup lines or tubes. *(Indiana State Department of Health; 410 IAC 7-20-198; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-199 CIP equipment

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 199. (a) CIP equipment shall meet the characteristics specified under section 198 of this rule and shall be designed and constructed so that:

(1) cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces; and

(2) the system is self-draining or capable of being completely drained of cleaning and sanitizing solutions.

(b) CIP equipment that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned. *(Indiana State Department of Health; 410 IAC 7-20-199; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-200 "V" threads; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 200. "V" type threads may not be used on food-contact surfaces. This section does not apply to hot oil cooking or filtering equipment. *(Indiana State Department of Health; 410 IAC 7-20-200; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-201 Hot oil filtering equipment

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 201. Hot oil filtering equipment shall meet the characteristics specified under section 198 or 199 of this rule and shall be readily accessible for filter replacement and cleaning of the filter. *(Indiana State Department of Health; 410 IAC 7-20-201; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1951)*

410 IAC 7-20-202 Cleanability of can openers

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 202. Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement. *(Indiana State Department of Health; 410 IAC 7-20-202; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)*

410 IAC 7-20-203 Cleanability of nonfood-contact surfaces

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 203. Nonfood-contact surfaces shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance. *(Indiana State Department of Health; 410 IAC 7-20-203; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)*

410 IAC 7-20-204 Kick plates; removable

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 204. Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

(1) removable by one (1) of the methods specified under section 198 of this rule or capable of being rotated open; and

(2) removable or capable of being rotated open without unlocking equipment doors.

(Indiana State Department of Health; 410 IAC 7-20-204; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)

410 IAC 7-20-205 Ventilation hood systems; filters

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 205. Filters or other grease extracting equipment shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place. *(Indiana State Department of Health; 410 IAC 7-20-205; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)*

410 IAC 7-20-206 Accuracy of temperature measuring devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 206. (a) Food temperature measuring devices that are scaled in Fahrenheit shall be accurate to plus or minus two (2) degrees Fahrenheit in the intended range of use.

(b) Food temperature measuring devices that are dually scaled in Celsius and Fahrenheit shall be accurate to plus or minus one (1) degree Celsius in the intended range of use. *(Indiana State Department of Health; 410 IAC 7-20-206; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)*

410 IAC 7-20-207 Accuracy of ambient air and water temperature measuring devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 207. (a) Ambient air and water temperature measuring devices that are scaled in Fahrenheit shall be accurate to plus or minus three (3) degrees Fahrenheit in the intended range of use.

(b) Ambient air and water temperature measuring devices that are dually scaled in Celsius and Fahrenheit shall be designed to be easily readable and accurate to plus or minus one and five-tenths (1.5) degrees Celsius in the intended range of use. *(Indiana State Department of Health; 410 IAC 7-20-207; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)*

410 IAC 7-20-208 Pressure measuring devices; mechanical warewashing equipment

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 208. Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse shall have increments of one (1) pounds per square inch or smaller and shall be accurate to two (2) pounds per square inch in the

fifteen (15) to twenty-five (25) pounds per square inch range. *(Indiana State Department of Health; 410 IAC 7-20-208; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)*

410 IAC 7-20-209 Ventilation hood systems; drip prevention

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 209. Exhaust ventilation hood systems in food preparation and warewashing areas, including components, such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles. *(Indiana State Department of Health; 410 IAC 7-20-209; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)*

410 IAC 7-20-210 Equipment openings, closures, and deflectors

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 210. (a) A cover or lid for equipment shall overlap the opening and be sloped to drain.

(b) An opening located within the top of a unit of equipment that is designed for use with a cover or lid shall be flanged upward at least two-tenths (.2) of an inch.

(c) Except as specified under subsection (d), fixed piping, temperature measuring devices, rotary shafts, and other parts extending into equipment shall be provided with a watertight joint at the point where the item enters the equipment.

(d) If a watertight joint is not provided:

(1) the piping, temperature measuring devices, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the food; and

(2) the opening shall be flanged as specified under subsection (b).

(Indiana State Department of Health; 410 IAC 7-20-210; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1952)

410 IAC 7-20-211 Dispensing equipment; protection of equipment and food

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 211. In equipment that dispenses or vends liquid food or ice in unpackaged form, the following applies:

(1) The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food.

(2) The delivery tube, chute, and orifice shall be protected from manual contact, such as by being recessed.

(3) The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the equipment is:

(A) located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(B) available for self-service during hours when it is not under the full-time supervision of a food employee.

(4) The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

(Indiana State Department of Health; 410 IAC 7-20-211; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1953)

410 IAC 7-20-212 Vending machine; vending stage closure

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 212. The dispensing compartment of a vending machine, including a machine that is designed to vend prepackaged snack

food, that is not potentially hazardous, such as chips, party mixes, and pretzels, shall be equipped with a self-closing door or cover if the machine is:

(1) located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or

(2) available for self-service during hours when it is not under the full-time supervision of a food employee.

(Indiana State Department of Health; 410 IAC 7-20-212; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1953)

410 IAC 7-20-213 Bearings and gearboxes; leakproof

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 213. Equipment containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant can not leak, drip, or be forced into food or onto food-contact surfaces. *(Indiana State Department of Health; 410 IAC 7-20-213; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1953)*

410 IAC 7-20-214 Beverage tubing; separation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 214. Beverage tubing and cold-plate beverage cooling devices may not be installed in contact with ice stored for human consumption. This section does not apply to cold plates that are constructed integrally with an ice storage bin. *(Indiana State Department of Health; 410 IAC 7-20-214; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1953)*

410 IAC 7-20-215 Ice units; separation of drains

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 215. Liquid waste drain lines may not pass through an ice machine or ice storage bin. *(Indiana State Department of Health; 410 IAC 7-20-215; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1953)*

410 IAC 7-20-216 Condenser unit; separation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 216. If a condenser unit is an integral component of equipment, the condenser unit shall be separated from the food and food storage space by a dustproof barrier. *(Indiana State Department of Health; 410 IAC 7-20-216; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1953)*

410 IAC 7-20-217 Can openers on vending machines

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 217. Cutting or piercing parts of can openers on vending machines shall be protected from manual contact, dust, insects, rodents, and other contamination. *(Indiana State Department of Health; 410 IAC 7-20-217; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1954)*

410 IAC 7-20-218 Molluscan shellfish tanks

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 218. (a) Except as specified under subsection (b), molluscan shellfish life support system display tanks may not be used

to display shellfish that are offered for human consumption and shall be conspicuously marked so that it is obvious to the consumer that the shellfish are for display only.

(b) Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained to ensure that:

(1) water used with fish other than molluscan shellfish does not flow into the molluscan tank;

(2) the safety and quality of the shellfish as they were received are not compromised by the use of the tank; and

(3) the identity of the source of the shellstock is retained as specified under section 135 of this rule.

(Indiana State Department of Health; 410 IAC 7-20-218; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1954)

410 IAC 7-20-219 Vending machines; automatic shutoff

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 219. (a) A machine vending potentially hazardous food shall have an automatic control that prevents the machine from vending food if:

(1) there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that can not maintain food temperatures as specified under sections 117 through 183 of this rule; and

(2) a condition specified under subdivision (1) occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified under sections 117 through 183 of this rule.

(b) When the automatic shutoff within a machine vending potentially hazardous food is activated in:

(1) a refrigerated vending machine, the ambient temperature may not exceed forty-one (41) degrees Fahrenheit or forty-five (45) degrees Fahrenheit as specified under section 173(3) of this rule for more than thirty (30) minutes immediately after the machine is filled, serviced, or restocked; or

(2) a hot holding vending machine, the ambient temperature may not be less than one hundred forty (140) degrees Fahrenheit for more than one hundred twenty (120) minutes immediately after the machine is filled, serviced, or restocked.

(Indiana State Department of Health; 410 IAC 7-20-219; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1954; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)

410 IAC 7-20-220 Function of temperature measuring devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 220. (a) In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.

(b) Except as specified in subsection (c), cold or hot holding equipment used for potentially hazardous food shall be designed to include and shall be equipped with at least one (1) integral or permanently affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.

(c) Subsection (b) does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers, and salad bars.

(d) Temperature measuring devices shall be designed to be easily readable.

(e) Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record, or digital readout in increments no greater than two (2) degrees Fahrenheit in the intended range of use. *(Indiana State Department of Health; 410 IAC 7-20-220; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1954)*

410 IAC 7-20-221 Warewashing machine; data plate operating specifications

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 221. A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine

by the manufacturer that indicates the machine's design and operating specifications, including the:

(1) temperatures required for washing, rinsing, and sanitizing;

(2) pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and

(3) conveyor speed for conveyor machines or cycle time for stationary rack machines.

(Indiana State Department of Health; 410 IAC 7-20-221; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1954)

410 IAC 7-20-222 Warewashing machines; internal baffles

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 222. Warewashing machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks. *(Indiana State Department of Health; 410 IAC 7-20-222; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1955)*

410 IAC 7-20-223 Warewashing machines; temperature measuring devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 223. A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:

(1) in each wash and rinse tank; and

(2) as the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.

(Indiana State Department of Health; 410 IAC 7-20-223; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1955)

410 IAC 7-20-224 Manual warewashing equipment; heaters and baskets

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 224. If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be:

(1) designed with an integral heating device that is capable of maintaining water at a temperature not less than one hundred seventy (170) degrees Fahrenheit; and

(2) provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.

(Indiana State Department of Health; 410 IAC 7-20-224; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1955)

410 IAC 7-20-225 Warewashing machines; sanitizer level indicator

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 225. A warewashing machine that uses a chemical for sanitization and that is installed after the effective date of this rule shall be equipped with a device that indicates audibly or visually when more chemical sanitizer needs to be added. *(Indiana State Department of Health; 410 IAC 7-20-225; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1955)*

410 IAC 7-20-226 Warewashing machines; flow pressure device

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 226. (a) Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine.

(b) If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device shall be mounted in a one-fourth (¼) inch iron pipe size (IPS) valve.

(c) Subsections (a) and (b) do not apply to a machine that uses only a pumped or recirculated sanitizing rinse. *(Indiana State Department of Health; 410 IAC 7-20-226; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1955)*

410 IAC 7-20-227 Warewashing sinks and drainboards; self-draining

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 227. Sinks and drainboards of warewashing sinks and machines shall be self-draining. *(Indiana State Department of Health; 410 IAC 7-20-227; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1955)*

410 IAC 7-20-228 Equipment compartments; drainage

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 228. Equipment compartments that are subject to accumulation of moisture due to conditions, such as condensation, food or beverage drip, or water from melting ice, shall be sloped to an outlet that allows complete draining. *(Indiana State Department of Health; 410 IAC 7-20-228; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1955)*

410 IAC 7-20-229 Vending machines; liquid waste products

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 229. (a) Vending machines designed to store beverages that are packaged in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.

(b) Vending machines that dispense liquid food in bulk shall be:

(1) provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow, or other internal wastes; and

(2) equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.

(c) Shutoff devices specified under subsection (b)(2) shall prevent water or liquid food from continuously running if there is a failure of a flow control device in the water or liquid food system or waste accumulation that could lead to overflow of the waste receptacle. *(Indiana State Department of Health; 410 IAC 7-20-229; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1955)*

410 IAC 7-20-230 Vending machine doors and openings

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 230. (a) Vending machine doors and access opening covers to food and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than one-sixteenth (1/16) inch by any of the following:

(1) Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than one-sixteenth (1/16) inch. Screening of twelve (12) mesh to one (1) inch meets this requirement.

(2) Being effectively gasketed.

(3) Having interface surfaces that are at least one-half (½) inch wide.

(4) Jambs or surfaces used to form an L-shaped entry path to the interface.

(b) Vending machine service connection openings through an exterior wall of a machine shall be closed by sealants, clamps, or grommets so that the openings are no larger than one-sixteenth (1/16) inch. *(Indiana State Department of Health; 410 IAC 7-20-230; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1956)*

410 IAC 7-20-231 Food equipment; certification and classification

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 231. Food equipment that is certified or classified for sanitation by an American National Standards Institute-accredited certification program will be deemed to comply with sections 184 through 230 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-231; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1956)*

410 IAC 7-20-232 Cooling, heating, and holding capacities

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 232. Equipment for cooling and heating food, and holding cold and hot food shall be sufficient in number and capacity to provide food temperatures as specified under sections 117 through 183 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-232; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1956)*

410 IAC 7-20-233 Manual warewashing; sink compartment requirements

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 233. (a) Except as specified in subsection (c), a sink with at least three (3) compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.

(b) Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in subsection (c) shall be used.

(c) Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include the following:

(1) High-pressure detergent sprayers.
(2) Low-pressure or line-pressure spray detergent foamers.
(3) Other task-specific cleaning equipment.
(4) Brushes or other implements.
(5) Two (2) compartment sinks as specified under subsections (d) and (e).
(6) Receptacles that substitute for the compartments of a multicompartment sink.

(d) Before a two (2) compartment sink is used:

(1) The retail food establishment shall have its use approved; and

(2) The nature of warewashing shall be limited to batch operations for cleaning kitchenware, such as between cutting one (1) type of raw meat and another or cleanup at the end of a shift as follows:

(A) A limited number of items shall be cleaned.

(B) The cleaning and sanitizing solutions shall be made up immediately before use and drained immediately after use; and

(C) A detergent-sanitizer shall be used to sanitize and shall be applied as specified under section 258 of this rule, or

(D) A hot water sanitization immersion step shall be used as specified under section 273(3) of this rule.

(e) A two (2) compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process. *(Indiana State Department of Health; 410 IAC 7-20-233; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1956)*

410 IAC 7-20-234 Drainboards

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 234. Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate

during hours of operation shall be provided for necessary utensil holding before cleaning and after sanitizing. *(Indiana State Department of Health; 410 IAC 7-20-234; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1957)*

410 IAC 7-20-235 Ventilation hood systems; adequacy

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 235. Ventilation hood systems and devices shall meet the requirements of the Indiana department of fire and building safety and be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings. *(Indiana State Department of Health; 410 IAC 7-20-235; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1957)*

410 IAC 7-20-236 Clothes washers and dryers

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 236. (a) Except as specified in subsection (b), if work clothes or linens are laundered on the premises, a mechanical clothes washer and dryer shall be provided and used.

(b) If on-premises laundering is limited to wiping cloths intended to be used wet, or wiping cloths are air-dried as specified under section 283 of this rule, a mechanical clothes washer and dryer need not be provided. *(Indiana State Department of Health; 410 IAC 7-20-236; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1957)*

410 IAC 7-20-237 Utensils; consumer self-service

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 237. A food dispensing utensil shall be available for each container displayed at a consumer self-service unit, such as a buffet or salad bar. *(Indiana State Department of Health; 410 IAC 7-20-237; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1957)*

410 IAC 7-20-238 Food temperature measuring devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 238. Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under sections 117 through 183 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-238; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1957)*

410 IAC 7-20-239 Temperature measuring devices; manual warewashing

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 239. In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures. *(Indiana State Department of Health; 410 IAC 7-20-239; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1957)*

410 IAC 7-20-240 Sanitizing solutions; testing devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 240. A test kit or other device that accurately measures the concentration in ppm of sanitizing solutions shall be provided. *(Indiana State Department of Health; 410 IAC 7-20-240; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1957)*

410 IAC 7-20-241 Equipment, clothes washers, dryers, and storage cabinets

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 241. (a) Except as specified in subsection (b), equipment, a cabinet used for the storage of food, or a cabinet that is used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be located:

(1) in locker rooms;
(2) in toilet rooms;
(3) in garbage rooms;
(4) in mechanical rooms, when contamination is likely to occur;
(5) under sewer lines that are not shielded to intercept potential drips;
(6) under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
(7) under open stairwells; or
(8) under other sources of contamination.

(b) A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.

(c) If a mechanical clothes washer or dryer is provided, it shall be located so that the washer or dryer is protected from contamination and only where there is no:

(1) exposed food;
(2) clean equipment, utensils, and linens; and
(3) unwrapped single-service and single-use articles.

(Indiana State Department of Health; 410 IAC 7-20-241; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1957)

410 IAC 7-20-242 Fixed equipment; spacing or sealing

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 242. (a) Equipment that is fixed because it is not easily movable shall be installed so that it is:

(1) spaced to allow access for cleaning along the sides, behind, and above the equipment;
(2) spaced from adjoining equipment, walls, and ceilings a distance of not more than one thirty-second (1/32) inch; or
(3) sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.

(b) Table-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being:

(1) sealed to the table; or
(2) elevated on legs as specified under section 243(d) of this rule.

(Indiana State Department of Health; 410 IAC 7-20-242; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1958)

410 IAC 7-20-243 Fixed equipment; elevation or sealing

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 243. (a) Except as specified in subsections (b) and (c), floor-mounted equipment that is not easily movable shall be sealed to the floor or elevated on legs that provide at least a six (6) inch clearance between the floor and the equipment.

(b) If no part of the floor under the floor-mounted equipment is more than six (6) inches from the point of cleaning access, the clearance space may be only four (4) inches.

(c) This section does not apply to display shelving units, display refrigeration units, and display freezer units located in consumer shopping areas, such as in a grocery store, if the floor under the units is maintained clean.

(d) Except as specified in subsection (e), table-mounted equipment that is not easily movable shall be elevated on legs that provide at least a four (4) inch clearance between the table and the equipment.

(e) The clearance space between the table and table-mounted equipment may be:

(1) three (3) inches if the horizontal distance of the table top under the equipment is no more than twenty (20) inches from the point of access for cleaning; or

(2) two (2) inches if the horizontal distance of the table top under the equipment is no more than three (3) inches from the point of access for cleaning.

(Indiana State Department of Health; 410 IAC 7-20-243; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1958)

410 IAC 7-20-244 Repair and proper adjustment of equipment

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 244. (a) Equipment shall be maintained in a state of repair and condition that meets the requirements specified under sections 184 through 231 of this rule.

(b) Equipment components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.

(c) Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened. *(Indiana State Department of Health; 410 IAC 7-20-244; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1958)*

410 IAC 7-20-245 Food equipment; cutting surfaces

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 245. Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded if they are not capable of being resurfaced. *(Indiana State Department of Health; 410 IAC 7-20-245; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1958)*

410 IAC 7-20-246 Microwave ovens

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 246. Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10. *(Indiana State Department of Health; 410 IAC 7-20-246; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1958)*

410 IAC 7-20-247 Warewashing equipment; cleaning frequency

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 247. A warewashing machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, or raw foods, or laundering wiping cloths; and drainboards or other equipment used to substitute for drainboards as specified under section 234 of this rule shall be cleaned:

(1) before use;

(2) throughout the day at a frequency necessary to prevent recontamination of equipment and utensils and to ensure that the equipment performs its intended function; and

(3) if used, at least every twenty four (24) hours.

(Indiana State Department of Health; 410 IAC 7-20-247; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1958)

410 IAC 7-20-248 Warewashing machines; manufacturer's operating instructions

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 248. (a) A warewashing machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.

(b) A warewashing machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance

with manufacturer's specifications. *(Indiana State Department of Health; 410 IAC 7-20-248; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1959)*

410 IAC 7-20-249 Warewashing sinks; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 249. (a) A warewashing sink may not be used for handwashing or as a service sink.

(b) If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink shall be cleaned as specified under section 247 of this rule before and after each time it is used to wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified under sections 275 and 276 of this rule before and after using the sink to wash or thaw food. *(Indiana State Department of Health; 410 IAC 7-20-249; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1959)*

410 IAC 7-20-250 Warewashing equipment; cleaning agents

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 250. When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in section 233(c) of this rule, shall contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions. *(Indiana State Department of Health; 410 IAC 7-20-250; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1959; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-251 Warewashing equipment; clean solutions

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 251. The wash, rinse, and sanitize solutions shall be maintained clean. *(Indiana State Department of Health; 410 IAC 7-20-251; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1959)*

410 IAC 7-20-252 Manual warewashing equipment; wash solution temperature

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 252. The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than one hundred ten (110) degrees Fahrenheit or the temperature specified on the cleaning agent manufacturer's label instructions. *(Indiana State Department of Health; 410 IAC 7-20-252; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1959)*

410 IAC 7-20-253 Mechanical warewashing equipment; wash solution temperature

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 253. (a) The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than:

(1) for a stationary rack, single temperature machine, one hundred sixty-five (165) degrees Fahrenheit;
(2) for a stationary rack, dual temperature machine, one hundred fifty (150) degrees Fahrenheit;
(3) for a single tank, conveyor, dual temperature machine, one hundred sixty (160) degrees Fahrenheit; or
(4) for a multi-tank, conveyor, multi-temperature machine, one hundred fifty (150) degrees Fahrenheit.

(b) The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than one hundred twenty (120) degrees Fahrenheit. *(Indiana State Department of Health; 410 IAC 7-20-253; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1959; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-254 Manual warewashing equipment; hot water sanitization temperatures

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 254. If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at one hundred seventy (170) degrees Fahrenheit or above. *(Indiana State Department of Health; 410 IAC 7-20-254; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1959)*

410 IAC 7-20-255 Mechanical warewashing equipment; hot water sanitization temperatures

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 255. (a) Except as specified in subsection (b), in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than one hundred ninety-four (194) degrees Fahrenheit, or less than:

(1) for a stationary rack, single temperature machine, one hundred sixty-five (165) degrees Fahrenheit; or

(2) for all other machines, one hundred eighty (180) degrees Fahrenheit.

(b) The maximum temperature specified under subsection (a) does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the in-place cleaning and sanitizing of equipment, such as meat saws. *(Indiana State Department of Health; 410 IAC 7-20-255; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1959)*

410 IAC 7-20-256 Mechanical warewashing equipment; sanitization pressure

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 256. The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine may not be less than fifteen (15) pounds per square inch or more than twenty-five (25) pounds per square inch as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve. *(Indiana State Department of Health; 410 IAC 7-20-256; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1960)*

410 IAC 7-20-257 Manual and mechanical warewashing equipment; chemical sanitization; temperature, pH, concentration, and hardness

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 257. A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at exposure times specified under section 276(3) of this rule shall be listed in 21 CFR 178.1010, used in accordance with the manufacturer's label use instructions, and used as follows:

(1) A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart:

Minimum Concentration	Minimum Temperature	
ppm	pH 10 or less ^{o}F	pH 8 or less ^{o}F
25	120	120
50	100	75
100	55	55

(2) An iodine solution shall have a:

(A) minimum temperature of seventy-five (75) degrees Fahrenheit;

(B) pH of five (5.0) or less or a pH no higher than the level for which the manufacturer specifies the solution is effective; and

(C) concentration between twelve and one-half (12.5) ppm and twenty-five (25) ppm.

(3) A quaternary ammonium compound solution shall:

(A) have a minimum temperature of seventy-five (75) degrees Fahrenheit;

(B) have a concentration as specified under section 413 of this rule and as indicated by the manufacturer's use directions included in the labeling; and

(C) be used only in water with five hundred (500) ppm hardness or less or in water having a hardness no greater than specified by the manufacturer's label.

(4) If another solution of a chemical specified under subdivisions (1) through (3) is used, the retail food establishment shall demonstrate to the regulatory authority that the solution achieves sanitization and the use of the solution shall be approved.

(5) If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling.

(Indiana State Department of Health; 410 IAC 7-20-257; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1960; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)

410 IAC 7-20-258 Manual warewashing equipment; chemical sanitization using detergent-sanitizers

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 258. If a detergent-sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step shall be the same detergent-sanitizer that is used in the washing step. *(Indiana State Department of Health; 410 IAC 7-20-258; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1960)*

410 IAC 7-20-259 Warewashing equipment; determining chemical sanitizer concentration

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 259. Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device. *(Indiana State Department of Health; 410 IAC 7-20-259; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1960)*

410 IAC 7-20-260 Good repair and calibration

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 260. (a) Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under sections 184 through 231 of this rule or shall be discarded.

(b) Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.

(c) Ambient air temperature, water pressure, and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use. *(Indiana State Department of Health; 410 IAC 7-20-260; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1960)*

410 IAC 7-20-261 Single-service and single-use articles; required use

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 261. A retail food establishment without facilities specified under sections 264 through 276 of this rule for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers. *(Indiana State Department of Health; 410 IAC 7-20-261; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1961)*

410 IAC 7-20-262 Single-service and single-use articles; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 262. (a) Single-service and single-use articles may not be reused.

(b) The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one (1) inch protruding from the chilled dispensing head. *(Indiana State Department of Health; 410 IAC 7-20-262; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1961)*

410 IAC 7-20-263 Shells; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 263. Mollusk and crustacea shells may not be used more than once as serving containers. *(Indiana State Department of Health; 410 IAC 7-20-263; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1961)*

410 IAC 7-20-264 Equipment, food-contact surfaces, nonfood-contact surfaces, and utensils

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 264. (a) Equipment food-contact surfaces and utensils shall be clean to sight and touch.

(b) The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations.

(c) Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris. *(Indiana State Department of Health; 410 IAC 7-20-264; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1961)*

410 IAC 7-20-265 Cleaning frequency of equipment food-contact surfaces and utensils

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 265. (a) Equipment food-contact surfaces and utensils shall be cleaned as follows:

(1) Except as specified in subsection (b), before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry.

(2) Each time there is a change from working with raw foods to working with ready-to-eat foods.

(3) Between uses with raw fruits and vegetables and with potentially hazardous food.

(4) Before using or storing a food temperature measuring device.

(5) At any time during the operation when contamination may have occurred.

(b) Subsection (a)(1) does not apply if the food-contact surface or utensil is in contact with a succession of different raw animal foods each requiring a higher cooking temperature as specified under section 161 of this rule than the previous food, such as preparing raw fish followed by cutting raw poultry on the same cutting board.

(c) Except as specified in subsection (d), if used with potentially hazardous food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every four (4) hours.

(d) Surfaces of utensils and equipment contacting potentially hazardous food may be cleaned less frequently than every four (4) hours if the following applies:

(1) In storage, containers of potentially hazardous food and their contents are maintained at temperatures specified under sections 117 through 183 of this rule and the containers are cleaned when they are empty.

(2) Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one (1) of the temperatures in the following chart and:

(A) The utensils and equipment are cleaned at the frequency in the chart in clause (A) that corresponds to the temperature:

Temperature	Cleaning Frequency
41˚F or less	24 hours
>41˚F - 45˚F	20 hours
>45˚F - 50˚F	16 hours
>50˚F - 55˚F	10 hours

(B) The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the retail food establishment.

(3) Containers in serving situations, such as salad bars, delis, and cafeteria lines, hold ready-to-eat potentially hazardous food that is maintained at the temperatures specified under sections 117 through 183 of this rule, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every twenty-four (24) hours.

(4) Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under sections 117 through 183 of this rule.

(5) Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues.

(6) The cleaning schedule is approved based on consideration of the following:

(A) Characteristics of the equipment and its use.

(B) The type of food involved.

(C) The amount of food residue accumulation.

(D) The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic micro-organisms that are capable of causing foodborne disease.

(7) In-use utensils are intermittently stored in a container of water in which the water is maintained at one hundred forty (140) degrees Fahrenheit or more and the utensils and container are cleaned at least every twenty-four (24) hours or at a frequency necessary to preclude accumulation of soil residues.

(e) Except when dry cleaning methods are used as specified under section 268 of this rule, surfaces of utensils and equipment contacting food that is not potentially hazardous shall be cleaned as follows:

(1) At any time when contamination may have occurred.

(2) At least every twenty-four (24) hours for iced tea dispensers and consumer self-service utensils, such as tongs, scoops, or ladles.

(3) Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers.

(4) In equipment such as ice bins and beverage dispensing nozzles, and enclosed components of equipment, such as ice makers, cooking oil storage tanks and distribution lines, beverage and syrup dispensing lines or tubes, coffee bean grinders, and water vending equipment:

(A) at a frequency specified by the manufacturer; or

(B) absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

(Indiana State Department of Health; 410 IAC 7-20-265; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1961)

410 IAC 7-20-266 Cooking and baking equipment

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 266. (a) The food-contact surfaces of cooking and baking equipment shall be cleaned at least every twenty-four (24) hours. This section does not apply to hot oil cooking and filtering equipment if it is cleaned as specified in section 265(d)(6) of this rule.

(b) The cavities and door seals of microwave ovens shall be cleaned at least every twenty-four (24) hours by using the manufacturer's recommended cleaning procedure. *(Indiana State Department of Health; 410 IAC 7-20-266; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1962)*

410 IAC 7-20-267 Nonfood-contact surfaces

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 267. Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues. *(Indiana State Department of Health; 410 IAC 7-20-267; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1962)*

410 IAC 7-20-268 Dry cleaning

Authority: IC 16-42-5-5
Affected: IC 16-42

Sec. 268. (a) If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not potentially hazardous.

(b) Cleaning equipment used in dry cleaning food-contact surfaces may not be used for any other purpose. *(Indiana State Department of Health; 410 IAC 7-20-268; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1962)*

410 IAC 7-20-269 Precleaning

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 269. (a) Food debris on equipment and utensils shall be scrapped over a waste disposal unit, garbage receptacle or shall be removed in a warewashing machine with a prewash cycle.

(b) If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked, or scrubbed with abrasives. *(Indiana State Department of Health; 410 IAC 7-20-269; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1962)*

410 IAC 7-20-270 Loading of soiled item; warewashing machines

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 270. Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

(1) exposes the items to the unobstructed spray from all cycles; and
(2) allows the items to drain.

(Indiana State Department of Health; 410 IAC 7-20-270; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1962)

410 IAC 7-20-271 Wet cleaning

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 271. (a) Equipment food-contact surfaces and utensils shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary, such as the application of:

(1) detergents containing wetting agents and emulsifiers;
(2) acid, alkaline, or abrasive cleaners;
(3) hot water;
(4) brushes;
(5) scouring pads;
(6) high-pressure sprays; or
(7) ultrasonic devices.

(b) The washing procedures selected shall be based on the:

(1) type and purpose of the equipment or utensil; and
(2) type of soil to be removed.

(Indiana State Department of Health; 410 IAC 7-20-271; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1963)

410 IAC 7-20-272 Washing; procedures for alternative manual warewashing equipment

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 272. If washing in sink compartments or a warewashing machine is impractical, such as when the equipment is fixed or the utensils are too large, washing shall be done by using alternative manual warewashing equipment as specified in section 233(c) of this rule in accordance with the following procedures:

(1) Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts.

(2) Equipment components and utensils shall be scraped or rough cleaned to remove food particle accumulation.

(3) Equipment and utensils shall be washed as specified under section 271(a) of this rule.

(Indiana State Department of Health; 410 IAC 7-20-272; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1963)

410 IAC 7-20-273 Rinsing procedures

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 273. Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one (1) of the following procedures:

(1) Use of a distinct, separate water rinse after washing and before sanitizing if using:

(A) a three (3) compartment sink;

(B) alternative manual warewashing equipment equivalent to a three (3) compartment sink as specified in section 233(c) of this rule; or

(C) a three (3) step washing, rinsing, and sanitizing procedure in a warewashing system for CIP equipment.

(2) Use of a detergent-sanitizer as specified under section 258 of this rule if using:

(A) alternative warewashing equipment as specified in section 233(c) of this rule that is approved for use with a detergent-sanitizer; or

(B) a warewashing system for CIP equipment.

(3) Use of a nondistinct water rinse that is integrated in the hot water sanitization immersion step of a two (2) compartment sink operation.

(4) If using a warewashing machine that does not recycle the sanitizing solution as specified under subdivision (5), or alternative manual warewashing equipment, such as sprayers, use of a nondistinct water rinse that is:

(A) integrated in the application of the sanitizing solution; and

(B) wasted immediately after each application.

(5) If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the sanitizing solution.

(Indiana State Department of Health; 410 IAC 7-20-273; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1963)

410 IAC 7-20-274 Returnables; cleaning for refilling

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 274. (a) Except as specified in this section, returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.

(b) Food containers for beverages may be refilled at a retail food establishment if:

(1) only a beverage that is not a potentially hazardous food is used as specified under section 151(a) of this rule;

(2) the design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow for effective cleaning;

(3) the consumer-owned container returned to the retail food establishment for refilling is refilled for sale or service only to the same consumer; and

(4) the container is refilled by:

(A) an employee of the retail food establishment; or

(B) the owner of the container if the beverage system includes a contamination-free transfer process that cannot be bypassed by the container owner.

(c) Consumer-owned containers that are not food-specific may be filled at a water vending machine or system. *(Indiana State Department of Health; 410 IAC 7-20-274; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1963)*

410 IAC 7-20-275 Sanitization of food-contact surfaces

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 275. Utensils and food-contact surfaces of equipment shall be sanitized immediately after cleaning. *(Indiana State Department of Health; 410 IAC 7-20-275; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1964)*

410 IAC 7-20-276 Hot water and chemical sanitizing methods

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 276. After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:

(1) hot water manual operations by immersion for at least thirty (30) seconds as specified under section 254 of this rule;

(2) hot water mechanical operations by being cycled through equipment that is set up as specified under sections 248, 255, and 256 of this rule and achieving a utensil surface temperature of one hundred sixty (160) degrees Fahrenheit as measured by an irreversible registering temperature indicator; or

(3) chemical manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under section 257 of this rule by providing:

(A) except as specified under clause (B), an exposure time of at least ten (10) seconds for a chlorine solution specified under section 257(1) of this rule;

(B) an exposure time of at least seven (7) seconds for a chlorine solution of fifty (50) ppm that has a pH of ten (10) or less and a temperature of at least one hundred (100) degrees Fahrenheit or a pH of eight (8) or less and a temperature of at least seventy-five (75) degrees Fahrenheit;

(C) an exposure time of at least thirty (30) seconds for other chemical sanitizing solutions; or

(D) an exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in section 72 of this rule.

(Indiana State Department of Health; 410 IAC 7-20-276; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1964)

410 IAC 7-20-277 Clean linens

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 277. Clean linens shall be free from food residues and other soiling matter. *(Indiana State Department of Health; 410 IAC 7-20-277; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1964)*

410 IAC 7-20-278 Specifications for laundering

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 278. (a) Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.

(b) Cloth gloves used as specified in section 149(d) of this rule shall be laundered before being used with a different type of raw animal food, such as beef, lamb, pork, and fish.

(c) Linens and napkins that are used as specified under section 147 of this rule and cloth napkins shall be laundered between

each use.

(d) Wet wiping cloths shall be laundered daily.

(e) Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils. *(Indiana State Department of Health; 410 IAC 7-20-278; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1964)*

410 IAC 7-20-279 Storage of soiled linens

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 279. Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single-service and single-use articles. *(Indiana State Department of Health; 410 IAC 7-20-279; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1964)*

410 IAC 7-20-280 Mechanical washing

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 280. (a) Except as specified in subsection (b), linens shall be mechanically washed.

(b) In retail food establishments in which only wiping cloths are laundered as specified in section 236(b) of this rule, the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a warewashing or food preparation sink that is cleaned as specified under section 247 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-280; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1964)*

410 IAC 7-20-281 Use of laundry facilities

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 281. (a) Except as specified in subsection (b), laundry facilities on the premises of a retail food establishment shall be used only for the washing and drying of items used in the operation of the establishment.

(b) Separate laundry facilities located on the premises for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering retail food establishment items. *(Indiana State Department of Health; 410 IAC 7-20-281; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1964)*

410 IAC 7-20-282 Equipment and utensils; air drying required

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 282. After cleaning and sanitizing, equipment and utensils:

(1) shall be air-dried or used after adequate draining as specified in 21 CFR 178.1010(a), before contact with food; and

(2) may not be cloth dried except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

(Indiana State Department of Health; 410 IAC 7-20-282; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1965)

410 IAC 7-20-283 Wiping cloths; air drying locations

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 283. Wiping cloths laundered in a retail food establishment that does not have a mechanical clothes dryer as specified in section 236(b) of this rule shall be air-dried in a location and in a manner that prevents contamination of food, equipment, utensils, linens, and single-service and single-use articles and the wiping cloths. This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified under section 257 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-*

283; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1965)

410 IAC 7-20-284 Lubricants for food-contact surfaces

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 284. Lubricants shall be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces. *(Indiana State Department of Health; 410 IAC 7-20-284; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1965)*

410 IAC 7-20-285 Protection of equipment

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 285. Equipment shall be reassembled so that food-contact surfaces are not contaminated. *(Indiana State Department of Health; 410 IAC 7-20-285; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1965)*

410 IAC 7-20-286 Equipment, utensils, linens, and single-service and single-use articles

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 286. (a) Except as specified in subsection (d), cleaned equipment and utensils, laundered linens, and single-service and single-use articles shall be stored as follows:

(1) In a clean, dry location.

(2) Where they are not exposed to splash, dust, or other contamination.

(3) At least six (6) inches above the floor.

(b) Clean equipment and utensils shall be stored as specified under subsection (a) and shall be stored as follows:

(1) In a self-draining position that allows air drying.

(2) Covered or inverted.

(c) Single-service and single-use articles shall be stored as specified under subsection (a) and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.

(d) Items that are kept in closed packages may be stored less than six (6) inches above the floor on dollies, pallets, racks, and skids. *(Indiana State Department of Health; 410 IAC 7-20-286; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1965)*

410 IAC 7-20-287 Storage prohibitions

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 287. (a) Except as specified in subsection (b), cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be stored as follows:

(1) In locker rooms.

(2) In toilet rooms.

(3) In garbage rooms.

(4) In mechanical rooms, when contamination is likely to occur.

(5) Under sewer lines that are not shielded to intercept potential drips.

(6) Under leaking water lines, including leaking automatic fire sprinkler heads or under lines on which water has condensed.

(7) Under open stairwells.

(8) Under other sources of contamination.

(b) Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room. *(Indiana State Department of Health; 410 IAC 7-20-287; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1965)*

410 IAC 7-20-288 Handling of kitchenware and tableware

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 288. (a) Single-service articles, single-use articles, and utensils that have been sanitized shall be handled, displayed, and dispensed so that contamination of food-contact and lip-contact surfaces is prevented.

(b) Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by employees and by consumers if consumer self-service is provided.

(c) Except as specified under subsection (b), single-service articles that are intended for food-contact or lip-contact shall be furnished for consumer self-service with the original individual wrapper intact or from an approved dispenser. *(Indiana State Department of Health; 410 IAC 7-20-288; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-289 Handling of soiled and clean kitchenware

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 289. Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated. *(Indiana State Department of Health; 410 IAC 7-20-289; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-290 Protection of preset tableware

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 290. If tableware is preset:

(1) it shall be protected from contamination by being wrapped, covered, or inverted;

(2) exposed unused settings shall be removed when a consumer is seated; or

(3) exposed, unused settings shall be cleaned and sanitized before further use if the settings are not removed when a consumer is seated.

(Indiana State Department of Health; 410 IAC 7-20-290; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)

410 IAC 7-20-291 Water source

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 291. Drinking water shall be obtained from a source which meets the quality standards as specified in 327 IAC 8-2. *(Indiana State Department of Health; 410 IAC 7-20-291; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-292 System flushing and disinfection

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 292. A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system. *(Indiana State Department of Health; 410 IAC 7-20-292; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-293 Bottled drinking water

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 293. Bottled drinking water used or sold in a retail food establishment shall be obtained from approved sources in accordance with 21 CFR 129. *(Indiana State Department of Health; 410 IAC 7-20-293; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-294 Nondrinking water

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 294. Nondrinking water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, fire protection, and irrigation. *(Indiana State Department of Health; 410 IAC 7-20-294; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-295 Water sampling

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 295. Except when used as specified under section 294 of this rule, water from a nonpublic water system shall be sampled and tested at least annually and as required by state water quality regulations. *(Indiana State Department of Health; 410 IAC 7-20-295; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-296 Water sample report

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 296. The most recent sample report for the nonpublic water system shall be provided to the regulatory authority upon request. *(Indiana State Department of Health; 410 IAC 7-20-296; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-297 Capacity

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 297. (a) The water source and system shall be of sufficient capacity to meet the water demands of the retail food establishment.

(b) Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the retail food establishment. *(Indiana State Department of Health; 410 IAC 7-20-297; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1966)*

410 IAC 7-20-298 Water pressure

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 298. Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water, except that water supplied as specified under sections *[section]* 300(1) and 300(2) of this rule to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure. *(Indiana State Department of Health; 410 IAC 7-20-298; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1967)*

410 IAC 7-20-299 Water distribution, delivery, and retention system

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 299. Water shall be received from the source through the use of either of the following:

(1) A public water main.

(2) One (1) or more of the following that shall be constructed, maintained, and operated according to law:

(A) Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances.

(B) Water transport vehicles.

(C) Water containers.

(Indiana State Department of Health; 410 IAC 7-20-299; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1967)

410 IAC 7-20-300 Alternative water supply

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 300. Water meeting the requirements specified under sections 291 through 298 of this rule shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a retail food establishment with a temporary interruption of its water supply through:

(1) a supply of containers of commercially bottled drinking water;
(2) one (1) or more closed portable water containers;
(3) an enclosed vehicular water tank;
(4) an on-premises water storage tank; or
(5) piping, tubing, or hoses connected to an adjacent approved source.

(Indiana State Department of Health; 410 IAC 7-20-300; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1967)

410 IAC 7-20-301 Approved plumbing system materials

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 301. (a) A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to law.

(b) Water treatment devices shall be made of safe materials. *(Indiana State Department of Health; 410 IAC 7-20-301; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1967)*

410 IAC 7-20-302 Design, construction, and installation of approved plumbing system and cleanable fixtures

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 302. (a) A plumbing system shall be designed, constructed, and installed according to applicable Indiana plumbing code.

(b) A plumbing fixture such as a handwashing facility, toilet, or urinal shall be easily cleanable. *(Indiana State Department of Health; 410 IAC 7-20-302; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1967)*

410 IAC 7-20-303 Handwashing facility; water temperature and flow

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 303. (a) A handwashing facility shall be equipped to provide hot and cold water tempered by means of a mixing valve or combination faucet.

(b) A steam mixing valve may not be used at a handwashing lavatory.

(c) A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least fifteen (15) seconds without the need to reactivate the faucet.

(d) An automatic handwashing facility shall be installed in accordance with manufacturer's instructions. *(Indiana State Department of Health; 410 IAC 7-20-303; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1967)*

410 IAC 7-20-304 Backflow prevention; air gap

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 304. An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than one (1) inch. *(Indiana State Department of Health; 410 IAC 7-20-304; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1967)*

410 IAC 7-20-305 Backflow prevention device; design standard

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 305. A backflow or backsiphonage prevention device installed on a water supply system shall meet the standards in 675 IAC 16-1.3 for construction, installation, maintenance, inspection, and testing for that specific application and type of device. *(Indiana State Department of Health; 410 IAC 7-20-305; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1967)*

410 IAC 7-20-306 Water conditioning device; design

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 306. A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type. *(Indiana State Department of Health; 410 IAC 7-20-306; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1968)*

410 IAC 7-20-307 Handwashing lavatories; numbers and capacities

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 307. (a) Except as specified in subsection (b), at least one (1) handwashing lavatory, a number of handwashing lavatories necessary for their convenient use by employees in areas specified under section 311 of this rule, and not fewer than the number of handwashing lavatories required by 675 IAC 16-1.3 shall be provided.

(b) If approved and capable of removing the types of soils encountered in the food operations involved, automatic handwashing facilities may be substituted for handwashing lavatories in a retail food establishment that has at least one (1) handwashing lavatory.

(c) If approved, when food exposure is limited, and handwashing lavatories can not be made available, employees in some mobile or temporary food establishments or at some vending machine locations may use other effective means for handwashing. *(Indiana State Department of Health; 410 IAC 7-20-307; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1968; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-308 Toilets and urinals

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 308. At least one (1) toilet and not fewer than the toilets required by law shall be provided. If authorized by law and urinals are substituted for toilets, the substitution shall be done as specified in laws of the Indiana department of fire and building safety. *(Indiana State Department of Health; 410 IAC 7-20-308; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1968)*

410 IAC 7-20-309 Service sink

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 309. At least one (1) service sink or one (1) curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste. *(Indiana State Department of Health; 410 IAC 7-20-309; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1968)*

410 IAC 7-20-310 Backflow prevention device; when required

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 310. A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the retail food establishment, including on hose bibbs with or without a hose attached, and backflow prevention is required by plumbing code, by:

(1) providing an air gap as specified under section 304 of this rule; or

(2) installing an approved backflow prevention device as specified under section 305 of this rule.

(Indiana State Department of Health; 410 IAC 7-20-310; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1968)

410 IAC 7-20-311 Handwashing facility location

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 311. A handwashing facility shall be accessible at all times and located as follows:

(1) To allow convenient use by employees in food preparation, food dispensing, and warewashing areas.

(2) In, or immediately adjacent to, toilet rooms.

(Indiana State Department of Health; 410 IAC 7-20-311; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1968)

410 IAC 7-20-312 Backflow prevention device; location

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 312. A backflow prevention device shall be located so that it may be serviced and maintained. *(Indiana State Department of Health; 410 IAC 7-20-312; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1968)*

410 IAC 7-20-313 Water conditioning device; location

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 313. A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning. *(Indiana State Department of Health; 410 IAC 7-20-313; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1968)*

410 IAC 7-20-314 Handwashing facility maintenance

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 314. (a) A handwashing facility shall be maintained clean at all times for employee use.

(b) A handwashing facility may not be used for purposes other than handwashing.

(c) A handwashing facility shall be used in accordance with manufacturer's instruction. *(Indiana State Department of Health; 410 IAC 7-20-314; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1969; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-315 Prohibiting a cross connection

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 315. (a) Except for firefighting purposes, a person may not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.

(b) The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water. *(Indiana State Department of Health; 410 IAC 7-20-315; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1969)*

410 IAC 7-20-316 Scheduling inspection and service for a water system device

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 316. A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be provided to the regulatory authority upon request. *(Indiana State Department of Health; 410 IAC 7-20-316; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1969)*

410 IAC 7-20-317 Water reservoir of fogging devices; cleaning

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 317. (a) A reservoir that is used to supply water to a device, such as a produce fogger, shall be:
(1) maintained in accordance with manufacturer's specifications; and
(2) cleaned in accordance with manufacturer's specifications or according to the procedures specified under subsection (b), whichever is more stringent.
(b) Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:
(1) Draining and complete disassembly of the water and aerosol contact parts.
(2) Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution.
(3) Flushing the complete system with water to remove the detergent solution and particulate accumulation.
(4) Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least fifty (50) ppm hypochlorite solution.

(Indiana State Department of Health; 410 IAC 7-20-317; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1969)

410 IAC 7-20-318 Plumbing system maintained in good repair

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 318. A plumbing system shall be:
(1) repaired according to law; and
(2) maintained in good repair.

(Indiana State Department of Health; 410 IAC 7-20-318; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1969)

410 IAC 7-20-319 Mobile water tank and mobile retail food establishment water tank materials

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 319. Materials that are used in the construction of a mobile water tank, mobile retail food establishment water tank, and appurtenances shall be:
(1) safe;
(2) durable, corrosion-resistant, and nonabsorbent; and
(3) finished to have a smooth, easily cleanable surface.

(Indiana State Department of Health; 410 IAC 7-20-319; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1969)

410 IAC 7-20-320 Enclosed system; sloped to drain

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 320. A mobile water tank shall be:
(1) enclosed from the filling inlet to the discharge outlet; and

(2) sloped to an outlet that allows complete drainage of the tank.
(Indiana State Department of Health; 410 IAC 7-20-320; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1969)

410 IAC 7-20-321 Inspection and cleaning port; protected and secured

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 321. If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

(1) flanged upward at least one-half (½) inch; and
(2) equipped with a port cover assembly that is:
(A) provided with a gasket and a device for securing the cover in place; and
(B) flanged to overlap the opening and sloped to drain.
(Indiana State Department of Health; 410 IAC 7-20-321; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1969)

410 IAC 7-20-322 "V" type threads; use limitation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 322. A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached. *(Indiana State Department of Health; 410 IAC 7-20-322; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)*

410 IAC 7-20-323 Tank vent; protected

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 323. If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

(1) sixteen (16) mesh to one (1) inch screen or equivalent when the vent is in a protected area; or
(2) a protective filter when the vent is in an area that is not protected from windblown dirt and debris.
(Indiana State Department of Health; 410 IAC 7-20-323; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)

410 IAC 7-20-324 Inlet and outlet; sloped to drain

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 324. (a) A water tank and its inlet and outlet shall be sloped to drain.

(b) A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease. *(Indiana State Department of Health; 410 IAC 7-20-324; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)*

410 IAC 7-20-325 Hose; construction and identification

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 325. A hose used for conveying drinking water from a water tank shall be:

(1) safe;
(2) durable, corrosion-resistant, and nonabsorbent;
(3) resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;
(4) finished with a smooth interior surface; and
(5) clearly and durably identified as to its use if not permanently attached.
(Indiana State Department of Health; 410 IAC 7-20-325; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)

410 IAC 7-20-326 Filter; compressed air

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 326. A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is used to pressurize the water tank system. *(Indiana State Department of Health; 410 IAC 7-20-326; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)*

410 IAC 7-20-327 Protective cover or device

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 327. A cap and keeper chain, closed cabinet, closed storage tube, or other approved protective cover or device shall be provided for a water inlet, outlet, and hose. *(Indiana State Department of Health; 410 IAC 7-20-327; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)*

410 IAC 7-20-328 Mobile retail food establishment tank inlet

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 328. A mobile retail food establishment's water tank inlet shall be:

(1) three-fourths (¾) inch in inner diameter or less; and

(2) provided with a hose connection of a size or type that will prevent its use for any other service.

(Indiana State Department of Health; 410 IAC 7-20-328; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)

410 IAC 7-20-329 System flushing and disinfection

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 329. A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse. *(Indiana State Department of Health; 410 IAC 7-20-329; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)*

410 IAC 7-20-330 Using a pump and hoses; backflow prevention

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 330. A person shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented. *(Indiana State Department of Health; 410 IAC 7-20-330; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)*

410 IAC 7-20-331 Protecting inlet, outlet, and hose fitting

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 331. If not in use, a water tank hose inlet and outlet fitting shall be protected using a cover or device as specified under section 327 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-331; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1970)*

410 IAC 7-20-332 Water tank, pump, and hoses dedication

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 332. (a) Except as specified in subsection (b), a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.

(b) Water tanks, pumps, and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water. *(Indiana State Department of Health; 410 IAC 7-20-332; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-333 Sewage holding tank of mobile retail food establishment; capacity and drainage

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 333. A sewage holding tank in a mobile retail food establishment shall be:

(1) sized fifteen percent (15%) larger in capacity than the water supply tank; and

(2) sloped to a drain that is one (1) inch in inner diameter or greater, equipped with a shut-off valve.

(Indiana State Department of Health; 410 IAC 7-20-333; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971)

410 IAC 7-20-334 Establishment drainage system

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 334. Retail food establishment drainage systems, including grease traps, that convey sewage shall be designed and installed as specified under section 302(a) of this rule. *(Indiana State Department of Health; 410 IAC 7-20-334; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971)*

410 IAC 7-20-335 Backflow prevention

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 335. (a) Except as specified in this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.

(b) If allowed under Indiana plumbing code, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within five (5) feet of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.

(c) If allowed by law, a warewashing or culinary sink may have a direct connection. *(Indiana State Department of Health; 410 IAC 7-20-335; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971)*

410 IAC 7-20-336 Grease trap

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 336. If used, a grease trap shall be located to be easily accessible for cleaning. *(Indiana State Department of Health; 410 IAC 7-20-336; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971)*

410 IAC 7-20-337 Conveying sewage

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 337. Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law. *(Indiana State Department of Health; 410 IAC 7-20-337; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971)*

410 IAC 7-20-338 Removing mobile retail food establishment wastes

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 338. Sewage and other liquid wastes shall be removed from a mobile retail food establishment at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created. *(Indiana State Department of Health; 410 IAC 7-20-338; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971)*

410 IAC 7-20-339 Flushing a waste retention tank

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 339. A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation. *(Indiana State Department of Health; 410 IAC 7-20-339; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971)*

410 IAC 7-20-340 Approved sewage disposal system

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 340. Sewage shall be disposed through an approved facility that is:

(1) a public sewage treatment plant; or

(2) an individual sewage disposal system that is sized, constructed, maintained, and operated according to law.

(Indiana State Department of Health; 410 IAC 7-20-340; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1971)

410 IAC 7-20-341 Other liquid wastes and rainwater

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 341. Condensate drainage and other nonsewage liquids and rainwater shall be drained from point of discharge to disposal according to law. *(Indiana State Department of Health; 410 IAC 7-20-341; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-342 Refuse, recyclables, and returnables indoor storage area

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 342. If located within the retail food establishment, a storage area for refuse, recyclables, and returnables shall meet the requirements specified under sections 362, 364 through 371, 376, and 377 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-342; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-343 Outdoor storage surface

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 343. An outdoor storage surface for refuse, recyclables, and returnables shall be constructed of nonabsorbent material, such as concrete or asphalt and shall be smooth, durable, and sloped to drain. *(Indiana State Department of Health; 410 IAC 7-20-343; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-344 Outdoor enclosure

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 344. If used, an outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials. *(Indiana State Department of Health; 410 IAC 7-20-344; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-345 Receptacles

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 345. (a) Except as specified in subsection (b), receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect-resistant, rodent-resistant, leakproof, and nonabsorbent.

(b) Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the retail food establishment, or within closed outside receptacles. *(Indiana State Department of Health; 410 IAC 7-20-345; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-346 Receptacles in vending machines

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 346. A refuse receptacle may not be located within a vending machine, except that a receptacle for beverage bottle crown closures may be located within a vending machine. *(Indiana State Department of Health; 410 IAC 7-20-346; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-347 Outside receptacles

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 347. (a) Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the retail food establishment shall be designed and constructed to have tight-fitting lids, doors, or covers.

(b) Receptacles and waste handling units for refuse and recyclables such as an on-site compactor shall be installed so that accumulation of debris and rodent/insect attraction or harborage are minimized. Such units shall be installed so that effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit. *(Indiana State Department of Health; 410 IAC 7-20-347; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-348 Storage areas, rooms, and receptacles; capacity and availability

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 348. (a) An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate.

(b) A receptacle shall be provided in each area of the retail food establishment or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.

(c) If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories. *(Indiana State Department of Health; 410 IAC 7-20-348; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-349 Toilet room receptacle; covered

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 349. A toilet room used by females shall be provided with a covered receptacle for sanitary napkins. *(Indiana State Department of Health; 410 IAC 7-20-349; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1972)*

410 IAC 7-20-350 Cleaning implements and supplies

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 350. (a) Except as specified in subsection (b), suitable cleaning implements and supplies, such as high pressure pumps, hot water, steam, and detergent, shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.

(b) If approved, off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided. *(Indiana State Department of Health; 410 IAC 7-20-350; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1973)*

410 IAC 7-20-351 Storage areas, redeeming machines, receptacles and waste handling units; location

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 351. (a) An area designated for refuse, recyclables, returnables, and, except as specified in subsection (b), a redeeming machine for recyclables or returnables shall be located so that it is separate from food, equipment, utensils, linens, and single-service and single-use articles and a public health hazard or nuisance is not created.

(b) A redeeming machine may be located in the packaged food storage area or consumer area of a retail food establishment if food, equipment, utensils, linens, and single-service and single-use articles are not subject to contamination from the machines and a public health hazard or nuisance is not created.

(c) The location of receptacles and waste handling units for refuse, recyclables, and returnables may not create a public health hazard or nuisance or interfere with the cleaning of adjacent space. *(Indiana State Department of Health; 410 IAC 7-20-351; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1973)*

410 IAC 7-20-352 Storing refuse, recyclables, and returnables

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 352. Refuse, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents. *(Indiana State Department of Health; 410 IAC 7-20-352; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1973)*

410 IAC 7-20-353 Storage areas, enclosures, and receptacles; good repair

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 353. Storage areas, enclosures, and receptacles for refuse, recyclables, and returnables shall be maintained in good repair. *(Indiana State Department of Health; 410 IAC 7-20-353; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1973; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-354 Outside storage prohibitions

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 354. (a) Except as specified in subsection (b), refuse receptacles not meeting the requirements specified under section 345(a) of this rule, such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue may not be stored outside.

(b) Cardboard or other packaging material that does not contain food residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem. *(Indiana State Department of Health; 410 IAC 7-20-354; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1973)*

410 IAC 7-20-355 Covering receptacles

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 355. Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept covered:

(1) inside the retail food establishment if the receptacles and units:

(A) contain food residue and are not in continuous use; or

(B) after they are filled; and

(2) with tight-fitting lids or doors if kept outside the retail food establishment.

(Indiana State Department of Health; 410 IAC 7-20-355; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1973)

410 IAC 7-20-356 Using drain plugs

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 356. Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place. *(Indiana State Department of Health; 410 IAC 7-20-356; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1973)*

410 IAC 7-20-357 Maintaining refuse areas and enclosures

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 357. A storage area and enclosure for refuse, recyclables, or returnables shall be maintained free of unnecessary items, as specified under section 405 of this rule, and clean. *(Indiana State Department of Health; 410 IAC 7-20-357; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1973)*

410 IAC 7-20-358 Cleaning receptacles

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 358. (a) Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of in a manner that does not create a public health hazard or nuisance.

(b) Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a build-up of soil or becoming attractants for insects and rodents. *(Indiana State Department of Health; 410 IAC 7-20-358; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1974; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-359 Receptacle removal; frequency

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 359. Refuse, recyclables, and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents. *(Indiana State Department of Health; 410 IAC 7-20-359; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1974)*

410 IAC 7-20-360 Receptacles removal; methods

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 360. Refuse, recyclables, and returnables shall be removed from the premises by way of:

(1) portable receptacles that are constructed and maintained according to law; or

(2) a transport vehicle that is constructed, maintained, and operated according to law.

(Indiana State Department of Health; 410 IAC 7-20-360; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1974)

410 IAC 7-20-361 Community or individual facility

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 361. Solid waste not disposed of through the sewage system, such as through grinders and pulpers, shall be:

(1) recycled or disposed of in an approved public or private community recycling or refuse facility; or

(2) disposed of in an individual refuse facility such as a landfill or incinerator that is sized, constructed, maintained, and operated according to law.

(Indiana State Department of Health; 410 IAC 7-20-361; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1974)

410 IAC 7-20-362 Surface characteristics of materials for indoor area construction and repair

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 362. (a) Except as specified in subsection (b), materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:

(1) smooth, durable, and easily cleanable for areas where retail food establishment operations are conducted;

(2) closely woven and easily cleanable carpet for carpeted areas; and

(3) nonabsorbent for areas subject to moisture, such as:

(A) food preparation areas;

(B) walk-in refrigerators;

(C) warewashing areas;

(D) toilet rooms;

(E) mobile retail food establishment servicing areas; and

(F) areas subject to flushing or spray cleaning methods.

(b) In a temporary food establishment:

(1) if graded to drain, a floor may be concrete, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other suitable materials that are effectively treated to control dust and mud; and

(2) walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.

(Indiana State Department of Health; 410 IAC 7-20-362; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1974)

410 IAC 7-20-363 Surface characteristics of materials for outdoor area construction and repair

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 363. (a) The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.

(b) Exterior surfaces of buildings and mobile retail food establishments shall be of weather-resistant materials and shall comply with law.

(c) Outdoor storage areas for refuse, recyclables, or returnables shall be of materials specified under sections 343 and 344 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-363; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1974)*

410 IAC 7-20-364 Cleanability of floors, walls, and ceilings

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 364. Except as specified under section 367 of this rule, the floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are smooth and easily cleanable, except that anti-slip floor coverings or applications may be used for safety reasons. *(Indiana State Department of Health; 410 IAC 7-20-364; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1975)*

410 IAC 7-20-365 Cleanability of floors, walls, and ceilings relative to utility lines

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 365. (a) Utility service lines and pipes may not be unnecessarily exposed.

(b) Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.

(c) Exposed horizontal utility service lines and pipes may not be installed on the floor. *(Indiana State Department of Health; 410 IAC 7-20-365; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1975)*

410 IAC 7-20-366 Cleanability of floors and wall junctures; coved, and enclosed or sealed

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 366. (a) In retail food establishments in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than one thirty-second (1/32) inch.

(b) The floors in retail food establishments in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and sealed. *(Indiana State Department of Health; 410 IAC 7-20-366; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1975)*

410 IAC 7-20-367 Installation and restrictions of floor carpeting

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 367. (a) A floor covering such as carpeting or similar material may not be installed as a floor covering in food preparation areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing lavatories, toilets, and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

(b) If carpeting is installed as a floor covering in areas other than those specified under subsection (a), it shall be:

(1) securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and

(2) installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.

(Indiana State Department of Health; 410 IAC 7-20-367; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1975)

410 IAC 7-20-368 Mats and duckboards as floor coverings

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 368. Mats and duckboards shall be designed to be removable and easily cleanable. *(Indiana State Department of Health; 410 IAC 7-20-368; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1975)*

410 IAC 7-20-369 Wall and ceiling coverings and coatings

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 369. (a) Wall and ceiling covering materials shall be attached so that they are easily cleanable.

(b) Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction shall be

finished and sealed to provide a smooth, nonabsorbent, easily cleanable surface. *(Indiana State Department of Health; 410 IAC 7-20-369; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1975)*

410 IAC 7-20-370 Wall and ceiling attachments

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 370. (a) Except as specified in subsection (b), attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be easily cleanable.

(b) In a consumer area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean. *(Indiana State Department of Health; 410 IAC 7-20-370; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1975)*

410 IAC 7-20-371 Exposure of wall and ceiling studs, joists, and rafters

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 371. Studs, joists, and rafters may not be exposed in areas subject to moisture. This requirement does not apply to temporary food establishments. *(Indiana State Department of Health; 410 IAC 7-20-371; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1975)*

410 IAC 7-20-372 Functionality of light bulbs and protective shielding

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 372. (a) Except as specified in subsection (b), light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is:

(1) exposed food;
(2) clean equipment, utensils, and linens; or
(3) unwrapped single-service and single-use articles.

(b) Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages if:

(1) the integrity of the packages can not be affected by broken glass falling onto them; and
(2) the packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

(c) An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed. *(Indiana State Department of Health; 410 IAC 7-20-372; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1976)*

410 IAC 7-20-373 Design of heating, ventilating, and air conditioning system vents

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 373. Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment, or utensils. *(Indiana State Department of Health; 410 IAC 7-20-373; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1976)*

410 IAC 7-20-374 Design and installation of insect control devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 374. (a) Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

(b) Insect control devices shall be installed so that:
(1) the devices are not located over a food preparation area; and
(2) dead insects and insect fragments are prevented from being impelled onto or falling on:
(A) exposed food;
(B) clean equipment, utensils, and linens; and
(C) unwrapped single-service and single-use articles.
(Indiana State Department of Health; 410 IAC 7-20-374; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1976)

410 IAC 7-20-375 Enclosed toilet rooms
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 375. (a) A toilet room located on the premises shall be completely enclosed and provided with a tight-fitting and self-closing door, except that this requirement does not apply to a toilet room that is located outside a retail food establishment and does not open directly into the retail food establishment, such as a toilet room that is provided by the management of a shopping mall.
(b) Toilet room doors shall be kept closed, except during cleaning and maintenance. *(Indiana State Department of Health; 410 IAC 7-20-375; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1976)*

410 IAC 7-20-376 Protected outer openings
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 376. (a) Except as specified in this section, outer openings of a retail food establishment shall be protected against the entry of insects and rodents by:
(1) filling or closing holes and other gaps along floors, walls, and ceilings;
(2) closed, tight-fitting windows; and
(3) solid, self-closing, and tight-fitting doors.
(b) Subsection (a) does not apply if a retail food establishment opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.
(c) External emergency exit doors that are solid and tight-fitting when closed and are restricted from nonemergency use, do not need to have a self-closing device installed.
(d) Except as specified in subsections (b) and (e), if the windows or doors of a retail food establishment, or of a larger structure within which a retail food establishment is located, are kept open for ventilation or other purposes or a temporary food establishment is not provided with windows and doors as specified under subsection (a), the openings shall be protected against the entry of insects and rodents by:
(1) sixteen (16) mesh to one (1) inch screens;
(2) properly designed and installed air curtains; or
(3) other effective means.
(e) Subsection (d) does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting condition. *(Indiana State Department of Health; 410 IAC 7-20-376; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1976; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-377 Protective barriers on exterior walls and roofs
Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 377. Perimeter walls and roofs of a retail food establishment shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals. *(Indiana State Department of Health; 410 IAC 7-20-377; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-378 Overhead protection on outdoor food vending areas

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 378. If located outdoors, a machine used to vend food shall be provided with overhead protection, except that machines vending canned beverages need not meet this requirement. *(Indiana State Department of Health; 410 IAC 7-20-378; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-379 Overhead protection on outdoor servicing areas

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 379. Servicing areas shall be provided with overhead protection, except that areas used only for the loading of water or the discharge of sewage and other liquid waste, through the use of a closed system of hoses, need not be provided with overhead protection. *(Indiana State Department of Health; 410 IAC 7-20-379; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-380 Outdoor walking and driving surfaces graded to drain

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 380. Exterior walking and driving surfaces shall be graded to drain. *(Indiana State Department of Health; 410 IAC 7-20-380; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-381 Outdoor refuse areas; curbed and graded to drain

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 381. Outdoor refuse areas shall be constructed in accordance with law and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the refuse and from cleaning the area and waste receptacles. *(Indiana State Department of Health; 410 IAC 7-20-381; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-382 Private homes and living or sleeping quarters; use prohibited

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 382. A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for retail food establishment operations. *(Indiana State Department of Health; 410 IAC 7-20-382; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-383 Separation of living or sleeping quarters

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 383. Living or sleeping quarters located on the premises of a retail food establishment, such as those provided for lodging registration clerks or resident managers, shall be separated from rooms and areas used for retail food establishment operations by complete partitioning and solid self-closing doors. *(Indiana State Department of Health; 410 IAC 7-20-383; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-384 Availability of handwashing cleanser

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 384. Each handwashing lavatory or group of two (2) adjacent lavatories shall be provided with a supply of hand cleaning liquid, powder, or bar soap. *(Indiana State Department of Health; 410 IAC 7-20-384; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-385 Hand drying provisions

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 385. Each handwashing lavatory or group of adjacent lavatories shall be provided with:
(1) individual, disposable towels;
(2) a continuous towel system that supplies the user with a clean towel; or
(3) a heated-air hand drying device.
(Indiana State Department of Health; 410 IAC 7-20-385; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)

410 IAC 7-20-386 Restrictions on handwashing aids and devices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 386. A sink used for food preparation or utensil washing, or a service sink or curbed cleaning facility used for the disposal of mop water or similar wastes, may not be provided with the handwashing aids and devices required for a handwashing lavatory as specified under sections 348(c), 384, and 385 of this rule. *(Indiana State Department of Health; 410 IAC 7-20-386; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1977)*

410 IAC 7-20-387 Waste receptacles for disposable towels

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 387. A handwashing lavatory or group of adjacent lavatories that is provided with disposable towels shall be provided with a waste receptacle as specified under section 348(c) of this rule. *(Indiana State Department of Health; 410 IAC 7-20-387; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)*

410 IAC 7-20-388 Availability of toilet tissue

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 388. A supply of toilet tissue shall be available at each toilet. *(Indiana State Department of Health; 410 IAC 7-20-388; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)*

410 IAC 7-20-389 Lighting intensity

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 389. (a) The light intensity shall be at least seventy (70) foot-candles on all food preparation surfaces and at equipment or utensil-washing work levels.
(b) The light intensity shall be at least twenty (20) foot-candles at a distance of thirty (30) inches above the floor in:
(1) utensil and equipment storage areas;
(2) lavatory and toilet areas;
(3) walk-in refrigeration units; and
(4) dry food storage areas; and
(5) all other areas.
This includes the areas where food is provided for consumer self-service, such as buffets and salad bars, and rooms during periods of cleaning.

(c) The light intensity shall be at least twenty (20) foot-candles inside equipment, such as reach-in and under-counter refrigerators. *(Indiana State Department of Health; 410 IAC 7-20-389; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)*

410 IAC 7-20-390 Mechanical ventilation

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 390. Mechanical ventilation shall be provided in accordance with requirements of the Indiana department of fire and building safety and shall be of sufficient capacity to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes. *(Indiana State Department of Health; 410 IAC 7-20-390; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)*

410 IAC 7-20-391 Designation of dressing areas or lockers

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 391. (a) Dressing rooms or dressing areas shall be designated and used if employees routinely change their clothes in the establishment.

(b) Lockers or other suitable facilities shall be provided and used for the orderly storage of employees' clothing and other possessions. *(Indiana State Department of Health; 410 IAC 7-20-391; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)*

410 IAC 7-20-392 Toilet rooms accessibility

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 392. Toilet rooms shall be conveniently located and accessible to employees during all hours of operation. *(Indiana State Department of Health; 410 IAC 7-20-392; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)*

410 IAC 7-20-393 Designated employee areas

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 393. (a) Areas designated for employees to eat, drink, and use tobacco shall be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.

(b) Lockers or other suitable facilities shall be located in a designated room or area where contamination of food, equipment, utensils, linens, and single-service and single-use articles can not occur. *(Indiana State Department of Health; 410 IAC 7-20-393; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)*

410 IAC 7-20-394 Segregation of distressed merchandise

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 394. Products that are held by the retail food establishment for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from food, equipment, utensils, linens, and single-service and single-use articles. *(Indiana State Department of Health; 410 IAC 7-20-394; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)*

410 IAC 7-20-395 Repairing premises, structures, and attachments

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 395. The physical facilities shall be maintained in good repair. *(Indiana State Department of Health; 410 IAC 7-20-395;*

filed Mar 30, 2000, 3:51 p.m.: 23 IR 1978)

410 IAC 7-20-396 Physical structures; restrictions and frequency of cleaning

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 396. (a) The physical facilities shall be cleaned as often as necessary to keep them clean.

(b) Cleaning shall be done during periods when the least amount of food is exposed, such as after closing. This requirement does not apply to cleaning that is necessary due to a spill or other accident. *(Indiana State Department of Health; 410 IAC 7-20-396; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979; errata filed Sep 8, 2000, 11:03 a.m.: 24 IR 381)*

410 IAC 7-20-397 Cleaning floors; dustless methods

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 397. (a) Except as specified in subsection (b), only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.

(b) Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:

(1) without the use of dust-arresting compounds; and

(2) in the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.

(Indiana State Department of Health; 410 IAC 7-20-397; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979)

410 IAC 7-20-398 Cleaning ventilation systems

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 398. (a) Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

(b) If vented to the outside, ventilation systems may not create a public health hazard or nuisance or unlawful discharge. *(Indiana State Department of Health; 410 IAC 7-20-398; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979)*

410 IAC 7-20-399 Cleaning maintenance tools and preventing contamination

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 399. Food preparation sinks, handwashing lavatories, and warewashing equipment may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes. *(Indiana State Department of Health; 410 IAC 7-20-399; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979)*

410 IAC 7-20-400 Drying mops

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 400. After use, mops shall be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies. *(Indiana State Department of Health; 410 IAC 7-20-400; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979)*

410 IAC 7-20-401 Limitation of absorbent materials on floors

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 401. Except as specified in section 397(b) of this rule, sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors. *(Indiana State Department of Health; 410 IAC 7-20-401; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979)*

410 IAC 7-20-402 Controlling pests

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 402. The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by:
(1) routinely inspecting incoming shipments of food and supplies;
(2) routinely inspecting the premises for evidence of pests;
(3) using methods, if pests are found, such as trapping devices or other means of pest control as specified under sections 411, 419, and 420 of this rule; and
(4) eliminating harborage conditions.
(Indiana State Department of Health; 410 IAC 7-20-402; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979)

410 IAC 7-20-403 Removing dead or trapped birds, insects, rodents, and other pests

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 403. Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or attraction of pests. *(Indiana State Department of Health; 410 IAC 7-20-403; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979)*

410 IAC 7-20-404 Storing maintenance tools

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 404. (a) Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be stored so they do not contaminate food, equipment, utensils, linens, and single-service and single-use articles.

(b) These same maintenance tools shall be stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools. *(Indiana State Department of Health; 410 IAC 7-20-404; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1979)*

410 IAC 7-20-405 Unnecessary items and litter

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 405. The premises shall be free of litter and items that are unnecessary to the operation or maintenance of the establishment such as equipment that is nonfunctional or no longer used. *(Indiana State Department of Health; 410 IAC 7-20-405; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1980)*

410 IAC 7-20-406 Prohibiting animals

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 406. (a) Except as specified in this section, live animals may not be allowed in the operational areas of a retail food establishment.

(b) Live animals may be allowed if the contamination of food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles cannot result as in the following situations:

(1) Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems.

(2) Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas.

(3) In areas that are not used for food preparation and are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person, if a health or safety hazard will not result from the presence or activities of the service animal.

(4) Pets in the common dining areas of group residences at times other than during meals if:

(A) effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas;

(B) condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present; and

(C) dining areas, including tables, countertops, and similar surfaces, are effectively cleaned before the next meal service.

(5) In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly restricted, such as in a variety store that sells pets or a tourist park that displays animals.

(c) Live or dead fish bait may be stored if contamination of:

(1) food;

(2) clean equipment, utensils, and linens; and

(3) unwrapped single-service and single-use articles;

cannot result. *(Indiana State Department of Health; 410 IAC 7-20-406; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1980)*

410 IAC 7-20-407 Identifying information on original containers

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 407. Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label. *(Indiana State Department of Health; 410 IAC 7-20-407; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1980)*

410 IAC 7-20-408 Working containers; common name

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 408. Working containers used for storing poisonous or toxic materials, such as cleaners and sanitizers taken from bulk supplies, shall be clearly and individually identified with the common name of the material. *(Indiana State Department of Health; 410 IAC 7-20-408; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1980)*

410 IAC 7-20-409 Separation of poisonous or toxic materials

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 409. Poisonous or toxic materials shall be stored so they cannot contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

(1) separating the poisonous or toxic materials by spacing or partitioning; and

(2) locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.

This section does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles. *(Indiana State Department of Health; 410 IAC 7-20-409; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1980)*

410 IAC 7-20-410 Restriction of poisonous or toxic materials

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 410. (a) Only those poisonous or toxic materials that are required for the operation and maintenance of a retail food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a retail food establishment.

(b) Subsection (a) does not apply to packaged poisonous or toxic materials that are for retail sale. *(Indiana State Department of Health; 410 IAC 7-20-410; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1980)*

410 IAC 7-20-411 Conditions of poisonous or toxic materials use

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 411. (a) Poisonous or toxic materials shall be used according to the following:

(1) The law and this rule.

(2) Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a retail food establishment.

(3) The conditions of certification for use of the pest control materials.

(4) Additional conditions that may be established by the regulatory authority.

(b) Poisonous or toxic materials shall be applied so that:

(1) a hazard to employees or other persons is not constituted; and

(2) contamination, including toxic residues due to drip, drain, fog, splash, or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted-use pesticide, this is achieved by:

(A) removing the items;

(B) covering the items with impermeable covers; or

(C) taking other appropriate preventive actions;

and cleaning and sanitizing equipment and utensils after application.

(c) A restricted use pesticide shall be applied only by an applicator certified according to law or a person under the direct supervision of a certified applicator. *(Indiana State Department of Health; 410 IAC 7-20-411; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1981)*

410 IAC 7-20-412 Poisonous or toxic material containers

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 412. A container previously used to store poisonous or toxic materials may not be used to store, transport, or dispense food. *(Indiana State Department of Health; 410 IAC 7-20-412; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1981)*

410 IAC 7-20-413 Sanitizers; criteria

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 413. Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010. *(Indiana State Department of Health; 410 IAC 7-20-413; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1981)*

410 IAC 7-20-414 Chemicals for washing fruits and vegetables; criteria

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 414. Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315. *(Indiana State Department of Health; 410 IAC 7-20-414; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1981)*

410 IAC 7-20-415 Boiler water additives; criteria

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 415. Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310. *(Indiana State Department of Health; 410 IAC 7-20-415; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1981)*

410 IAC 7-20-416 Drying agents; criteria

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 416. (a) Drying agents used in conjunction with sanitization shall contain only components that are listed as one (1) of the following:

(1) Generally recognized as safe for use in food as specified in 21 CFR 182 or 21 CFR 184.

(2) Generally recognized as safe for the intended use as specified in 21 CFR 186.

(3) Approved for use as a drying agent under a prior sanction specified in 21 CFR 181.

(4) Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR 175 through 21 CFR 178.

(5) Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39.

(b) When sanitization is with chemicals, the approval required under subsections *[subsection]* (a)(3) or (a)(5) or the regulation as an indirect food additive required under subsection (a)(4), shall be specifically for use with chemical sanitizing solutions. *(Indiana State Department of Health; 410 IAC 7-20-416; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1981)*

410 IAC 7-20-417 Incidental food contact with lubricants

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 417. Lubricants shall meet the requirements specified in 21 CFR 178.3570, if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces. *(Indiana State Department of Health; 410 IAC 7-20-417; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1981)*

410 IAC 7-20-418 Restricted use pesticides; criteria

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 418. Restricted use pesticides specified under section 411(c) of this rule shall meet the requirements specified in 40 CFR 152, Subpart I. *(Indiana State Department of Health; 410 IAC 7-20-418; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)*

410 IAC 7-20-419 Rodent bait stations

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 419. Rodent bait shall be contained in a covered, tamper-resistant bait station. *(Indiana State Department of Health; 410 IAC 7-20-419; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)*

410 IAC 7-20-420 Use of tracking powders; pest control and monitoring

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 420. (a) A toxic tracking powder pesticide may not be used in a retail food establishment.

(b) If used, a nontoxic tracking powder, such as talcum or flour, may not contaminate food, equipment, utensils, linens, and single-service and single-use articles. *(Indiana State Department of Health; 410 IAC 7-20-420; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)*

410 IAC 7-20-421 Medicine restrictions and storage

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 421. (a) Only those medicines that are necessary for the health of employees shall be allowed in a retail food establishment. This section does not apply to medicines that are stored or displayed for retail sale.

(b) Medicines that are in a retail food establishment for the employees' use shall be labeled as specified under section 407 of this rule and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. *(Indiana State Department of Health; 410 IAC 7-20-421; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)*

410 IAC 7-20-422 Refrigerated medicines; storage

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 422. Medicines belonging to employees or to children in a child care center that require refrigeration and are stored in a food refrigerator shall be stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; and located so they are inaccessible to children. *(Indiana State Department of Health; 410 IAC 7-20-422; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)*

410 IAC 7-20-423 Storage of first aid supplies

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 423. (a) First aid supplies that are in a retail food establishment for the employees' use shall be labeled as specified under section 407 of this rule.

(b) First aid supplies shall be stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles. *(Indiana State Department of Health; 410 IAC 7-20-423; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)*

410 IAC 7-20-424 Storage of other personal care items

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 424. Except as specified under sections 422 and 423 of this rule, employees shall store their personal care items in facilities as specified under section 391(b) of this rule. *(Indiana State Department of Health; 410 IAC 7-20-424; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)*

410 IAC 7-20-425 Separate storage and display of poisonous or toxic materials

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 425. Poisonous or toxic materials shall be stored and displayed for retail sale so they can not contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

(1) separating the poisonous or toxic materials by spacing or partitioning; and

(2) locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.

(Indiana State Department of Health; 410 IAC 7-20-425; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)

410 IAC 7-20-426 Public health protection

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 426. (a) The regulatory authority shall uniformly apply this rule to all retail food establishments in a reasonable manner that promotes its underlying purpose of safeguarding public health and ensuring that food is safe, not misbranded, unadulterated, and honestly presented when offered to the consumer.

(b) In enforcing the provisions of this rule, the regulatory authority shall assess existing facilities or equipment that were in use before the effective date of this rule based on the following considerations:

(1) Whether the facilities or equipment are in good repair and capable of being maintained in a sanitary condition.

(2) Whether food-contact surfaces comply with sections 184 through 195 of this rule.

(3) Whether the capacities of cooling, heating, and holding equipment are sufficient to comply with section 232 of this rule.

(4) The existence of a documented agreement with the retail food establishment that the facilities or equipment will be replaced or upgraded.

(Indiana State Department of Health; 410 IAC 7-20-426; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1982)

410 IAC 7-20-427 Prerequisite for operation

Authority: IC 16-42-5-5
Affected: IC 16-42-1-6; IC 16-42-5

Sec. 427. (a) A person may not operate a retail food establishment without first having registered with the department as required under IC 16-42-1-6.

(b) A retail food establishment registered with a local health department or other regulatory authority shall be considered registered with the department under IC 16-42-1-6.

(c) To allow verification that the retail food establishment is constructed, equipped, and otherwise meets requirements of this rule, the regulatory authority shall be notified of an intent to operate at least thirty (30) days prior to registering under this rule. *(Indiana State Department of Health; 410 IAC 7-20-427; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1983)*

410 IAC 7-20-428 Access allowed at reasonable times after due notice

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 428. After the regulatory authority presents official credentials and expresses an intent to conduct an inspection, investigation, or to collect food samples, the person-in-charge shall allow the regulatory authority to determine if the retail food establishment is in compliance with this rule by allowing access to the establishment, and providing information and records specified in this rule and to which the regulatory authority is entitled according to law, during the retail food establishment's hours of operation and other reasonable times. *(Indiana State Department of Health; 410 IAC 7-20-428; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1983)*

410 IAC 7-20-429 Ceasing operations, reporting, and resumption of operations

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 429. (a) Except as specified in subsection (b), a retail food establishment shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist because of an emergency, such as:

(1) a fire;

(2) a flood;

(3) an extended interruption of electrical or water service;

(4) a sewage backup;

(5) a misuse of poisonous or toxic materials;

(6) an onset of an apparent foodborne illness outbreak;

(7) a gross insanitary occurrence or condition; or

(8) other circumstance that may endanger public health.

(b) A retail food establishment need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

(c) If operations are discontinued as specified under this section or otherwise according to law, the retail food establishment shall obtain approval from the regulatory authority before resuming operations. *(Indiana State Department of Health; 410 IAC 7-20-429; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1983)*

410 IAC 7-20-430 Requirement for facility and operating plans

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 430. The owner or other authorized agent of an existing or proposed retail food establishment shall submit to the regulatory authority properly prepared plans and specifications for review and approval before:

(1) the construction of a retail food establishment;

(2) the conversion of an existing structure for use as a retail food establishment; or

(3) the remodeling of a retail food establishment or a change of type of retail food establishment or food operation if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this rule.

(Indiana State Department of Health; 410 IAC 7-20-430; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1983)

410 IAC 7-20-431 Contents and specifications for facility and operating plans

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 431. The plans and specifications for a retail food establishment shall include, as required by the regulatory authority based on the type of operation, type of food preparation and, foods prepared, the following information to demonstrate compliance with rule provisions:

(1) Intended menu.

(2) Anticipated volume of food to be stored, prepared, and sold or served.

(3) Proposed layout, mechanical schematics, construction materials, and finish schedules.

(4) Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications.

(5) Evidence that standard procedures that ensure compliance with this rule are developed or are being developed.

(6) Other information that may be required by the regulatory authority for the proper review of the proposed construction, conversion, or modification, and procedures for operating a retail food establishment.

(Indiana State Department of Health; 410 IAC 7-20-431; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1983)

410 IAC 7-20-432 Preventing health hazards; provisions for conditions not addressed

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 432. (a) If necessary to protect against public health hazards or nuisances, the regulatory authority may temporarily impose specific requirements in addition to the requirements contained in this rule that are authorized by law.

(b) The regulatory authority shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the retail food establishment and, a copy shall be maintained in the regulatory authority's file for the retail food establishment. *(Indiana State Department of Health; 410 IAC 7-20-432; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

410 IAC 7-20-433 Incorporation by reference

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 433. (a) When used in this article, references to the following publications shall mean the version of that publication listed below. The following publications are hereby incorporated by reference:

(1) 7 CFR 56 (January 1, 1999 Edition).
(2) 9 CFR 317 (January 1, 1999 Edition).
(3) 9 CFR 318.7 (January 1, 1999 Edition).
(4) 9 CFR 319 (January 1, 1999 Edition).
(5) 9 CFR 381, Subpart N (January 1, 1999 Edition).
(6) 9 CFR 381.147 (January 1, 1999 Edition).
(7) 9 CFR 590 (January 1, 1999 Edition).
(8) 21 CFR 101 (April 1, 1999 Edition).
(9) 21 CFR 129 (April 1, 1999 Edition).
(10) 21 CFR 130 (April 1, 1999 Edition).
(11) 21 CFR 131 through 21 CFR 169 (April 1, 1999 Edition).
(12) 21 CFR 170 through 21 CFR 186 (April 1, 1999 Edition).
(13) 21 CFR 1030.10 (April 1, 1999 Edition).
(14) 40 CFR 152, Subpart I (July 1, 1999 Edition).
(15) 40 CFR 185 (July 1, 1999 Edition).
(16) Food, Drug and Cosmetic Act, Section 201(s).
(17) Food, Drug and Cosmetic Act, Section 201(t).
(18) Food, Drug and Cosmetic Act, Section 409.
(19) Food, Drug and Cosmetic Act, Section 706.
(20) U.S. Standards, Grades, and Weight Classes for Shell Eggs (AMS 56.200 et seq.) (Effective April 6, 1995). Copies are available from the United States Department of Agriculture, Agricultural Marketing Service, Poultry Programs, P.O. Box 964, Washington, D.C. 20090-6456.
(21) National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (1997 Revision). Copies are available from the United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, Shellfish Sanitation Program, HFS-628, 200 "C" Street, S.W., Washington, D.C. 20204.

(b) Federal rules which have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. *(Indiana State Department of Health; 410 IAC 7-20-433; filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984)*

Rule 21. Wholesale Food Establishment Sanitation Requirements

410 IAC 7-21-1 Applicability

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 7-21-1; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1615, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-2 "Acid foods" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 2. "Acid foods" means foods that have a natural pH of 4.6 or below. *(Indiana State Department of Health; 410 IAC 7-21-2; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1615, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-3 "Acidified foods" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 3. (a) "Acidified foods" means low-acid foods to which acid or acid food is added; these foods include, but are not limited to:

(1) beans;
(2) cucumbers;
(3) cabbage;
(4) artichokes;
(5) cauliflower;
(6) puddings;
(7) peppers;
(8) tropical fruits; and
(9) fish;

singly or in any combination. They have a water activity (a_w) greater than eighty-five hundredths (0.85) and have a finished equilibrium pH of 4.6 or below. These foods may be called pickled, such as "pickled cauliflower".

(b) Excluded from the definition of acidified foods are:

(1) carbonated beverages;
(2) jams;
(3) jellies;
(4) preserves; and
(5) acid foods;

(including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid food and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored, distributed, and retailed under refrigeration. *(Indiana State Department of Health; 410 IAC 7-21-3; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1615, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-4 "Adequate" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 4. "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice. *(Indiana State Department of Health; 410 IAC 7-21-4; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1615, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-5 "Adulterated" defined

Authority: IC 16-42-5-5
Affected: IC 16-42

Sec. 5. "Adulterated" has the meaning set forth under IC 16-42-1 through IC 16-42-4. *(Indiana State Department of Health; 410 IAC 7-21-5; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1615, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-6 "Allergen" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 6. "Allergen" means foods that are commonly known to cause serious allergenic responses, including, but not limited to, the following:

(1) Milk.
(2) Eggs.
(3) Fish.
(4) Crustacea.
(5) Mollusks.
(6) Tree nuts.

(7) Wheat.

(8) Legumes, particularly peanuts and soybeans.

(Indiana State Department of Health; 410 IAC 7-21-6; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1615, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-7 "Batter" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 7. "Batter" means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods. *(Indiana State Department of Health; 410 IAC 7-21-7; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-8 "Blanching" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 8. "Blanching", except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to affect other physical or biochemical changes in the food. *(Indiana State Department of Health; 410 IAC 7-21-8; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-9 "Bottled drinking water" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 9. "Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption, including bottled mineral water. *(Indiana State Department of Health; 410 IAC 7-21-9; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-10 "CFR" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 10. "CFR" means the Code of Federal Regulations. *(Indiana State Department of Health; 410 IAC 7-21-10; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-11 "CIP system" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 11. "CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning. The term does not include the cleaning of equipment, such as band saws, slicers, or mixers that are subjected to in-place manual cleaning without the use of a CIP system. *(Indiana State Department of Health; 410 IAC 7-21-11; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-12 "Critical control point" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 12. "Critical control point" means a point or procedure in a specific food process where loss of control may result in an unacceptable health risk. *(Indiana State Department of Health; 410 IAC 7-21-12; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-13 "Department" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 13. "Department" means the Indiana state department of health or its authorized representative. *(Indiana State Department of Health; 410 IAC 7-21-13; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-14 "Drinking water" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 14. "Drinking water" means water that meets the requirements of 327 IAC 8. The term is traditionally known as potable water. The term includes water, except where the term used connotes that the water is not potable, such as boiler water, mop water, wastewater, and nondrinking water. *(Indiana State Department of Health; 410 IAC 7-21-14; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-15 "Food" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 15. "Food" means the following:

(1) All articles used for food, drink, confectionery, or condiment whether simple, mixed, or compound.

(2) All substances or ingredients used in the preparation of the items described in subdivision (1).

(Indiana State Department of Health; 410 IAC 7-21-15; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-16 "Food-contact surface" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 16. "Food-contact surface" means a surface of equipment or a utensil:

(1) with which food normally comes into contact; or

(2) from which food may drain, drip, or splash into a food, or onto a surface normally in contact with food.

(Indiana State Department of Health; 410 IAC 7-21-16; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1616, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-17 "Food employee" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 17. "Food employee" means an individual working with food, food equipment or utensils, or food-contact surfaces. *(Indiana State Department of Health; 410 IAC 7-21-17; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-18 "HACCP plan" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 18. "HACCP plan" means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by the National Advisory Committee on Microbiological Criteria for Foods. *(Indiana State Department of Health; 410 IAC 7-21-18; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-19 "Lot" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 19. "Lot" means the food produced during a period of time indicated by a specific code. *(Indiana State Department of Health; 410 IAC 7-21-19; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-20 "Low-acid food" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 20. "Low-acid food" means any food, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than eighty-five hundredths (0.85). *(Indiana State Department of Health; 410 IAC 7-21-20; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-21 "Micro-organisms" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 21. "Micro-organisms" means yeasts, molds, bacteria, protozoa, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable micro-organisms" includes those micro-organisms that are of public health significance and those of nonpublic health significance that result in food spoilage or that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. "Microbial" is used in some instances instead of using an adjectival phrase containing the word micro-organism. *(Indiana State Department of Health; 410 IAC 7-21-21; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-22 "Pest" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 22. "Pest" refers to any objectionable animals or insects, including, but not limited to, the following:
(1) Birds.
(2) Rodents.
(3) Flies.
(4) Larvae.
(Indiana State Department of Health; 410 IAC 7-21-22; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-23 "pH" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 23. "pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between zero (0) and seven (7) indicate acidity, and values between seven (7) and fourteen (14) indicate alkalinity. The value for pure distilled water is seven (7), which is considered neutral. *(Indiana State Department of Health; 410 IAC 7-21-23; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-24 "Plant" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 24. "Plant" means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, holding, or storing of human food. *(Indiana State Department of Health; 410 IAC 7-21-24; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-25 "Potentially hazardous food" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 25. (a) "Potentially hazardous food" means a natural or synthetic food and requires temperature control because it is in a form capable of supporting any of the following:

(1) The rapid and progressive growth of infectious or toxigenic micro-organisms.
(2) The growth and toxin production of Clostridium botulinum.
(3) In raw shell eggs, the growth of Salmonella enteritidis.

(b) The term includes the following:

(1) A food of animal origin that is raw or heat-treated.
(2) A food of plant origin that is heat-treated or consists of raw seed sprouts.
(3) Cut melons.
(4) Garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under subsection (a).

(c) The term does not include any of the following:

(1) An air-cooled hard-boiled egg with shell intact.
(2) A food with a water activity (a_w) value of eighty-five hundredths (0.85) or less.
(3) A food with a pH level of four and six-tenths (4.6) or below when measured at seventy-five (75) degrees Fahrenheit.
(4) A food, in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution.
(5) A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic micro-organisms or the growth of Salmonella enteritidis in eggs or Clostridium botulinum cannot occur, such as a food that:
    (A) has an a_w and a pH that are above the levels specified under subdivisions (2) and (3); and
    (B) may contain a preservative, other barrier to the growth of micro-organisms, or a combination of barriers that inhibit the growth of micro-organisms.
(6) A food that may contain an infectious or toxigenic micro-organism or chemical or physical contaminant at a level sufficient to cause illness, but that does not support the growth of micro-organisms as specified under subsection (a).

(Indiana State Department of Health; 410 IAC 7-21-25; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1617, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-26 "Public health significance" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 26. "Public health significance" means:

(1) the potential for causing diseases with symptoms, such as, but not limited to:

(A) diarrhea;
(B) fever;
(C) jaundice;
(D) vomiting or sore throat with fever; or
(E) boils; or

(2) for diseases such as, but not limited to:
(A) Salmonella spp.;
(B) Shigella spp.;
(C) Escherichia coli 0157:H7; or
(D) Hepatitis A virus associated with foodborne or waterborne transmission that are reportable according to 410 IAC 1-2.3.

(Indiana State Department of Health; 410 IAC 7-21-26; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1618, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-27 "Quality control operation" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-2-2; IC 16-42-5

Sec. 27. "Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated as defined under IC 16-42-2-2. *(Indiana State Department of Health; 410 IAC 7-21-27; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1618, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-28 "Reduced oxygen packaging" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 28. (a) "Reduced oxygen packaging" means the following:

(1) The reduction of the amount of oxygen in a package by:
(A) removing oxygen;
(B) displacing oxygen and replacing it with another gas or combination of gases; or
(C) otherwise controlling the oxygen content to a level below that normally found in the surrounding twenty-one percent (21%) oxygen atmosphere.

(2) A process as specified in subdivision (1) that involves a food for which Clostridium botulinum is identified as a microbiological hazard in the final packaged form.

(b) The term includes the following:

(1) Vacuum packaging in which air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package, such as sous vide.

(2) Modified atmosphere packaging in which the atmosphere of a package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmosphere packaging includes any of the following:
(A) Reduction in the proportion of oxygen.
(B) Total replacement of oxygen.
(C) An increase in the proportion of other gases, such as carbon dioxide or nitrogen.

(3) Controlled atmosphere packaging in which the atmosphere of a package of food is modified so that, until the package is opened, its composition is different from air, and continuous control of that atmosphere is maintained as such by using oxygen scavengers or a combination of total replacement of oxygen, nonrespiring food, and impermeable packaging material.

(Indiana State Department of Health; 410 IAC 7-21-28; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1618, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-29 "Restricted use pesticide" defined

Authority: IC 16-42-5-5
Affected: IC 15-3-3.5-2; IC 16-42-5

Sec. 29. "Restricted use pesticide" has the same meaning as defined in IC 15-3-3.5-2(27). *(Indiana State Department of Health; 410 IAC 7-21-29; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1619, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-30 "Rework" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 30. "Rework" means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. *(Indiana State Department of Health; 410 IAC 7-21-30; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1619, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-31 "Sanitization" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 31. "Sanitization" means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of five (5) logs, which is equal to a ninety-nine and nine hundred ninety-nine thousandths percent (99.999%) reduction of representative disease-causing micro-organisms of public health significance. *(Indiana State Department of Health; 410 IAC 7-21-31; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1619, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-32 "Scheduled process" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 32. "Scheduled process" means the process selected by a processor as adequate for use under food manufacturing conditions to achieve and maintain a food that will not permit the growth of micro-organisms having a public health significance. The term includes control of pH and other critical factors equivalent to the process established by a competent processing authority. *(Indiana State Department of Health; 410 IAC 7-21-32; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1619, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-33 "Water activity" defined

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 33. "Water activity" indicated by the symbol a_w means water activity that is a measure of the free moisture in a food and the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature. *(Indiana State Department of Health; 410 IAC 7-21-33; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1619, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-34 "Wholesale food establishment" defined

Authority: IC 16-42-5-5
Affected: IC 15-2.1-23; IC 15-2.1-24; IC 16-42-11

Sec. 34. (a) "Wholesale food establishment" means any establishment within Indiana that manufactures, packages, stores,

repackages, or transports human food products for distribution to another entity for resale or redistribution.

(b) The term does not include the following:

(1) A residential kitchen in a private home.

(2) Bed and breakfast establishments subject to 410 IAC 7-15.5.

(3) An establishment engaged solely in the harvesting, storage, or distribution of one (1) or more raw agricultural commodities, that is not ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(4) Meat and poultry processing plants subject to IC 15-2.1-24; dairy processing plants subject to IC 15-2.1-23 and 345 IAC 8; or shell egg plants subject to 370 IAC 1-10-1 and IC 16-42-11.

(5) Any establishments as defined in 410 IAC 7-20-70, except when engaged in activities under subsection (a) or when producing acidified foods in hermetically sealed containers.

(Indiana State Department of Health; 410 IAC 7-21-34; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1619, eff one hundred twenty (120) days after filing with secretary of state; errata filed Jan 9, 2002, 12:50 p.m.: 25 IR 1644)

410 IAC 7-21-35 Personnel health

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 35. (a) The plant management shall take all reasonable measures and precautions to ensure compliance with the following:

(1) Any person who, by medical examination or supervisory observation, is shown to have, or appears to have:

(A) an illness;

(B) an open lesion, including:

(i) boils;

(ii) sores; or

(iii) infected wounds; or

(C) any other abnormal source of microbial contamination;

by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated shall be excluded or restricted from any operations, which may result in contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to supervisory personnel.

(2) An exclusion shall be applied if a food employee is diagnosed with an illness due to Salmonella spp., Shigella spp., Escherichia coli 0157:H7, or Hepatitis A virus. A food employee shall be restricted from working with exposed food, food-contact surfaces, clean equipment, and utensils or food-packaging materials if the food employee:

(A) has a symptom caused by illness, infection, or other source that is associated with an acute gastrointestinal illness, such as diarrhea, fever, vomiting, jaundice, or sore throat with fever;

(B) has a lesion containing pus, such as a boil or infected wound that is open or draining and is:

(i) on the hands or wrists unless an impermeable cover, such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover;

(ii) on exposed portions of the arms unless the lesion is protected by an impermeable cover; or

(iii) on the other parts of the body unless the lesion is covered by a dry, durable, tight-fitting bandage; or

(C) is not experiencing a symptom of acute gastroenteritis as specified in this subdivision, but has a stool that yields a specimen culture that is positive for Salmonella spp., Shigella spp., or Escherichia coli 0157:H7.

(3) An exclusion may be removed when supervisory personnel obtains from the excluded person written medical documentation from a physician, a nurse practitioner, or a physician assistant that the excluded person may work in an unrestricted capacity.

(4) A restriction may be removed by supervisory personnel when the restricted person:

(A) is free of the symptoms of illness specified in subdivision (2) and no foodborne illness occurs that may have been caused by the restricted person;

(B) is suspected of causing foodborne illness but:

(i) is free of the symptoms specified under subdivision (2)(A); and

(ii) provides written medical documentation from a physician, a nurse practitioner, or a physician assistant stating

that the restricted person is free of the infectious agent that is suspected of causing the person's symptoms or causing foodborne illness; or

(C) provides written medical documentation from a physician, a nurse practitioner, or a physician assistant stating that the symptoms experienced result from a chronic noninfectious condition, such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis.

(b) The department may issue an order of restriction or exclusion to a wholesale food establishment without prior warning, notice of a hearing, or a hearing if the order states the following:

(1) The reasons for the restriction or exclusion that is ordered.

(2) The evidence that the wholesale food establishment shall provide in order to demonstrate that the reasons for the restriction or exclusion has been eliminated.

(3) That a suspected food employee or the wholesale food establishment may request an appeal hearing by submitting a timely request as provided in law.

(4) The name and address of the department's representative to whom a request for an appeal hearing may be made.

(Indiana State Department of Health; 410 IAC 7-21-35; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1619, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-36 Personnel hygienic practices

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 36. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to good hygienic practices while on duty. The methods for maintaining good hygiene include, but are not limited to, the following:

(1) Wearing clean outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness, including:

(A) keeping fingernails clean and neatly trimmed; and

(B) not wearing fingernail polish or artificial fingernails;

while working with exposed food.

(3) Washing hands thoroughly in an adequate hand washing facility as follows:

(A) Before starting work.

(B) After each absence from the work station.

(C) After touching bare human body parts other than clean hands and clean, exposed portions of arms.

(D) After using the toilet room.

(E) After caring for or handling service animals or aquatic animals.

(F) After coughing, sneezing, or using a handkerchief or disposable tissue.

(G) After drinking, unless the handling of the container allows for no direct contamination, and after eating or using tobacco.

(H) After handling soiled surfaces, equipment, or utensils.

(I) During food preparation, as often as necessary to remove soil and contamination and to prevent cross-contamination when changing tasks.

(J) When switching between working with raw food and working with ready-to-eat food.

(K) Directly before touching ready-to-eat food or food-contact surfaces.

(L) At any other time when the hands may have become soiled or contaminated.

(4) Wearing no jewelry while preparing food. If hand jewelry cannot be removed or if approval is given by supervisory personnel for the wearing of a wedding band, it may be covered by an impermeable cover, such as a glove, that can be maintained in an intact, clean, and sanitary condition and that protects against contamination.

(5) Maintaining gloves in an intact, clean, and sanitary condition if they are used in direct contact with food. The gloves shall be made of an impermeable material.

(6) Wearing hair restraints, such as nets, hats, beard restraints, and clothing that covers body hair, which are designed and worn effectively to keep hair from contacting exposed food, clean food-contact equipment, and utensils.

(7) Storing employees' food and personal belongings in a designated location separate from food processing, storage, and

packaging areas.

(8) Confining the following to areas other than where food and food processing equipment may be exposed or where equipment or utensils are washed and stored:

(A) eating food;

(B) chewing gum;

(C) drinking beverages; or

(D) using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with micro-organisms or foreign substances, including, but not limited to, the following:

(A) Perspiration.

(B) Hair.

(C) Cosmetics.

(D) Tobacco.

(E) Chemicals.

(F) Medicines applied to the skin.

(Indiana State Department of Health; 410 IAC 7-21-36; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1620, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-37 Personnel training

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 37. (a) Personnel responsible for identifying sanitation failures or food contamination shall have an educational background or experience, or a combination thereof, to provide a level of competency necessary for production of unadulterated, honestly presented, safe food. Food employees and supervisory personnel involved in food processing shall receive appropriate training in proper food-handling techniques, foodborne illness prevention, and food protection principles and be informed of the danger of poor personal hygiene and insanitary practices.

(b) Competent supervisory personnel shall be clearly assigned responsibility for assuring compliance by all food employees engaged in food processing with all requirements. Supervisory personnel shall hold a certification or be trained at a minimum on the following areas of knowledge as are applicable to the operations conducted at the wholesale food establishment:

(1) The relationship between the prevention of foodborne disease and the personal hygiene of a food employee.

(2) Responsibility of supervisory personnel for preventing the transmission of foodborne disease by a food employee who has an illness or medical condition that may cause foodborne disease.

(3) Symptoms associated with the diseases that are transmissible through food.

(4) Required food temperatures and times for safe cooking, cooling and reheating of potentially hazardous foods, and refrigerated storage temperatures include those for meat, poultry, eggs, and fish.

(5) The relationship between the prevention of foodborne illness and the management and control of the following:

(A) Cross-contamination.

(B) Hand contact with ready-to-eat foods.

(C) Hand washing.

(D) Maintaining the wholesale food establishment in a clean condition and in good repair.

(6) The correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment.

(7) Poisonous or toxic materials identification and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law.

(8) Knowledge of important processing points in the operation from purchasing through sale or service.

(9) The principles and details of a HACCP plan, if used, or if required by federal or state law, or if an agreement between the department and the establishment exists.

(10) Water sources identification and measures taken to ensure that it remains protected from contamination, such as providing protection from backflow and precluding the creation of cross-connections.

(Indiana State Department of Health; 410 IAC 7-21-37; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1621, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-38 Physical facilities and grounds

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 38. (a) The grounds surrounding a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to, the following:

(1) Properly storing or removing unnecessary equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the physical facility that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, footborne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and removal of liquid and solid waste at such a frequency that the waste does not constitute a source of contamination in areas where food is exposed.

(5) Constructing, if needed, an outdoor storage surface of nonabsorbent material, such as concrete or asphalt that shall be smooth, durable, and sloped to drain for refuse, recyclables, and returnables. Refuse, recyclables, and returnables shall be handled by:

(A) storing them in receptacles or waste handling units so that they are inaccessible to insects and rodents;

(B) keeping receptacles and waste handling units for refuse, recyclables, and returnables covered with tight-fitting lids or doors; and

(C) locating receptacles and waste handling equipment at a distance from the building that minimizes the entrance of pests and other vermin.

(b) If the wholesale food establishment grounds are bordered by grounds not under the operator's control and not maintained in the manner described in subsection (a)(1) through (a)(3), care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(c) Physical facilities shall be adequate in size, construction, and design to facilitate maintenance and sanitary operations for food manufacturing purposes. Methods for maintaining a sanitary operation include, but are not limited to, the following:

(1) Providing sufficient space for placement of equipment and storage of materials.

(2) Taking precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with micro-organisms, chemicals, filth, or other extraneous material. The potential for contamination shall be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one (1) or more of the following means:

(A) Location.

(B) Time.

(C) Partition.

(D) Air flow.

(E) Enclosed systems.

(F) Other effective means.

(3) Locating areas designated for employees to eat, drink, and use tobacco so that food and equipment are protected from contamination.

(4) Prohibiting a person from living or sleeping in a room used for food-handling or in a room opening directly into a wholesale food establishment. If living or sleeping quarters are located on the premises, such as those provided for security personnel, it shall be separated from rooms and areas used for wholesale food establishment operations by complete partitioning and solid self-closing doors.

(5) Protecting food in outdoors bulk fermentation vessels by any effective means, including, but not limited to, the following:

(A) Using protective coverings.

(B) Controlling areas over and around the vessels to eliminate harborages for pests.

(C) Checking on a regular basis for pests and pest infestation.

(D) Skimming the fermentation vessels, when necessary.

(6) Constructing facility in such a manner that:

(A) floors, walls, and ceilings may be adequately cleaned and maintained in good repair;

(B) drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-

packaging materials; and

(C) aisles or working spaces are provided between equipment and walls and food products and walls and are adequately unobstructed and have adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(7) Providing sufficient lighting in hand washing areas, dressing and locker rooms, toilet rooms, and all areas where food is examined, processed, or stored and where equipment or utensils are cleaned. Light bulbs shall be protected in the following manner:

(A) Shielded, coated, or otherwise shatter-resistant in areas suspended over exposed food in any step of preparation and over clean equipment, utensils, and linens.

(B) Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages if:

(i) the integrity of the packages cannot be affected by broken glass falling onto them; and

(ii) the packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

(8) Providing adequate ventilation or control equipment to minimize odors and vapors, including steam and noxious fumes, in areas where they may contaminate food, and locate and operate fans and other air blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces. To comply:

(A) intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials; and

(B) ventilation systems may not create a public health hazard or nuisance or unlawful discharge, if vented to the outside.

(9) Protecting outer openings against the entry of insects, rodents, or other vermin by:

(A) filling or closing holes and other gaps along floor, walls, and ceilings;

(B) closed, tight-fitting windows;

(C) solid, self-closing, and tight-fitting doors, except emergency exit and dock doors do not need to be self-closing; and

(D) using screening, air curtains, or other effective means, when appropriate.

(Indiana State Department of Health; 410 IAC 7-21-38; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1621, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-39 Sanitary operations; general maintenance

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 39. (a) The plant shall be:

(1) maintained in a sanitary condition; and

(2) kept in repair sufficient to prevent food from becoming adulterated.

Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) Food-contact surfaces, utensils, and equipment shall be cleaned as frequently as necessary to protect against contamination of food by performing the following:

(1) Food-contact surfaces of equipment and utensils used for manufacturing or holding low moisture food shall be in a dry, clean, and sanitary condition at the time of use. When the food-contact surfaces are wet cleaned, they shall be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is performed to protect against the introduction of micro-organisms into food, food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated.

(3) Where equipment and utensils are used in a continuous production operation, food-contact surfaces of the equipment shall be cleaned and sanitized as necessary to prevent contamination.

(4) Nonfood-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(5) Single-service articles, such as utensils intended for one-time use, paper cups, and paper towels, should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination

of food or food-contact surfaces.

(6) Cleaned and sanitized portable equipment with food-contact surfaces and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination.

(7) Sanitizing agents shall be effective and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and sanitized.

(8) Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010.

(Indiana State Department of Health; 410 IAC 7-21-39; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1623, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-40 Toxic and poisonous substances; pest control

Authority: IC 16-42-5-5
Affected: IC 15-3-3.6; IC 16-42-5

Sec. 40. (a) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable micro-organisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by an effective means, including, but not limited to, purchase of substances under a supplier's guarantee or certification, or examination of the substances for contamination.

(b) Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(1) Chemicals required for maintaining clean and sanitary conditions.

(2) Chemicals necessary for use in laboratory testing procedures.

(3) Chemicals necessary for plant and equipment maintenance and operation.

(4) Chemicals necessary for use in the plant's operations.

(c) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. Poisonous or toxic materials shall be stored and transported according to the following:

(1) Separating the poisonous or toxic materials by spacing or partitioning.

(2) Locating the poisonous or toxic materials in an area that is not above food, equipment, linens, or food-contact surfaces.

(d) Poisonous or toxic materials shall be applied and used according to all relevant regulations promulgated by other federal, state, and local government agencies and according to the following:

(1) Manufacturers' use directions on the label.

(2) The conditions of certification for use of the pest control materials.

(3) Applied in a manner that does not constitute a hazard to personnel or does not contaminate by drip, drain, fog, splash, or spray any food, equipment, utensils, linens, or other food-contact surface. For pesticide use, this is achieved by:

(A) removing the items;

(B) covering the items with impermeable covers; or

(C) taking other appropriate preventive action and cleaning and sanitizing equipment, utensils, and food-contact surfaces after application.

(4) Chemicals used to wash or peel whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315.

(5) Chemicals used as boiler water additives shall meet the requirements as specified in 21 CFR 173.310.

(6) A restricted use pesticide shall be applied only by an applicator certified according to 312 IAC 15-3-3.6 or a person under the direct supervision of a certified applicator.

(e) Pests shall not be allowed in any area of a wholesale food establishment. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that protect against the contamination of food, food-contact surfaces, and food-packaging materials, such as the following:

(1) Rodent bait shall be contained in a covered, tamper-resistant bait station.

(2) Toxic tracking powder pesticide may not be used in wholesale food establishments.

(f) Guard dogs and service animals may be allowed in some areas of a plant if the presence of the animals cannot result in contamination of food, food-contact surfaces, or food-packaging materials. *(Indiana State Department of Health; 410 IAC 7-21-40;*

filed Jan 7, 2002, 10:16 a.m.: 25 IR 1623, eff one hundred twenty (120) days after filing with secretary of state; errata filed Jan 9, 2002, 12:50 p.m.: 25 IR 1645)

410 IAC 7-21-41 Plumbing and sewage systems

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 41. Each facility shall be equipped with effective plumbing and sewage facilities and adequate accommodations, including, but not limited to, the following:

(1) The water supply shall be sufficient for the operations intended and shall be derived from an approved source. Drinking water and water used for food processing operations shall meet bacteriological and chemical quality standards specified in 327 IAC 8-2. Running water at a suitable temperature and under pressure as needed shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(2) If a food processing plant obtains water from a water system not subject to 327 IAC 8-2 for its operations, the operator shall sample the water at least annually for bacterial analysis by a certified laboratory, maintain records of analyses of sample results for three (3) years, and provide such records to the department upon request.

(3) A plumbing system shall be of sufficient size and shall be designed, constructed, installed, and maintained according to the applicable Indiana plumbing code, 675 IAC 16-1.3, to do the following:

(A) Carry sufficient quantities of water to required locations throughout the facility.

(B) Properly convey sewage and liquid disposable waste from the facility.

(C) Avoid constituting a source of contamination to food, water supplies, equipment, and utensils or creating an unsanitary condition.

(D) Provide sufficient floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(E) Prevent backflow or backsiphonage from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing. This shall be accomplished by the following:

(i) Installing a backflow or backsiphonage prevention device on a water supply system which meets the standards in 675 IAC 16-1.3 for construction, installation, maintenance, inspection, and testing for that specific application and type of approved device.

(ii) Using an air gap, if necessary, between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment. It shall be at least twice the diameter of the water supply inlet and may not be less than one (1) inch.

It shall be a minimum of two (2) pipe diameters of the pipe or six (6) inches, whichever is the lesser.

(4) Sewage disposal shall be conveyed into an approved sanitary sewerage system or other system, including the use of sewage transport vehicles, pumps, hoses, and connections that are constructed, maintained, and operated according to law.

(Indiana State Department of Health; 410 IAC 7-21-41; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1624, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-42 Sanitary facilities and controls

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 42. (a) Each facility shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement shall be accomplished by, but not limited to, the following:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against contamination, such as double doors or positive airflow systems.

(b) Each facility shall provide its employees with hand washing facilities that are adequate, readily accessible, and convenient. Compliance with this requirement shall be accomplished by providing the following:

(1) Hand washing facilities at each location in the plant where good sanitary practices require employees to wash their hands. Each hand washing facility shall be:

(A) furnished with hot and cold running water tempered by means of a mixing valve or combination faucet; and

(B) capable of reaching a minimum water temperature of eighty-five (85) degrees Fahrenheit within sixty (60) seconds.

(2) Effective hand-cleaning preparations.

(3) Sanitary towel service, paper towels, or suitable drying devices.

(4) Devices or fixtures, such as water control valves, designed and constructed to protect against recontamination of clean hands.

(5) Signs directing food employees handling unprotected food, unprotected food-packaging materials, and food-contact surfaces to wash and, where appropriate, sanitize their hands. These signs should be posted in the processing room and in all other areas where employees handle food, food-packaging materials, or food-contact surfaces. If necessary, the signs should be multilingual.

(c) If mops or similar wet floor cleaning tools are used, at least one (1) service sink or one (1) curbed cleaning facility equipped with a floor drain and supplied with hot and cold water under pressure shall be provided and conveniently located.

(d) Receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect-resistant, rodent-resistant, leakproof, nonabsorbent, and maintained in good repair.

(e) Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces. *(Indiana State Department of Health; 410 IAC 7-21-42; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1625, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-43 Equipment and utensils

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 43. (a) All processing equipment and utensils shall be so designed and of such material and workmanship as to be effectively cleanable and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment shall be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives by the following means:

(1) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of micro-organisms.

(2) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be maintained in a clean condition.

(3) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(b) Each freezer and refrigeration unit, including transportation vehicles, used to store, hold, or transport food capable of supporting growth of micro-organisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately within the compartment and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation. The operator shall do the following:

(1) Record the temperature shown by each measuring device installed in the unit, with the date on which the temperature reading was taken. Temperature shall be monitored and recorded at least weekly.

(2) Retain and have available for inspection the temperature records for the last six (6) months.

(c) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable micro-organisms in food shall be accurate and adequately maintained,

sufficient in number for their designated uses, and calibrated at the frequency recommended by the manufacturer of the device. The ambient air temperature measuring devices that are scaled in Fahrenheit shall be accurate to plus or minus three (3) degrees Fahrenheit in the intended range of use.

(d) The amount of food stored in a refrigerator or frozen food storage unit shall not exceed the designed capacity of that unit.

(e) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives. *(Indiana State Department of Health; 410 IAC 7-21-43; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1625, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-44 Raw materials; production and process controls

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 44. (a) All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with current sanitation principles as follows:

(1) Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(2) Overall sanitation of the plant shall be under the supervision of one (1) or more competent individuals assigned responsibility for this function.

(3) All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source by adhering to the following:

(A) Chemical, microbial, or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination.

(B) All food that has become contaminated to the extent that it is adulterated shall be rejected or, if permissible, treated or processed to eliminate the contamination.

(b) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ensure that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration by the following:

(1) Washing or cleaning raw materials as necessary to remove soil or other contamination.

(2) Using water for washing, rinsing, or conveying food that is safe and meets the quality standards specified in 327 IAC 8-2.

(3) Reusing water for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.

(4) Inspecting on receipt containers and carriers of raw materials to ensure that their condition has not contributed to the contamination or deterioration of food.

(c) Raw materials and other ingredients shall not contain levels of micro-organisms that may produce foodborne illness or other disease in humans. If the potential for high levels of disease-causing micro-organisms is present, food shall be pasteurized or otherwise treated during manufacturing operations so that the food no longer contains levels that would cause the product to be adulterated. Compliance with this requirement may be verified by any effective means, such as with a HACCP plan or purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(d) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current state and federal regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by:

(1) purchasing raw materials and other ingredients under a supplier's guarantee or certification; or

(2) verifying by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(e) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable micro-organisms, or extraneous material shall comply with applicable state and federal regulations, guidelines, and defect action levels for natural or unavoidable defects, as specified in 21 CFR 110.110, if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, such as:

(1) purchasing the materials under a supplier's guarantee or certification; or

(2) examination of these materials for contamination.

(f) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed to protect against contamination and shall be held at proper temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework shall be identified as such.

(g) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be stored in a manner that protects against contamination.

(h) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(i) Food may not contain unapproved food additives or additives that exceed amounts specified in 21 CFR 170 through 21 CFR 180 relating to food additives generally recognized as safe, or prior sanctioned substances that exceed amounts specified in 21 CFR 181, 21 CFR 182, 21 CFR 184, and 21 CFR 186. *(Indiana State Department of Health; 410 IAC 7-21-44; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1626, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-45 Manufacturing operations

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 45. (a) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing and when necessary the following:

(1) Equipment shall be taken apart for thorough cleaning and sanitizing.

(2) A CIP system may be used when the design of the equipment requires the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution.

(b) All food manufacturing, including packaging and storage, shall be conducted under conditions and controls as necessary to minimize the potential for the growth of micro-organisms or the contamination of food. Compliance with this subsection may require careful monitoring of physical factors, such as time, temperature, humidity, water activity (a_w), pH, pressure, flow rate, and manufacturing operations, such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(c) Food that can support the rapid growth of undesirable micro-organisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated. Compliance with this subsection shall be accomplished by an effective means, including, but not limited to, the following:

(1) Maintaining cold, potentially hazardous foods at forty-one (41) degrees Fahrenheit or below. Exceptions to this requirement are when the receiving and storage temperatures are specified in another law, such as laws governing milk, molluscan shellfish, and shell eggs. These foods may be received and stored at the temperature specified in law.

(2) Maintaining hot, potentially hazardous foods at one hundred forty (140) degrees Fahrenheit or above.

(3) Heat treating acid or acidified foods to destroy mesophilic micro-organisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(d) Frozen foods shall be maintained in a frozen state and should be stored at zero (0) degrees Fahrenheit or below. Frozen foods shall not be refrozen after having been thawed unless the products are to be further processed by the processor, as necessary to control microbial growth.

(e) Frozen foods during transportation shall remain frozen and should be at zero (0) degrees Fahrenheit or below. Refrigerated foods during transportation shall be at forty-one (41) degrees Fahrenheit or below unless law governing their distribution applies, such as temperature requirements for shell eggs.

(f) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH, or controlling a_w that is taken to destroy or prevent the growth of undesirable micro-organisms, particularly those of public health significance, shall be effective under the conditions of manufacturing, handling, and distribution to prevent food from being adulterated.

(g) Work-in-process shall be handled in a manner that protects against contamination.

(h) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, including potential food allergens, or refuse in the following manner:

(1) When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in receiving, loading, or shipping areas if that handling could result in contaminated food.

(2) Food transported by conveyor shall be protected against contamination as necessary.

(i) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be of a food grade quality and constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(j) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this subsection shall be accomplished by using sieves, traps, magnets, and electronic metal detectors, or other effective means. If lubricants are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces, they shall meet the requirements specified in 21 CFR 178.3570.

(k) Food, raw materials, and other ingredients that are adulterated shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated before being incorporated into other food.

(l) Mechanical manufacturing steps, such as washing, peeling, trimming, cutting, sorting, and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this subsection shall be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection shall be provided by adequate cleaning and sanitizing of all food-contact surfaces and by using time and temperature controls at and between each manufacturing step.

(m) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delays. Thermophilic growth and contamination in blanchers should be minimized by the use of effective operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and meet the quality standards specified in 327 IAC 8-2.

(n) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. If the products are potentially hazardous they shall be held at forty-one (41) degrees Fahrenheit or below or at one hundred forty (140) degrees Fahrenheit or above. Compliance with this subsection shall be accomplished by an effective means, including one (1) or more of the following:

(1) Using ingredients free of contamination.

(2) Employing adequate heat processes where applicable.

(3) Using adequate time and temperature controls.

(4) Providing effective physical protection of food or equipment from contaminants that may drip, drain, or be drawn into them.

(5) Rapid cooling to a storage temperature of forty-one (41) degrees Fahrenheit or below.

(6) Disposing of batters at appropriate intervals to protect against the growth of micro-organisms.

(o) Filling, assembling, packaging, and other operations shall be performed in a way that the food is protected against contamination. Compliance with this subsection shall be accomplished by the following:

(1) Using a quality control operation in which the critical control points are identified and controlled during manufacturing, if applicable.

(2) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(3) Using materials for food containers and food-packaging materials that are safe and intended for food use.

(4) Providing effective physical protection from contamination, particularly airborne contamination.

(5) Using sanitary handling procedures.

(6) Utilizing adequate control procedures to prevent allergen cross contact.

(p) Food, such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable micro-organisms shall be processed to and maintained at a safe moisture level of eighty-five hundredths (0.85) or less. Compliance with this subsection shall be accomplished by any effective means, including the employment of one (1) or more of the following practices:

(1) Monitoring the a_w of food.

(2) Controlling the soluble solids/water ratio in finished food.

(3) Protecting finished food from moisture pick-up by use of a moisture barrier or by other means so that the a_w of the food does not increase to an unsafe level.

(q) When ice is used as an ingredient or in contact with food, it shall be made from water that is safe and meets the quality standards specified in 327 IAC 8-2. It shall be used only if it has been manufactured in accordance with this rule.

(r) Bottled drinking water, manufactured, used, or sold, shall meet the requirements of 21 CFR 129 and 21 CFR 165.

(s) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human

food.

(t) The operator of a wholesale food establishment that manufactures ready-to-eat, potentially hazardous foods shall report to the department the results of any microbiological test or other laboratory analysis, which shows a likelihood that any ready-to-eat food produced by that operator contains pathogenic organisms, undeclared allergens, or other health hazards. The operator shall report to the department within twenty-four (24) hours after receiving positive test results. The operator may report orally, electronically, or in writing, except as specified in the following:

(1) A wholesale food establishment operator is not required to report test results if the following conditions apply:

(A) A product code or production date identifies the ready-to-eat food lot number.

(B) The wholesale food establishment operator has not sold or distributed any of the food represented by the product code or production lot number as specified under clause (A).

(2) The department shall be notified in a timely manner if the wholesale food establishment initiates a recall and if positive testing results in the disposition of products.

(Indiana State Department of Health; 410 IAC 7-21-45; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1627, eff one hundred twenty (120) days after filing with secretary of state; errata filed Jan 9, 2002, 12:50 p.m.: 25 IR 1645)

410 IAC 7-21-46 Reduced oxygen packaging

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 46. (a) A wholesale food establishment that packages food using a reduced oxygen packaging method, with Clostridium botulinum identified as a microbiological hazard in the final packaged form, shall ensure that there are at least two (2) barriers in place to control the growth and toxin formation of Clostridium botulinum. These controls may include refrigeration, pH, and water activity.

(b) An establishment that packages food using a reduced oxygen packaging method, with Clostridium botulinum identified as a microbiological hazard in the final packaged form, shall have a HACCP plan that does the following:

(1) Contains a flow diagram by specific food or category type identifying critical control points and providing information on the following:

(A) Ingredients, materials, and equipment used in the preparation of that food.

(B) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved.

(2) Contains a statement of standard operating procedures for the plan that clearly identifies the following:

(A) Each critical control point.

(B) The critical limits for each critical control point.

(C) The method and frequency for monitoring and controlling each critical control point by the food employee designated by supervisory personnel.

(D) The method and frequency for supervision to routinely verify that the food employee is following standard operating procedures and monitoring critical control points.

(E) Action to be taken by supervision if the critical limits for each critical control point is not met.

(F) Records to be maintained by supervision to demonstrate that the HACCP plan is properly operated and managed.

(3) Identifies the food to be packaged.

(4) Limits the food packaged to a food that does not support the growth of Clostridium botulinum because it meets with one (1) of the following criteria:

(A) Has an a_w of ninety-one hundredths (0.91) or less.

(B) Has a pH of four and six-tenths (4.6) or less.

(C) Is a meat or poultry product cured at a food processing plant regulated by the United States Department of Agriculture and is received in an intact package.

(D) Is a food with a high level of competing organisms, such as raw meat or raw poultry.

(5) Specifies methods for maintaining food at forty-one (41) degrees Fahrenheit or below.

(6) Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(A) maintain the food at forty-one (41) degrees Fahrenheit or below; and

(B) discard the food if within fourteen (14) calendar days of its packaging it is not sold for consumption.

(7) Limits the shelf life to no more than fourteen (14) calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first.

(8) Includes operational procedures that:

(A) prohibit contacting food with bare hands;

(B) identify a designated area and the method by which:

(i) physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination; and

(ii) access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation; and

(C) delineate cleaning and sanitization procedures for food-contact surfaces.

(9) Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(A) concepts required for a safe operation;

(B) equipment and facilities; and

(C) procedures specified under subdivisions (2) and (8).

(Indiana State Department of Health; 410 IAC 7-21-46; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1629, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-47 Acidified foods

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 47. A wholesale food establishment that processes acidified foods shall employ appropriate quality control procedures to ensure that finished foods do not present a health hazard as follows:

(1) All operators of processing and packaging systems shall be under the operating supervision of a person who has:

(A) attended a school giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls, and critical factors in acidification; and

(B) been identified by that school as having satisfactorily completed the prescribed course of instruction.

A United States Food and Drug Administration (FDA) sponsored Better Processing Control School is an approved school. Other equivalent schools approved by the department may be attended. The department shall consider students who have satisfactorily completed required portions of the school to be in compliance with the requirement of this subdivision.

(2) Acidified foods shall be manufactured, processed, and packaged so that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods. Manufacturing shall be in accordance with the scheduled process. Acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of micro-organisms of public health significance and those of nonhealth significance, such as yeast and mold, capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed, and held by the user. FDA approved preservatives may be used to inhibit reproduction of micro-organisms of nonhealth significance in lieu of thermal processing.

(3) Sufficient control, including frequent testing and recording of results, shall be exercised so that the finished equilibrium pH values for acidified foods are not higher than 4.6. Measurement of acidity of foods in process may be made by potentiometric methods, titratable acidity, or colorimetric methods. If the finished equilibrium pH of the food is above 4.0, the measurement of the finished equilibrium pH shall be by a potentiometric method, and the in-process measurements by titration or colorimetry shall be related to the finished equilibrium pH. If the finished equilibrium pH is 4.0 or below, then the measurement of acidity of the final product may be made by any suitable method. When food ingredients have been subjected to lye, lime, or similar high pH materials, they may alter the pH of the product.

(4) Procedures for acidification to attain acceptable equilibrium pH levels in the final food include, but are not limited to, the following:

(A) Blanching of the food ingredients in acidified aqueous solutions.

(B) Immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, process controls must be taken to ensure that the acid concentration is properly maintained.

(C) Direct batch acidification, which can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification.

(D) Direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than solid or pelleted acids. Process controls must be taken to ensure that the proper amount of acid is added to each container.

(E) Addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations.

(5) Testing and examinations of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination.

(6) pH meters shall be standardized to get an accurate pH measurement. The directions for standardization and storage supplied by the manufacturer of the equipment shall be followed.

(7) Each container or product shall be marked with an identifying code permanently visible to the naked eye. If the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, as long as the label is securely affixed to the product container. The required identification shall specify in code the wholesale food establishment where the product was packed, the product contained therein, and the year, day, and period during which it was packed. The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Codes may be changed periodically on one (1) of the following bases:

(A) Intervals of four (4) to five (5) hours.

(B) Personnel shift changes.

(C) Batches, as long as the containers constituting the batch do not represent those processed during more than one (1) personnel shift.

(8) A qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods shall establish the scheduled process and be considered a processing authority. A written document or published paper prepared by experts in acidified food processing, such as the "Ball Canning Book", may qualify. Any modifications to a process listed in a document or paper shall be substantiated by a qualified person, and that person shall be listed as the processing authority. Copies of the scheduled process shall be kept at the facility.

(9) Whenever any process operation deviates from the scheduled process for any acidified food and/or the equilibrium pH of the finished product is higher than 4.6, the commercial processor of the acidified food shall do any of the following:

(A) Fully reprocess that portion of the food by a process established by a competent processing authority as effective to ensure a safe product.

(B) Thermally process the food as a low-acid food under 21 CFR 113.

(C) Set aside that portion of the food involved for further evaluation as to any potential public health significance. The evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. Unless the evaluation demonstrates that the food has undergone a process that has rendered it safe the food set aside shall either be fully reprocessed to render it safe or be destroyed. A record shall be made of the procedures used in the evaluation and the results. Either upon completion of full reprocessing and the attainment of a safe food, or after the determination that no significant micro-organisms for public health hazard exists, that portion of the food involved may be shipped in normal distribution. Otherwise, the portion of the food involved shall be destroyed.

(10) Records shall be maintained of examinations of raw materials, packaging materials, and finished products and of suppliers' guarantees or certifications that verify compliance with this rule.

(11) Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, shall be maintained and shall contain sufficient additional information, such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production.

(12) Records shall be kept of all departures from scheduled processes having a possible bearing on public health or the safety of the food. The records shall delineate the action taken and the final disposition of the product involved.

(13) Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.

(14) If a processor makes an electronic record of pH by connection of the pH meter to a computer or by manually keying the pH values into a computer as the primary record, then that record is subject to 21 CFR 11.

(15) Copies of all records provided for in subdivisions (10) through (14) shall be retained at the processing plant or other

reasonable, accessible location for a period of three (3) years from the date of manufacture.
(Indiana State Department of Health; 410 IAC 7-21-47; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1630, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-48 Warehousing and distribution

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 48. Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. Potentially hazardous foods shall be transported at the temperatures as specified in section 45(c)(1) of this rule and sections 45(d) through 45(e) of this rule *[section 45(c)(1) and 45(d) through 45(e) of this rule]*. *(Indiana State Department of Health; 410 IAC 7-21-48; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1631, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-49 Accurate representation of packaged food using standards of identity, honest presentation of food, and food labels

Authority: IC 16-42-5-5
Affected: IC 16-42-1; IC 16-42-2

Sec. 49. (a) Packaged food shall comply with standard of identity requirements in 21 CFR 130 through 21 CFR 169.

(b) Food shall be offered for human consumption in a way that does not mislead or misinform the consumer.

(c) Food or color additives, colored overwraps, or lights may not be used to misrepresent the true appearance, color, or quality of the food.

(d) Food packaged or stored in a wholesale food establishment shall be labeled as specified in law, including the following:

(1) IC 16-42-1.

(2) IC 16-42-2.

(3) 410 IAC 7-5.

(4) 21 CFR 101.

(e) Label information shall include the following:

(1) The common name of the food or, absent a common name, an adequately descriptive identity statement.

(2) If made from two (2) or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food.

(3) An accurate declaration of the quantity of contents as required in 410 IAC 12-1.

(4) The name and place of business of the manufacturer, packer, or distributor.

(Indiana State Department of Health; 410 IAC 7-21-49; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1631, eff one hundred twenty (120) days after filing with secretary of state)

410 IAC 7-21-50 Public health protection; access; reporting imminent health hazards

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 50. (a) The department shall uniformly apply this rule to all wholesale food establishments in a reasonable manner that promotes its underlying purpose of safeguarding public health and ensuring that food is safe, not misbranded, unadulterated, and honestly presented when offered to the consumer.

(b) Facilities and equipment that were installed prior to the effective date of this rule, that do not fully meet all of the design and fabrication requirements, shall be deemed acceptable in that wholesale food establishment if it is in good repair, capable of being maintained in a sanitary condition, and the food-contact surfaces are nontoxic.

(c) After the department presents official credentials and expresses an intent to inspect, investigate, or collect food samples, the supervisory personnel shall allow the department access to the establishment during the establishment's hours of operation and other reasonable times. Information and records to which the department is entitled according to law and are specified in this rule shall be provided upon request.

(d) A wholesale food establishment shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist because of an emergency, such as:

(1) a fire;

(2) a flood;

(3) an extended interruption of electrical or water service;

(4) a sewage backup;

(5) a misuse of poisonous or toxic materials;

(6) an onset of an apparent foodborne illness outbreak;

(7) a gross unsanitary occurrence or condition; or

(8) other circumstance that may endanger public health.

(e) Operation need not be discontinued in an area of a wholesale food establishment that is unaffected by the imminent health hazard.

(f) If operations are discontinued as specified under this subsection or otherwise according to law, the wholesale food establishment shall obtain approval from the department before resuming operations. *(Indiana State Department of Health; 410 IAC 7-21-50; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1632, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-51 Registration of a wholesale food establishment

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 51. (a) A wholesale food establishment that maintains a place of business in Indiana shall file with the department, on forms to be furnished by the department, a written statement of the name and address of the owner, the name of the business, the character of the business, and the business address of each place of business in Indiana.

(b) A new wholesale food establishment shall not be established in Indiana until the place of business has been registered as provided in this subsection. The department shall be notified of intent to operate at least thirty (30) days prior to beginning operations.

(c) If ownership of a registered place of business changes, the new owner shall register the place of business before operating the same.

(d) If the name of the business or the address of a registered place of business changes, the owner shall register the change. *(Indiana State Department of Health; 410 IAC 7-21-51; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1632, eff one hundred twenty (120) days after filing with secretary of state)*

410 IAC 7-21-52 Incorporation by reference

Authority: IC 16-42-5-5
Affected: IC 16-42-5

Sec. 52. (a) The following are hereby incorporated by reference:

(1) 21 CFR 11 (April 1, 2001 Edition).

(2) 21 CFR 110.110 (April 1, 2001 Edition).

(3) 21 CFR 101 (April 1, 2001 Edition).

(4) 21 CFR 113 (April 1, 2001 Edition).

(5) 21 CFR 129 (April 1, 2001 Edition).

(6) 21 CFR 130 through 21 CFR 169 (April 1, 2001 Edition).

(7) 21 CFR 170 through 21 CFR 180 (April 1, 2001 Edition).

(8) 21 CFR 181 through 21 CFR 182, 21 CFR 184, and 21 CFR 186 (April 1, 2001 Edition).

(9) 21 CFR 173.310 (April 1, 2001 Edition).

(10) 21 CFR 173.315 (April 1, 2001 Edition).

(11) 21 CFR 178.1010 (April 1, 2001 Edition).

(12) 21 CFR 178.3570 (April 1, 2001 Edition).

(b) Federal rules, which have been incorporated by reference, do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents,

Government Printing Office, Washington, D.C. 20402. *(Indiana State Department of Health; 410 IAC 7-21-52; filed Jan 7, 2002, 10:16 a.m.: 25 IR 1632, eff one hundred twenty (120) days after filing with secretary of state)*

ARTICLE 8. DAIRY PRODUCTS

Rule 1. General Provision; Definitions and Standards of Identity (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 2. Construction and Operation of Milk Products Plants and Counter Type Frozen Desserts Freezing (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 3. Milk Products Distributors (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 4. Construction of Dairies and Milk Production (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 5. Approved Graders of Raw Milk and Raw Cream (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 6. Pasteurization; Optional Method (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 7. Brucellosis Testing Requirement (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 8. Flavored Milk and Flavored Milk Products (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 9. Bacteriological Control (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120) days after filing with secretary of state)

Rule 10. Standards for Milk and Milk Products; Production and Packaging (Repealed)
(Repealed by Indiana State Department of Health; filed Aug 27, 1980, 2:20 pm: 3 IR 1808)

Rule 11. Somatic Cell Count Standard–Grade A Raw Milk (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-11) to the Indiana State Board of Animal Health (345 IAC 8-1) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 12. Bulk Milk Collection and Sampling Operations (Repealed)
(Repealed by Indiana State Department of Health; HDP 86; filed Apr 26, 1979, 12:00 pm: 2 IR 700, eff one hundred twenty (120)

days after filing with secretary of state)

Rule 13. Production, Handling, Processing, Packaging and Distribution of Milk and Milk Products (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-13) to the Indiana State Board of Animal Health (345 IAC 8-2) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 14. Standards for the Production, Processing, Handling, Packaging and Storing of Grade A Milk Products

410 IAC 8-14-1 Definitions (Repealed)

Sec. 1. *(Repealed by Indiana State Department of Health; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994)*

410 IAC 8-14-2 Grade A raw milk for pasteurization; health and sanitation standards (Repealed)

Sec. 2. *(Repealed by Indiana State Department of Health; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994)*

410 IAC 8-14-3 Grade A pasteurized milk and milk products plants; health and sanitation standards (Repealed)

Sec. 3. *(Repealed by Indiana State Department of Health; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994)*

410 IAC 8-14-4 Toilets and sewage disposal facilities; construction standards (Repealed)

Sec. 4. *(Repealed by Indiana State Department of Health; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994)*

410 IAC 8-14-5 Water sources (Repealed)

Sec. 5. *(Repealed by Indiana State Department of Health; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994)*

410 IAC 8-14-6 Chemical and bacterial tests (Repealed)

Sec. 6. *(Repealed by Indiana State Department of Health; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994)*

410 IAC 8-14-7 Pasteurization equipment and procedures; design specifications (Repealed)

Sec. 7. *(Repealed by Indiana State Department of Health; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994)*

410 IAC 8-14-8 Pasteurization equipment and controls; test standards (Repealed)

Sec. 8. *(Repealed by Indiana State Department of Health; filed Jan 27, 1994, 5:00 p.m.: 17 IR 1224, eff Feb 1, 1994)*

410 IAC 8-14-8.1 Grade A milk (Transferred)

Sec. 8.1. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-8.1) to the Indiana State Board of Animal Health (345 IAC 8-3-1) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 8-14-8.2 Grade A milk storage (Transferred)

Sec. 8.2. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-8.2) to the Indiana State Board of Animal Health (345 IAC 8-3-2) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 8-14-8.3 Grade A milk transfer (Transferred)

Sec. 8.3. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-8.3) to the Indiana State Board of Animal Health (345 IAC 8-3-3) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 8-14-9 Milk, milk products, and condensed or dry milk products; health and sanitation standards (Transferred)

Sec. 9. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-9) to the Indiana State Board of Animal Health (345 IAC 8-3-4) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 8-14-10 Water reclaimed from milk, milk products, and whey (Transferred)

Sec. 10. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-10) to the Indiana State Board of Animal Health (345 IAC 8-3-5) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 8-14-11 Air supply equipment (Transferred)

Sec. 11. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-11) to the Indiana State Board of Animal Health (345 IAC 8-3-6) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 8-14-12 Culinary steam (Transferred)

Sec. 12. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-12) to the Indiana State Board of Animal Health (345 IAC 8-3-7) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 8-14-13 Thermometer specifications (Transferred)

Sec. 13. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-13) to the Indiana State Board of Animal Health (345 IAC 8-3-8) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 8-14-14 Pasteurization equipment and controls; test standards (Transferred)

Sec. 14. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 8-14-14) to the Indiana State Board of Animal Health (345 IAC 8-3-9) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

ARTICLE 9. MEAT AND MEAT PRODUCTS INSPECTION

Rule 1. Conformance with Federal Regulations; Definitions (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-1) to the Indiana State Board of Animal Health (345 IAC 9-1) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 2. Application of Inspection and Other Requirements (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-2) to the Indiana State Board of Animal Health (345 IAC 9-2) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 3. Exemptions (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-3) to the Indiana State Board of Animal Health (345 IAC 9-3) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 4. Application for Inspection: Grant or Refusal of Inspection

410 IAC 9-4-1 Application for inspection (Transferred)

Sec. 1. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-4-1) to the Indiana State Board of Animal Health (345 IAC 9-4-1) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

410 IAC 9-4-1.1 Meat and poultry establishment fee (Repealed)

Sec. 1.1. *(Repealed by Indiana State Department of Health; filed Apr 16, 1996, 4:10 p.m.: 19 IR 2285)*

410 IAC 9-4-2 Submission of plans; granting inspection; refusal (Transferred)

Sec. 2. *(NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-4-2) to the Indiana State Board of Animal Health (345 IAC 9-4-2) by P.L.138-1996, SECTION 76, effective July 1, 1996.)*

Rule 5. Official Numbers; Inauguration of Inspection; Withdrawal of Inspection; Reports of Violations (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-5) to the Indiana State Board of Animal Health (345 IAC 9-5) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 6. Assignments and Authorities of Division Employees (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-6) to the Indiana State Board of Animal Health (345 IAC 9-6) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 7. Facilities for Inspection (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-7) to the Indiana State Board of Animal Health (345 IAC 9-7) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 8. Sanitation (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-8) to the Indiana State Board of Animal Health (345 IAC 9-8) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 9. Ante-Mortem Inspection (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-9) to the Indiana State Board of Animal Health (345 IAC 9-9) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 10. Post-Mortem Inspection (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-10) to the Indiana State Board of Animal Health (345 IAC 9-10) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 11. Disposal of Diseased or Otherwise Adulterated Carcasses and Parts (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-11) to the Indiana State Board of Animal Health (345 IAC 9-11) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 12. Official Marks, Devices and Certificates (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-12) to the Indiana State Board of Animal Health (345 IAC 9-12) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 13. Handling and Disposal of Condemned or other Inedible Products at Official Establishments (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-13) to the Indiana State Board of Animal Health (345 IAC 9-13) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 14. Rendering or Other Disposal of Carcasses and Parts Passed for Cooking (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-14) to the Indiana State Board of Animal Health (345 IAC 9-14) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 15. Marking Products and Their Containers (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-15) to the Indiana State Board of Animal Health (345 IAC 9-15) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 16. Labeling, Marking Devices, and Containers (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-16) to the Indiana State Board of Animal Health (345 IAC 9-16) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 17. Entry into Official Establishments; Reinspection and Preparation of Products (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-17) to the Indiana State Board of Animal Health (345 IAC 9-17) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 18. Definitions and Standards of Identity or Composition (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-18) to the Indiana State Board of Animal Health (345 IAC 9-18) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 19. Records, Registration, and Reports (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-19) to the Indiana State Board of Animal Health (345 IAC 9-19) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 20. Cooperation with Federal Programs (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-20) to the Indiana State Board of Animal Health (345 IAC 9-20) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 21. Transportation (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-21) to the Indiana State Board of Animal Health (345 IAC 9-21) by P.L.138-1996, SECTION 76, effective July 1, 1996.

Rule 22. Detention; Seizure and Condemnation; Criminal Offenses (Transferred)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 9-22) to the Indiana State Board of Animal Health (345 IAC 9-22) by P.L.138-1996, SECTION 76, effective July 1, 1996.

ARTICLE 10. POULTRY AND POULTRY PRODUCTS INSPECTION (TRANSFERRED)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 10) to the Indiana State Board of Animal Health (345 IAC 10) by P.L.138-1996, SECTION 76, effective July 1, 1996.

ARTICLE 11. HUMANE SLAUGHTER OF ANIMALS AND POULTRY (TRANSFERRED)
NOTE: Transferred from the Indiana State Department of Health (410 IAC 11) to the Indiana State Board of Animal Health (345 IAC 11) by P.L.138-1996, SECTION 76, effective July 1, 1996.

ARTICLE 12. WEIGHTS AND MEASURES

Rule 1. Commercial Weighing and Measuring Devices

410 IAC 12-1-1 Standards for weights and measures; adoption by reference (Repealed)

Sec. 1. *(Repealed by Indiana State Department of Health; emergency rule filed Sep 21, 1993, 2:00 p.m.: 17 IR 210)*

410 IAC 12-1-1.1 Weighing and measuring devices

Authority: IC 24-6-3-2
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 1.1. Handbook 44: Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, 1998 edition, adopted by the National Conference on Weights and Measures, and published by the National Institute of Standards and Technology, excluding paragraph S.5. of Section 3.30, is hereby incorporated by reference as requirements of the Indiana state department of health for weighing and measuring devices. However, paragraph UR 2.2 of Section 3.31 shall apply only to those vehicle tanks used for the measurement and delivery of petroleum products, or liquid agricultural chemicals, or for bulk delivery of water and equipped with a ticket printer on or before the effective date of this rule; and to all new vehicle tanks used for the measurement and delivery of petroleum products, or liquid agricultural chemicals, or for bulk delivery of water, after the effective date of this rule. The incorporated document is available for public view at the Indiana state department of health. Copies of the incorporated document may be obtained by request mailed to the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402-9328. *(Indiana State Department of Health; 410 IAC 12-1-1.1; emergency rule filed Sep 21, 1993, 2:00 p.m.: 17 IR 209; filed Nov 25, 1998, 4:58 p.m.: 22 IR 1072; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-1.2 Packaging and labeling

Authority: IC 24-6-3-2
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 1.2. Section IV (A), entitled Uniform Packaging and Labeling Regulation, of Handbook 130: Uniform Laws and Regulations, 1998 edition, adopted by the National Conference on Weights and Measures and published by the National Institute of Standards and Technology, is hereby incorporated by reference as requirements of the Indiana state department of health for packaging and labeling. The incorporated document is available for public view at the Indiana state department of health. Copies of the incorporated document may be obtained by request mailed to the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402-9328. *(Indiana State Department of Health; 410 IAC 12-1-1.2; emergency rule filed Sep 21, 1993, 2:00 p.m.: 17 IR 209; filed Nov 25, 1998, 4:58 p.m.: 22 IR 1072; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-1.3 Method of sale of commodities

Authority: IC 24-6-3-2
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 1.3. Section IV (B), entitled Uniform Regulation for the Method of Sale of Commodities, of Handbook 130: Uniform Laws and Regulations, 1998 edition, adopted by the National Conference on Weights and Measures, and published by the National Institute of Standards and Technology, excluding Section 2.20, is hereby incorporated by reference as requirements of the Indiana state department of health for the method of sale of commodities. The incorporated document is available for public view at the Indiana state department of health. Copies of the incorporated document may be obtained by request mailed to the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402-9328. *(Indiana State Department of Health; 410 IAC 12-1-1.3; emergency rule filed Sep 21, 1993, 2:00 p.m.: 17 IR 209; filed Nov 25, 1998, 4:58 p.m.: 22 IR 1073; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-1.4 Checking the net content of packaged goods

Authority: IC 24-6-3-2
Affected: IC 16-44-2; IC 16-44-3 IC 24-6

Sec. 1.4. (a) The following are adopted by reference:
(1) NBS Handbook 133–Third Edition, Checking the Net Content of Packaged Goods, 1988 edition.
(2) NBS Handbook 133–Third Edition, Supplement, Checking the Net Content of Packaged Goods, 1990 edition.
(3) NBS Handbook 133–Third Edition, Supplement 2, Checking the Net Content of Packaged Goods, 1991 edition.

(4) NBS Handbook 133–Third Edition, Supplement 3, Checking the Net Content of Packaged Goods, 1992 edition.

(5) NBS Handbook 133–Third Edition, Supplement 4, Checking the Net Content of Packaged Goods, 1994 edition.

(b) All of the documents listed in subsection (a) are adopted by the National Conference on Weights and Measures and published by the National Institute of Standards and Technology, are hereby incorporated by reference as requirements of the Indiana state department of health for checking the net content of packaged goods. The incorporated documents are available for public view at the Indiana state department of health. Copies of the incorporated document may be obtained by request mailed to the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402-9328. *(Indiana State Department of Health; 410 IAC 12-1-1.4; emergency rule filed Sep 21, 1993, 2:00 p.m.: 17 IR 209; filed Nov 25, 1998, 4:58 p.m.: 22 IR 1073; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-1.5 National type evaluation

Authority: IC 24-6-3-2
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 1.5. Section IV (F), entitled Uniform Regulation for National Type Evaluation, of Handbook 130: Uniform Laws and Regulations, 1998 edition, adopted by the National Conference on Weights and Measures, and published by the National Institute of Standards and Technology, is hereby incorporated by reference as requirements of the Indiana state department of health for the method of sale of commodities. The incorporated document is available for public view at the Indiana state department of health. Copies of the incorporated document may be obtained by request mailed to the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402-9328. *(Indiana State Department of Health; 410 IAC 12-1-1.5; filed Nov 25, 1998, 4:58 p.m.: 22 IR 1073; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-2 Poultry sold by weight

Authority: IC 24-6-3-16
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 2. (1) When poultry is sold or offered for sale as "dressed poultry", on a weight basis, such sale or offer of sale shall be exclusively upon the basis of net avoirdupois weight of the poultry in the condition in which it is so sold or offered for sale.

(2) Poultry means and includes chickens, turkeys, ducks, geese, pigeons, guineas, and any other kind of domesticated bird commercially processed and sold for human consumption. *(Indiana State Department of Health; Reg WM 2; filed Feb 23, 1950, 2:00 pm: Rules and Regs. 1951, p. 175; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-3 Specific product sold by weight

Authority: IC 24-6-3-16
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 3. When cauliflower, cabbage, head lettuce, melons, and hands or bunches of bananas are sold or offered for sale on a weight basis, such produce shall either (1) bear an accurate statement of its weight, or (2) be weighed at the time of sale. *(Indiana State Department of Health; Reg WM 3; filed Feb 23, 1950, 2:00 pm: Rules and Regs. 1951, p. 175; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-4 Vehicle scales; approval requirements

Authority: IC 24-6-3-16
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 4. Official approval of a vehicle scale extends exclusively to the use of that scale in weighing loads whose entire wheelbase can be accommodated on the scale platform at one time. *(Indiana State Department of Health; Reg WM 4; filed Feb 23, 1950, 2:00 pm: Rules and Regs. 1951, p. 175; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-5 Vehicle weighing restrictions

Authority: IC 24-6-3-16
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 5. All weighings of vehicles shall be made with no person in or on the vehicle or on the scale platform. *(Indiana State Department of Health; Reg WM 5; filed Feb 23, 1950, 2:00 pm: Rules and Regs. 1951, p. 175; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12-1-6 Weighmasters; appointment; certificates of weight

Authority: IC 24-6-3-16
Affected: IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 6. The following provisions govern the appointment and prescribe the duties of weighmasters:

(a) Any county, city, town, corporation, individual, firm, association or institution in the State of Indiana, wishing to have designated as State weighmasters one or more of its employees or other suitable person or persons, shall forward written application therefor to the Director of the State Division of Weights and Measures, Indiana State Board of Health, 1098 West Michigan Street, Indianapolis, Indiana, upon such form as may be prescribed by the said Division of Weights and Measures. Such form will be furnished upon request.

(b) A certificate of appointment as a weighmaster under the law of Indiana will be issued only to an individual, natural person, and each such certificate of appointment shall be posted at the location of the scale or scales designated in the application for its issuance. Each certificate shall be open to inspection and may be revoked and canceled by the Director of the said Division of Weights and Measures after hearing, upon due notice to the appointee, for incompetency, inaccuracy, or failure to perform the duties of such weighmaster in accordance with the law. Each certificate of appointment must be returned to the Director of the State Division of Weights and Measures for cancellation when the weighmaster has lost his employment at the location for which the certificate of appointment was issued. Unless sooner revoked or canceled, each certificate of appointment as State weighmaster shall automatically expire four (4) years after the date of its issuance.

(c) Each certificate of weight or measure, issued by a State weighmaster, shall include all of the following information to be clearly shown on each such certificate issued:

(I) The date of the Weighing.

(II) The nature of the commodity weighed.

(III) The actual weight of the consignment; in the case of a certificate of weight of a commodity transported in a vehicle and not susceptible of being readily weighed by itself, both the actual gross weight and the actual tare weight must be shown, together with the net weight computed therefrom.

(IV) In any case where the weighmaster does not ascertain both gross and tare weights, the unused space therefore shall be out before certification.

(V) The name of the declared owner of the commodity.

(VI) The name of the purchaser of the commodity, if known.

(VII) The autographic signature of the weighmaster.

(d) A copy of each certificate of weight shall be retained and be kept available for official inspection at the location designated in the application for certificate of appointment as State weighmaster, for a period of not less than 12 months from the date of the weighing to which that certificate applies.

(e) No certificate of weight shall be issued by a State weighmaster under any one or more of the following conditions:

(I) When the scale at his disposal has not been officially approved by the Director of the State Division of Weights and Measures or one of his assistants, deputies or inspectors, at the last previous official examination within a period of 12 months preceding the date of weighing.

(II) When the total length of wheelbase of the vehicle to be weighed exceeds the length of the platform of the scale at the weighmaster's disposal.

(III) When the weight of the gross load exceeds the nominal or rated capacity of the scale at the weighmaster's disposal.

(IV) When a vehicle is to be weighed, either empty or loaded, and any person is in or on the vehicle or on the scale platform at the time of weighing.

(V) When the loaded or unloaded vehicle weighs less than 1,000 pounds, and the scale at the weighmaster's disposal

is a vehicle scale.

(Indiana State Department of Health; Reg WM 6; filed Feb 23, 1950, 2:00 pm: Rules and Regs. 1951, p. 176; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: The current address of the State Division of Weights and Measures is: 1330 West Michigan Street, Indianapolis, Indiana, 46206

410 IAC 12-1-7 Schedule of civil penalties

Authority: IC 16-19-7-3; IC 24-6-3-2
Affected: IC 4-21.5-3-8; IC 16-19-7; IC 16-44-2; IC 16-44-3; IC 24-6

Sec. 7. (a) The Indiana state department of health may commence an action under IC 16-19-7-3, IC 24-6-1, IC 24-6-2, IC 24-6-3, IC 24-6-4, IC 24-6-5, IC 24-6-6, IC 4-21.5-3-8, and to levy civil penalties against a person who:

(1) fails to comply with IC 24-6-3 or this rule; or

(2) interferes with or obstructs the Indiana state department of health or its designated agent in the performance of duties pursuant to IC 24-6-3.

(b) A civil penalty in an amount in the appropriate range specified in subsection (d) may be sought for each day of each violation.

(c) In determining the seriousness of the violation and the specific amount of the civil penalty to be sought for each violation, the Indiana state department of health will consider, but is not limited to, the following:

(1) The potential for harm or imminent threat to public health.

(2) The extent of deviation from statutory or regulatory requirements.

(3) Degree of willfulness or negligence.

(4) History of noncompliance.

The absence of direct harm will not result in assessment of a lower penalty for a violation.

(d) Unless adjusted as provided for in subsection (e), all penalties shall be in accordance with the following schedule:

VIOLATION	CODE	RANGE OF PENALTY
Right of entry	IC 24-6-3-9	$0 to $1,000
Use of standard weights and measures	IC 24-6-3-10	$0 to $ 500
Use of false scales or measuring devices	IC 24-6-3-11	$0 to $1,000
Use of dry capacity measures	IC 24-6-3-12	$0 to $ 200
Standard weights and measures	IC 24-6-1-1	$0 to $ 200
Marking of containers	IC 24-6-6-2 IC 24-6-6-3 IC 24-6-6-4	$0 to $ 500
False representation of contents	IC 24-6-6-5	$0 to $1,000
Articles sold by weight or count	IC 24-6-4-1	$0 to $ 200
Inspection of devices	IC 24-6-3-7	$0 to $ 500
Commodity sold by count	IC 24-6-3-10	$0 to $ 200
Used containers	IC 24-6-6-6	$0 to $ 200
Failure to take tare at time of sale	IC 24-6-3-12	$0 to $1,000
Weighmaster duties	410 IAC 12-1-6	$0 to $1,000
Specification and tolerances of devices	410 IAC 12-1-1.1	$0 to $1,000
Packaging and labeling	410 IAC 12-1-1.2	$0 to $1,000
Method of sale of commodities	410 IAC 12-1-1.3	$0 to $1,000
Net content of packaged goods	410 IAC 12-1-1.4	$0 to $1,000
National type evaluation	410 IAC 12-1-1.5	$0 to $1,000
Use of illegal device	410 IAC 12-1-1.1	$0 to $1,000

Split draft weighing	410 IAC 12-1-4	$0 to $ 500
Person in vehicle during weighing	410 IAC 12-1-5	$0 to $500

(e) After determining the appropriate penalty based on the schedule in subsection (d), the Indiana state department of health may adjust the penalty to reflect a good faith effort to comply to the following:

(1) Each individual penalty will be multiplied by the number of days the particular violation occurred. Penalties for violations occurring on two (2) consecutive inspections by the Indiana state department of health shall be assessed on the basis that the violations have remained uncorrected over the period of time between the two (2) inspections. However, if the person found in violation has requested reinspection and has produced substantive evidence that the violation(s) have been corrected, the penalties shall be assessed for the period between initial discovery of violation and the receipt of request for reinspection.

(2) Penalties for all violations will be totaled and sought under one (1) cause of action.

(f) After filing an action pursuant to IC 4-21.5, and in an attempt to resolve violations of IC 24-6-1, IC 24-6-2, IC 24-6-3, IC 24-6-4, IC 24-6-5, IC 24-6-6, IC 4-21.5-3-8, and this rule without resort to a hearing, the Indiana state department of health may negotiate and enter into agreed orders. An agreed order may suspend all or part of the civil penalty calculated under the requirements and deadlines established in the agreed order. *(Indiana State Department of Health; 410 IAC 12-1-7; filed Jun 18, 1991, 10:10 a.m.: 14 IR 1958; filed Dec 21, 2000, 2:21 p.m.: 24 IR 1343; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. State Metrology Laboratory Fees

410 IAC 12-2-1 State metrology laboratory fees

Authority: IC 16-19-5-1
Affected: IC 16-19-5; IC 24-6

Sec. 1. The following are the fees for services performed by the state metrology laboratory under IC 24-6:

Standards of Mass

Procedure: Modified Substitution or Direct Reading	
OIML Class “M2”	
ANSI/ASTM Class “6” and “7”	
NIST Class “C”, “F”, and “T”	Test
25 or fewer weights	$30
26–40 weight sets	$40
41 or more weight sets	$80
Up to and including 5 lbs or 3 kgs	$4
Over 5 lbs or 3 kgs and including 50 lbs or 25 kgs	$6
Over 50 lbs or 25 kgs and including 500 lbs or 250 kgs	$8
Over 500 lbs or 250 kgs and including 1,000 lbs or 500 kgs	$12
Over 1,000 lbs or 500 kgs	$20

Procedure: Modified Substitution or Double Substitution	
OIML Class “F2” and “M1”	
ANSI/ASTM Class “4” and “5”	
NIST Class “P” and “Q”	Test
Up to and including 5 lbs or 3 kgs	$6
Over 5 lbs or 3 kgs and including 50 lbs or 25 kgs	$10
Over 50 lbs or 25 kgs and including 500 lbs or 250 kgs	$14
Over 500 lbs or 250 kgs and including 1,000 lbs or 500 kgs	$16
Over 1,000 lbs or 500 kgs	$25

Procedure: Decade Design 3-1, Double Substitution Combinations
OIML Class “F1”
ANSI/ASTM Class “1” and “1.1”, “2”, and “3”

NIST Class "S" and "S-1"	Test
Up to and including 5 lbs or 3 kgs	$10
Over 5 lbs or 3 kgs and including 50 lbs or 30 kgs	$20
Over 50 lbs or 30 kgs and including 1,000 lbs or 500 kgs	$30
Over 1,000 lbs or 500 kgs	$50

Procedure: Advanced Weighing Designs	
OIML Class "E1" and "E2"	
ANSI/ASTM Class "0"	
(Tests for other than Metric Weights will be considered Special Tests)	Test
Up to and including 1 kg	$40
Over 1 kg	$60

Standards of Volume

Test Measures and Glassware	Test
Up to and including 5 gallons or 20 liters	$10
Over 5 gallons or 20 liters and including 50 gallons or 200 liters	$50
Over 50 gallons or 200 liters	$100

Standards of Length

Tapes	$20 per device tested, PLUS $4 per point tested above 5

Other Test Fees

Special Tests (Not Listed in Fee Schedule)	$15 per quarter hour
Cleaning of Standards (If Necessary)	$10 per quarter hour

Public schools and state and local government agencies are exempt from the fees established in this section. *(Indiana State Department of Health; 410 IAC 12-2-1; filed Jun 30, 2000, 4:14 p.m.: 23 IR 2709)*

ARTICLE 12.1. MOTOR FUEL

Rule 1. Definitions

410 IAC 12.1-1-1 Applicability

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 12.1-1-1; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1803; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-2 "ASTM" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 2. "ASTM" means the American Society for Testing and Materials. *(Indiana State Department of Health; 410 IAC 12.1-1-2; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1803; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-3 "Calibration chart" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 3. "Calibration chart" means a chart used to convert a linear depth measurement of motor fuel contained in a tank to a volumetric measurement of motor fuel. *(Indiana State Department of Health; 410 IAC 12.1-1-3; filed Feb 12, 1993, 5:00 p.m.: 16*

IR 1803; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 12.1-1-4 "Department" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 4. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 12.1-1-4; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1803; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-5 "Gasoline" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 5. "Gasoline" means a volatile mixture of liquid hydrocarbons generally containing small amounts of additives suitable for use as a fuel in a spark-ignition internal combustion engine. *(Indiana State Department of Health; 410 IAC 12.1-1-5; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1803; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-6 "Gasoline-oxygenate blend" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 6. "Gasoline-oxygenate blend" means a blend consisting of gasoline and oxygen containing ashless organic compounds, such as alcohols or ethers. *(Indiana State Department of Health; 410 IAC 12.1-1-6; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-7 "Motor fuel" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 7. "Motor fuel" means gasoline or gasoline-oxygenate blends suitable for use as a fuel in a motor vehicle. *(Indiana State Department of Health; 410 IAC 12.1-1-7; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-8 "Motor fuel outlet" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 8. "Motor fuel outlet" means a location where motor fuel is sold at retail to the public. *(Indiana State Department of Health; 410 IAC 12.1-1-8; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-9 "Motor octane number" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 9. "Motor octane number" means the measure of the resistance of a fuel to knock, which is assigned to a test fuel based upon operation in the knock testing unit at the same standard knock intensity as that of a specific primary reference fuel blend. *(Indiana State Department of Health; 410 IAC 12.1-1-9; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-10 "Octane index" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 10. "Octane index" means the number obtained by adding the research octane number and the motor octane number and dividing the sum by two (2). *(Indiana State Department of Health; 410 IAC 12.1-1-10; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-11 "Person" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 11. "Person" means an individual, a corporation, a partnership, an association, or other legal entity. *(Indiana State Department of Health; 410 IAC 12.1-1-11; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-1-12 "Research octane number" defined

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 12. "Research octane number" means a number determined by comparing motor fuel's knocking tendency with those for blends of ASTM reference fuels of known octane number under standard operating conditions. *(Indiana State Department of Health; 410 IAC 12.1-1-12; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. Motor Fuel Inspection

410 IAC 12.1-2-1 Inspection by the department

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 1. The department or its authorized agents shall have access to motor fuel outlets during normal business hours for the following purposes:

(1) Examination.
(2) Inspection.
(3) Investigation.

(Indiana State Department of Health; 410 IAC 12.1-2-1; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 12.1-2-2 Octane standards

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 2. (a) Motor fuel shall conform to ASTM D4814, "Standard Specification for Automotive Spark-Ignition Engine", 1991 Edition.

(b) The research octane number shall be determined using the test method and tolerance identified in ASTM D2699, "Standard Test Method for Knock Characteristics of Motor Fuels by the Research Method", 1991 Edition.

(c) The motor octane number shall be determined using the test method and tolerance identified in ASTM D2700, "Standard Test Method for Knock Characteristics of Motor and Aviation Fuels by the Motor Method", 1991 Edition.

(d) The octane index of a motor fuel shall not be less than the octane index certified on the motor fuel dispenser. *(Indiana State Department of Health; 410 IAC 12.1-2-2; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-2-3 Labeling and documentation

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 3. (a) When motor fuel is delivered in bulk to a retail motor fuel outlet, an invoice, bill of lading, shipping paper, or other documentation must accompany the delivery. Such documentation must identify the name of the motor fuel as registered with the department, the alcohol content (if any) of the motor fuel, and the date and source location of the delivery from bulk storage. This documentation must be retained at the retail motor fuel outlet for a period of not less than thirty (30) days.

(b) The minimum octane rating of all motor fuel sold to consumers shall be posted on each retail dispensing device. One (1) label on each face of each motor fuel dispenser must be posted. If two (2) or more grades of motor fuel are sold through a single dispenser, separate labels for each grade must be posted. The label, or labels, must be placed conspicuously on the dispenser so as to be in full view of consumers and as close as is reasonably practicable to the price per gallon of the motor fuel. The label must meet the specifications as detailed in 16 CFR 306.11.

(c) Each retail motor fuel outlet location must maintain on file a current calibration chart for each storage tank utilized.

(d) Any person who removes a motor fuel from storage because of a stop-sale order issued by the department must send to the department documentation outlining the final disposition of the motor fuel.

(e) Before upgrading a motor fuel rejected by a stop-sale order of the department, a person must first contact the weights and measures program of the department to confirm that the motor fuel used for upgrading is registered with the department and to describe the upgrading procedure. The department may require that this procedure be witnessed by a department representative and that written documentation be provided to the department regarding the upgrading procedure. *(Indiana State Department of Health; 410 IAC 12.1-2-3; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1804; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-2-4 Registration of motor fuels

Authority: IC 16-44-3-5
Affected: IC 16-44-3-9

Sec. 4. (a) A person who sells a motor fuel at a retail motor fuel outlet shall do the following:

(1) Separately register each motor fuel outlet with the department.

(2) Comply with the requirements of IC 16-6-13-12 *[IC 16-6 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-44-3-9.]* for each motor fuel outlet.

(b) The registration required must include the following:

(1) The name and principal business address of the person registering the motor fuel.

(2) The name and address of the motor fuel outlet where the motor fuel is sold.

(3) The name, brand, or trademark and the octane index of the fuel to be marketed at the motor fuel outlet.

(c) Registration is not transferable.

(d) Registration expires annually on January 1 and shall be renewed before March 31 of each year unless suspended, denied, or revoked by the department. *(Indiana State Department of Health; 410 IAC 12.1-2-4; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1805; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-2-5 Violations

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 5. The department may issue a stop-sale order or revoke, suspend, or deny motor fuel registration for violation of this rule or for a motor fuel found not to be in compliance with IC 16-6-13 *[IC 16-6 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-44-3.]* and this rule. If a stop-sale order is issued by the department with respect to a motor fuel, no motor fuel may be sold to the public from the motor fuel dispenser which delivers the motor fuel subject to the order until the fuel has been upgraded in accordance with section 3(e) of this rule or has been disposed of in accordance with section 3(d) of this rule. *(Indiana State Department of Health; 410 IAC 12.1-2-5; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1805; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 12.1-2-6 Matters incorporated by reference

Authority: IC 16-44-3-5
Affected: IC 16-44-3

Sec. 6. (a) The following ASTM standards are incorporated by reference as part of this rule:

(1) ASTM D4814, "Standard Specification for Automotive Spark-Ignition Engine Fuel", 1991 Edition.

(2) ASTM D2699, "Standard Test Method for Knock Characteristics of Motor Fuels by the Research Method", 1991 Edition.

(3) ASTM D2700, "Standard Test Method for Knock Characteristics of Motor and Aviation Fuels by the Motor Method", 1991 Edition.

These standards may be obtained from ASTM, 1916 Race Street, Philadelphia, Pennsylvania 19103-1187.

(b) 16 CFR 306.11 (January 1, 1991 Edition) is hereby incorporated by reference as part of this rule. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.

(c) All incorporated material is available for public review at the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 12.1-2-6; filed Feb 12, 1993, 5:00 p.m.: 16 IR 1805; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 13. SANITARY BEDDING

Rule 1. General Provisions; Dimensions; Labeling; Sterilization

410 IAC 13-1-1 Applicability of rule

Authority: IC 16-19-3-5; IC 16-41-32-14
Affected: IC 16-41-32

Sec. 1. Scope. These regulations and the provisions herein set forth shall be construed to cover and apply to the manufacture, renovation, supply, storage and sterilization or disinfection of all articles of bedding or filling materials thereof which are intended for use or sale as defined in Chap. 148, Acts of 1949. They shall apply to all manufacturing and other mercantile establishments, both wholesale and retail, when articles of bedding or filling materials thereof are in their possession for purposes as stated above. *(Indiana State Department of Health; Scope; filed Apr 26, 1950, 3:15 pm: Rules and Regs. 1951, p. 117; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 13-1-2 Manufacture or sale of unclean bedding; prohibition

Authority: IC 16-19-3-5; IC 16-41-32-14
Affected: IC 16-41-32

Sec. 2. No article of bedding shall be manufactured or sold in the State of Indiana which is unclean or insanitary or which contains filling material which is unclean or insanitary. No material which is unclean or insanitary shall be used in the remaking or renovating of any article of bedding. *(Indiana State Department of Health; Reg HSB 1; filed Apr 26, 1950, 3:15 pm: Rules and Regs. 1951, p. 117; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 13-1-3 Filing material; labeling

Authority: IC 16-19-3-5; IC 16-41-32-14
Affected: IC 16-41-32

Sec. 3. Label Bulk Filling Material. (A) Containers of processed filling materials wholesaled in Indiana for use in articles of bedding, shall be labeled by the processor and the label shall bear his registry number.

(A1) The following and similar materials shall be deemed to be processed: Cotton, felt, batting, shoddy; scoured and carbonized wool, wool felt, or batting; processed hair, curled or uncurled, felted or rubberized; processed feathers and down; processed foam or sponge rubber; jute felt; sisal pads; curled tampico; processed vegetable and synthetic fibers, and processed synthetic foams.

(B) Containers of unprocessed filling material shipped into Indiana by a jobber for use in articles of bedding, or such material held in possession for resale by a jobber in Indiana for like purposes, shall be labeled by the jobber and the label shall bear the registry number of the jobber.

(B1) The following and similar materials shall be deemed to be unprocessed: Staple cotton, cotton and spinning mill products or by-products; unprocessed feathers and down, wool, hair, and foam or sponge rubber; kapok; moss; palm fiber; sisal fiber; tampico fiber (not curled); coconut husk fiber; excelsior; jute tow; flax tow; unprocessed vegetable and synthetic fibers, and unprocessed synthetic foams.

(Indiana State Department of Health; Reg HSB 1A; filed Dec 10, 1951, 10:45 am: Rules and Regs. 1952, p. 201; filed Sep 27, 1960, 10:20 am: Rules and Regs. 1961, p. 220; filed Dec 9, 1963, 11:15 am: Rules and Regs. 1964, p. 279; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 13-1-4 Minimum dimensions; mattress pads

Authority: IC 16-19-3-5; IC 16-41-32-14
Affected: IC 16-41-32

Sec. 4. Minimum Dimensions. (a) Fancy cushions which do not exceed 10 inches in greatest dimension or which are not designed or intended for use for human sleeping or reclining purposes shall not be deemed to be articles of bedding. Nothing herein contained however, shall be deemed to exempt from the law any stuffed article or pad simply because it is designated as a toy or for animal pets or for dolls.

(b) If any pad used as an insulator over the springs of innerspring mattresses made of sisal fiber, curled hair or any other material is smaller than the entire top and bottom surfaces of the mattress then the size of the pad must be stated on the label. *(Indiana State Department of Health; Reg HSB 2; filed Apr 26, 1950, 3:15 pm: Rules and Regs. 1951, p. 117; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 13-1-5 Labeling requirements; definitions

Authority: IC 16-19-3-5; IC 16-41-32-14
Affected: IC 16-41-32

Sec. 5. Labeling. (A) Every new or secondhand article of bedding processed for sale shall be properly labeled in accordance with I.C. 16-9-4 *[IC 16-9 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, as formerly found in Chap. 148, Acts of 1949 as amended by Chap. 30, Acts of 1951 and Chap. 157, Acts of 1963 and these regulations *[410 IAC 13-1]*. The required secondhand label shall be attached when the article of bedding contains secondhand material in whole or in part, including innerspring unit. Each manufacturer, renovator, sterilizer, and disinfector shall furnish his own labels.

(B) The wording on the required label describing the filling materials shall be stamped or printed in bold-face type not less than 1/8 inch in height and shall employ only the terms which follow after (J) Basic Definitions *[subsection (J) of this section]* of this Regulation.

(B1) The kinds and percentages of various filling materials shall be shown on the label. Percentages shall be computed on the basis of weight. Any deviation from percentages stated shall not exceed ten percent (10%) of the smaller component except as otherwise provided in these regulations *[410 IAC 13-1]*. When the filling material consists of one kind only, the percentage need not be stated.

(C) No trade, superfluous or substitute terms shall be used on the required label except as authorized in Regulation Q *[subsection Q of this section]*.

(C1) Trade marks, insignia or advertisements may be placed on another label and attached to the article of bedding in such manner that it will not interfere with the required label nor contradict any statement thereon.

(D) The terms “All”, “Pure”, “100%”, or similar terms shall be used only with the understanding that no tolerance whatever is allowed when such terms are used and that the slightest departure from the indicated quality makes the label misleading and therefore unlawful.

(E) Labels shall be of good grade vellum cloth or cloth of comparable quality or better which will not flake out when abraded. Paper or paperfaced labels shall not be used.

(F) Labels shall not be less than six (6) square inches in size, exclusive of the portion required to affix the label to article. Labels may be greater in size as the need demands.

(G) Labels shall be securely attached to articles of bedding so that they may be conveniently examined, and the information thereon is visible. Where possible, they shall be securely sewed, but in instances where sewing is not practicable, application can be made to the Board in writing for authorization to otherwise secure.

(H) Every dual purpose article of bedding having one or more cushions requires but one label when the cushions are a necessary part of that article. This label shall contain a statement of the filling materials used in the article as well as that used in the cushions. Where extra cushions are provided that are not an integral part of the article each cushion shall be labeled separately.

(H1) Dual purpose articles of bedding such as bed-davenports, studio couches, hide-a-beds, etc., having loose cushions shall have the labels attached under a cushion on top and near the center of the front edge of the platform.

(I) No person other than a purchaser for his own use, shall remove from any article of bedding or alter or deface the required label except as herein otherwise provided.

(J) BASIC DEFINITIONS. It is the purpose of the following definitions to provide names, terms and nomenclature as are commonly used, and are recognized in the manufacture, sale and distribution of bedding products. The following definitions are also intended to have understandable meaning to the ultimate consumer.

(K) COTTON.

(K1) Cotton, Virgin Cotton or Staple Cotton: Any of these terms shall mean the staple fibrous growth as removed from cottonseed in the usual process of ginning (first cut from seed), containing no foreign material. The presence of the usual amount of leaves, hull, etc., shall not be considered foreign matter.

(K2) Cotton By-Products: This term shall mean the by-products removed from the various machine operations necessary in the manufacture of cotton yarn up to but not including the process of spinning, and shall include only the following materials commonly known in cotton mill terms as (1) cotton comber, (2) cotton card strips or cotton vacuum strips, (3) cotton fly and (4) cotton picker.

(K3) Cotton Linters: This term shall mean the fibrous growth removed from cottonseed subsequent to the usual process of ginning and shall be so designated on the label.

(K4) Cotton Waste: This term shall be used when any “card”, “stripes” or “stripping”, “comber”, “fly”, “noils”, “picker”, or “motes” contain more than 7 percent hull, leaf, stem or other foreign material. When hull, leaf, stem or other foreign material exceed 10 percent, such material shall be designated as “trash”.

(K5) Garnetted Clippings: This term shall mean any new material which has been spun into yarn, knit or woven into fabric and subsequently reduced by a garnetting process into a fibrous state.

(K6) Shredded Clippings: This term shall mean any new material which has been spun into yarn, knit or woven into fabric and subsequently reduced to a fibrous state.

(K7) Shoddy: This term shall mean any garnetted or shredded clippings made of new material containing more than 5 percent of any foreign material.

(K8) Blends or Mixtures: Unfelted blends or mixtures of staple cotton, cotton linters, or cotton by-products shall be described as “Blended Cotton”. If the blends or mixtures are felted, they shall be described as “Blended Cotton Felt”.

(K9) Cotton Felt: This term shall be used only when fibers are garnetted or carded and used in layer form. It cannot be used when cotton batting or cotton felt scraps or clippings are stuffed or blown in the same manner as unfelted materials.

(K9a) Colored Cotton Felt: This term shall be used when all or any portion of garnetted or carded cotton fibers are colored. This term shall not be used to describe garnetted cotton shoddy.

(K10) Oil Percentages: When any filling material contains more than five percent (5%) of oil, it must be described as Oily.

(K11) Dirt or Foreign Material: When any filling material contains more than five percent (5%) of dirt of any other foreign material, it must be described as Dirty.

(K12) Colored: This term shall be used when all or any portion of the cotton fibers are colored.

(K13) Damaged Cotton Fibers: This term shall apply to cotton fibers which in whole or in part, has deteriorated through excessive exposure to the elements, faulty storage, fire, water, irradiation or mildew.

(L) FEATHERS AND DOWN.

(L1) Down: This term shall mean the soft undercoating of waterfowl, consisting of the light fluffy filaments growing from one quill point but without any quill shaft. This term includes all real downs and it shall not be necessary to indicate the kind of down used, but if indicated on the label as a particular kind of down, such as goose down, duck down or eider down, the material must be as stated.

(L1a) Down Fiber: This term shall mean the barbs of down plumes separated by any process from the quill point. Any individual fibers resembling down closely enough to create doubt as to whether they are down fiber or feather fiber may

be classed as down.

(L1b) A tolerance of 10 percent by weight of the down content stated on the label is permissible. Articles labeled as containing Down must contain not less than 90 percent pure down.

(L2) Feathers or Natural Feathers: This term shall mean the original or natural form and means feathers which have not been processed in any manner other than washing, dusting, sterilizing or disinfecting.

(L3) Crushed Feathers: This term shall mean feathers which have been processed by a curling or crushing machine which has changed the original form of the feather without removing the quill. Such stock shall be designated on the label as Crushed followed by the name of the fowl from which it came.

(L4) Chopped Feathers: This term shall mean feathers which have been chopped or cut into pieces. Such stock shall be designated on the label as Chopped followed by the name of the fowl from which they came.

(L5) Stripped Feathers: This term shall mean the barbs of feathers stripped by any process from the feather shaft, but not separated into feather fiber. Such designation shall include the name of the fowl from which they came.

(L6) Quill Feathers or Wing and Tail Feathers: Either of these terms shall mean the wing or tail feathers of any fowl.

(L7) Waterfowl Feathers: This term shall mean goose or duck feathers or any mixture thereof.

(L8) Damaged Feathers: This term shall mean feathers which have been broken, injured by insects, or depreciated from the original value in any manner; provided however, that this term shall not apply to crushed feathers as defined in L3. Damaged feathers in excess of 10 percent by weight of the total feathers shall be indicated on the label and the name of the feathers shall be stated.

(L9) Blends or Mixtures: Feather or down mixtures shall be designated by the foregoing definitions, by the name, character and percentage of each material used, or the entire mixture shall be designated by the name of the lowest grade of material used.

(L10) Color: The color of feathers or down need not be stated on the label, but if stated the contents shall be as declared. Feathers or down from waterfowl may be designated on the label as White or Gray as the case may be. Chicken or turkey feathers may be designated on the label as White or Colored as the case may be.

(L11) Tolerance: A tolerance of 10 percent by weight of the feather content stated on the label is permissible. Feathers of any fowl named on the label must contain not less than 90 percent of such feathers.

(L12) Cleanliness: All feather and down stocks shall be thoroughly cleaned prior to use by washing, dusting, sterilizing or disinfecting. Feather and down stocks having an oxygen number above 20 shall be deemed to be “not properly clean”.

(L13) Secondhand Feathers or Down: Either of these terms means any such material which has been previously used for any purpose and shall be so designated on the required label for secondhand material with the proper classification of such feathers or down.

(M) HAIR.

Classifications:

Horse Tail Hair

Horse Mane Hair

Cattle Tail Hair

Cattle Hide Hair (Body Hair)

Hog Hair

Goat Hair

(M1) Hair is the coarse filamentous epidermal outgrowth of such mammals as horses, cattle, hogs and goats. When used in the manufacture of bedding or as filling material thereof, it shall be clean, properly cured, free from epidermis, excreta or other foreign or objectionable substances or odors.

(M2) Curled Hair: This term applies when any hair has been curled. The appropriate designation as to origin shall appear on the label preceded by the word Curled.

(M3) Uncurled Hair: This term applies when any hair has not passed through a curling process. The appropriate designation as to origin shall appear on the label preceded by the word Uncurled.

(M4) Rubberized Hair: This term shall mean any hair treated with liquid latex or synthetic rubber. When hair is rubberized the designation on the label shall state whether the rubber is Latex or Synthetic.

(M5) Rubberized Curled Hair Pieces: This term shall mean trimmings and pieces of rubberized curled hair of indefinite size. The term shall be preceded by the term Latex or Synthetic.

(M6) Hair Blends or Mixtures: When hair of two different origins is used in a blend or mixture, the kind and percentage by

weight of each shall be stated on the label.
(M7) Hair and Fiber Blends or Mixtures: When any other filling material of whatever origin is used in a blend or mixture with hair, the kind and percentage by weight of each such material shall be designated on the label.
(M8) Hair Pad: This term shall mean hair which is interwoven or punched on burlap or any other woven material or otherwise fabricated into a pad, including the application of latex or synthetic rubber as a component and as a factor in the fabricating process. Percentages shall be based on the hair and fiber content only. No reference to or inclusion of the burlap or woven material backing is required on the label nor is the quantity or percentage of rubber when the rubber is used solely as a binder element.
(M9) Color: Hair need not be identified as to color on the label, but if it is so identified it shall be as represented in all respects.
(M10) Tolerance: A tolerance of 10 percent by weight of the percentages stated on the label shall be permitted.
(M11) Secondhand Hair: This term shall mean any hair which has sustained prior use and such hair shall be so designated on the required second-hand label with the proper classification of such hair.

M12. Labeling Examples for Hair

Curled Hair Pad	Cattle Tail ..... 15% Hog 85%	100%
Curled Hair and Fiber Pad	Hog ..... 70% Sisal Fiber 30%	100%
Latex Rubberized Curled Hair Pad	Horse Mane .... 35% Hog 65%	100%
Cattle Hide Hair Felt Pad		100%

(N) WOOL.
(N1) Wool or Virgin Wool: Either of these terms shall apply to the fleece of the sheep or lamb, which has been scoured or scoured and carbonized. It shall not be the by-product of any process of manufacture nor shall it have sustained prior use. It shall be free from kemp and vegetable matter.
(N2) Choice Wool or Choice Virgin Wool: (Optional for those manufacturers who want to use and get credit for using a finer quality of wool). Either of these terms shall apply to Wool or Virgin Wool as defined above that is " 1/4 blood" (48s) or finer in grade, according to the United States Standards for grades of wool, and shall be natural or bleached white in color. The fibers shall be reasonably uniform in length, viz., it shall contain no admixture of short wool fibers. The term Choice Wool or Choice Virgin Wool shall not be used in describing the component parts of Wool Blends or Mixtures.
(N3) Wool By-Products: This term shall include noils and fulling flocks from fabrics made entirely of new wool fibers.
(N4) Wool Waste: This term shall embrace all other by-products and wastes of machines in any process of manufacture employing only new wool fibers and shall include wool pills, and shank and tag wools.
(N5) Tanners Wool: This term shall apply to wool reclaimed from tanned sheepskins.
(N6) Wool Shoddy: This term shall apply to any wool fiber which has been spun into yarn, knit or woven into fabric and subsequently cut up, torn up, broken up, ground up or otherwise defabricated and shall be designated on the label as Wool Shoddy. Wool shoddy shall not contain in excess of five percent (5%) of fibers other than wool.
(N7) Wool Blends or Mixtures: When two or more of the above materials are used in a product, they shall be described on the label as required above in the order of their predominance.
(N8) Wool Batt or Wool Felt: Either of these terms shall be used only when wool fibers alone are garnetted or carded and used in layer form. Neither can be used when wool batting or wool felt scraps or clippings are stuffed or blown in the same manner as unfelted materials. Either of these terms must be followed by a listing of the component material as required above.
(N9) Oil and Grease Percentages: When any wool filling material contains more than five percent (5%) oil, wool grease or other free fat, it shall be described as Oily.
(N10) Damaged Wool: This term shall be applied to wool, although new, which has been damaged through excessive exposure to the elements, faulty storage, fire, or in any other manner, or has begun to disintegrate.
(N11) Tolerance: Materials which contain not less than 95 percent wool shall be considered wool.
(N12) Secondhand Wool: This term shall apply to any wool which has been previously used for any purpose.
(O) MISCELLANEOUS FILLING MATERIALS.
(O1) Casein Fiber: This term shall mean the textile filament or fiber made from casein by chemical and mechanical processes.
(O2) Casein Fiber Waste: This term shall mean the by-product of any preparing or spinning machinery through which the

casein filaments or fibers pass in any operation prior to the weaving or knitting process and shall include "napper" and "fulling flocks."

(O3) Coconut Husk Fiber or Coir Fiber: This term shall apply to fibers obtained from the husks or outer shell of the coconut.

(O4) Excelsior: This term shall mean shredded threadlike wood fibers but shall not include waste products such as shavings, sawdust or similar waste. Terms such as Woodwool shall not be used to describe excelsior.

(O5) Flax Tow: This term shall mean the coarse, broken and refuse parts of flax separated from the fine fibrous parts in preparing the fibers for spinning.

(O6) Fur Fiber: This term shall mean the fine soft under fur, with or without the usual guard hair, removed from the tanned or untanned pelts of mammals of the class of furbearers. The name of the animal may be stated on the label, and when so indicated shall be a true statement.

(O7) Glass Fiber: This term shall mean the very fine filaments or fibers made of glass.

(O8) Hay: This term shall mean any grass, properly cured and dried, free from dust, burrs, sticks or other objectionable material.

(O9) Jute Fiber: This term shall mean the bast fiber derived from any species of the corchorus plant.

(O10) Jute Tow: This term shall mean the broken and refuse parts of jute separated from the fine fibrous parts in preparing the fibers for spinning.

(O11) Jute Waste: This term shall mean the by-product of any machines through which jute fiber passes in spinning into yarn or cordage, but prior to the process of weaving.

(O12) Kapok: This term shall mean the mass of fibers investing the seed of the kapok tree (Ceiba Pentandra). Any additional statement, descriptive of the geographical origin or of the quality of such fibers, shall be a true statement when designated on a label.

(O13) Latex Foam Rubber: This term shall mean natural rubber which has been converted into a stable foamy mass and molded into suitable shapes for use in bedding products.

(A) Latex Foam Rubber Pieces: This term shall mean latex foam rubber which has been cut or broken into pieces of indefinite size, but shall not apply to shredded latex foam rubber.

(B) Shredded Latex Foam Rubber: This term shall mean latex foam rubber which has been subjected to a shredding process.

(C) Molded Shredded Latex Foam Rubber: This term shall mean shredded latex foam rubber molded together by use of an adhesive binder.

(D) Synthetic Foam Rubber: This term shall mean any of the various artificial substances closely resembling natural rubber converted into a staple foamy mass and molded into suitable shapes for use in bedding products.

(E) Cemented Foam Rubber Pieces: The use of this term may be applied to foam rubber pieces which have been cemented together.

(F) Cemented Shredded Foam Rubber: This term may be applied to shredded foam rubber which has been cemented together.

(G) When a fabric-topped foam or sponge rubber product is used as a cover for an article of bedding, its presence shall be disclosed on the tag and its percentage by weight given.

(O14) Latex Sponge Rubber: This term shall mean natural rubber expanded into cellular sheets and vulcanized in that state into slabs.

(A) Latex Sponge Rubber Pieces: This term shall mean latex sponge rubber cut or broken into pieces of indefinite size, but shall not apply to shredded latex sponge rubber.

(B) Shredded Latex Sponge Rubber: This term shall mean latex sponge rubber which has been subjected to a shredding process.

(C) Molded Shredded Latex Sponge Rubber: This term shall mean shredded latex sponge rubber molded together by use of an adhesive binder.

(D) Synthetic Sponge Rubber: This term shall mean any of the various artificial substances closely resembling natural rubber expanded into cellular sheets and vulcanized in that state into slabs.

(E) Cemented Sponge Rubber Pieces: The use of this term may be applied to sponge rubber pieces which have been cemented together.

(F) Cemented Shredded Sponge Rubber: This term may be applied to shredded sponge rubber which has been cemented together.

(O15) Milkweed Fiber: This term shall mean the surface fiber from the inside of the seed pods of milkweed plants (Asclepias).
(O16) Moss: This term shall mean the processed material derived from the moss growth found in swamps and on trees.
(O17) Nylon: This term applies to a synthetic protein-like filament or textile fiber (Polymide).
(O18) Nylon Waste: This term shall mean the by-product of any preparing or spinning machinery through which the nylon filaments or fibers pass in any operation prior to the weaving or knitting process.
(O19) Palm Fiber: This term shall mean the fibrous material obtained from the leaf of the palm, palmetto or palmyra tree.
(O20) Rayon: This term shall mean the synthetic filament or fiber made from modified cellulose.
(O21) Rayon Waste: This term shall mean the by-product of any preparing or spinning machinery through which the rayon fibers pass in any operation prior to the weaving or knitting process and shall include "napper" and "fulling flocks."
(O22) Sea Grass: This term shall mean any of the material obtained from maritime plants or seaweeds.
(O23) Silk Waste: This term shall mean the by-product of any preparing or spinning machinery through which the silk filaments or fibers pass.
(O24) Sisal Fiber: This term shall mean the leaf fiber derived from the Agave Sisalana and similar species of Agaves.
(O25) Sisal Fiber Tow: This term shall mean the residual fibers left after the extraction of the spinnable sisal fiber from the leaf. For the purpose of these regulations, this includes the product known as Bagassi. It shall not contain over 3 percent (3%) pulp.
(O26) Sisal Fiber Waste: This term applies to the sisal fiber waste of cordage mills including rope and cordage ends, but shall not contain knots and refuse.
(O27) Straw: This term shall mean the stalk or stem of grain, such as wheat, rye, oats, rice and the like, after threshing. The kind of straw need not be stated on the label, but if so indicated, shall be a true statement. It shall be free from chaff, beards, bristles, husks, glumes, dirt or other extraneous matter.
(O28) Tula Fiber: This term shall mean the leaf fiber derived from the Tula istle and similar species of Agaves; sometimes called Tulatex. The term Tulatex is a trade name and shall not be used.
(O29) Vinyon Fiber: This term shall apply to a synthetic filament or fiber which is a vinyl resin product prepared by the conjoint polymerization of vinyl chloride and vinyl acetate.
(O30) Vinyon Fiber Waste: This term shall apply to the by-product of any preparing or spinning machinery through which the vinyon filaments or fibers pass in any operation prior to the weaving or knitting process, and shall include "napper" and "fulling flocks."
(O31) Wood Fiber Pad: This term shall apply to wood which has been reduced to a fibrous state and subsequently fabricated into a flat resilient mass.
(O32) Cleanliness: All miscellaneous filling materials used in the manufacture of bedding products shall be clean and free from trash, pith, pulp, extraneous matter, oil and grease.
(O33) Fiber: This term shall mean any threadlike tissue. The term shall be preceded by a designation which will disclose the true source from which the fiber was obtained. Labeling examples for fiber would be Hemp Fiber, Flax Tow Fiber, etc.
(O34) Secondhand: This term shall be applied to any of the above materials which have been previously used for any purpose.
(O35) Tolerances are allowed only where specifically designated for the purpose of adjusting errors due to difficulties in arriving at exact percentages. Tolerances are not intended to permit deliberate admixture of inferior materials.
(P) Vegetable and Synthetic Fibers and Synthetic Foams
(P1) Acetate Fibers or Cellulose Acetate Fibers: These terms shall be used for filling materials made of acetate.
(P2) Acrylic Fibers: This term shall be used for a long-chain synthetic polymer which contains not less than 85 percent acrylonitrile and which is formed into a filament.
(P3) Azlon: A generic term for fibers or filaments manufactured from modified proteins or derivatives thereof, with or without lesser amounts of nonfiber-forming materials. The term "Azlon" shall be used to designate fibers manufactured from azlon.
(P4) Dacron: This term shall not be used. See Polyester Fibers.
(P5) Polyester Fibers: This term shall be used to designate long-chain synthetic polymers which contain 85 percent or more of the polymeric esters.
(P6) Polyethylene Fibers: This term shall be used to designate fibers made from polymers and/or copolymers of ethylene.
(P7) Vinyl Fibers: This term shall be used to designate fibers of filaments manufactured from vinyl.
(P8) A foam product means a polymerized material consisting of a mass of thin-walled cells produced chemically or physically and shall be designated on the tag as Foam together with the name of the organic base from which it is made.
(P9) Polyurethane Foam: This term applies to a cellular urethane product which is created by the interaction of an ester and

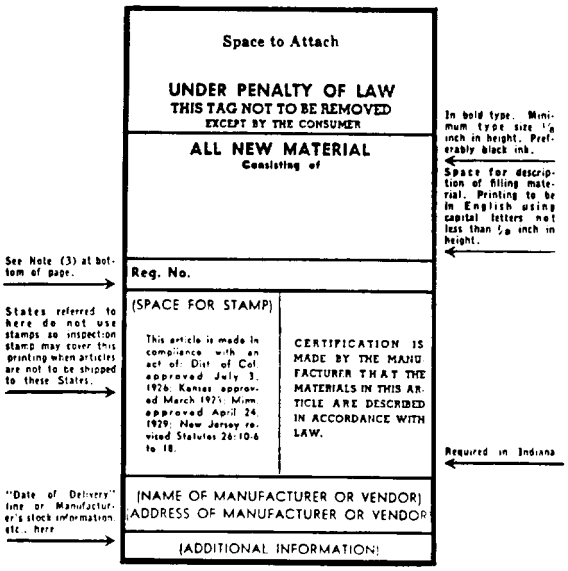
a carbamic acid derivative.
(P10) Polystyrene Foam: This term shall be applied to foam produced during the polymerization of a styrene monomer.
(P11) Vinyl Foam: This term shall be applied to a foam produced from vinyl.
(P12) The term "pieces" shall follow the terms set forth in P9, P10, and P11 above, whenever the foam product consists of mere pieces.
(P13) The term "shredded" shall precede the terms set forth above whenever the foam product has been subjected to shredding process.
(P14) The term "cemented" shall be applied to a shredded foam which has been cemented together; e. g., cemented shredded urethane foam.
(P15) When a fabric-topped foam or sponge product is used as a cover for an article of bedding, its presence shall be disclosed on the tag and its percentage given.
(P16) Textile Fiber Waste: This term shall apply to fibers which are in whole or in part the by-product removed or resulting from any of the various machine operations necessary in the preparation or manufacture of filament, fiber, thread or fabric and which has no established pattern of length or denier distribution.
(P17) Polyurethane Foam Skins: This term shall apply to the top skin of polyurethane foam and shall be identified on the law label and percent by weight given.

Q. FACSIMILES OF LABELS APPROVED FOR USE IN INDIANA

NO. 1

LABEL FOR ALL NEW MATERIAL

For Filling Materials *NOT* Requiring Sterilization or Disinfection



Note: (1) All above printing preferably in black ink on white vellum cloth or a cloth of considerable quality, which shall not flake out when abraded.

(2) Size of Label: Exclusive of the portion required to affix the tag to the article, the minimum size of the tag shall be not less than six (6) square inches, but may be greater as the need demands.

(3) Indiana approves and recognizes the uniform registry number and will accept the registration number issued by another State if registrant so desires, providing such registration follows the policy of uniform registration.

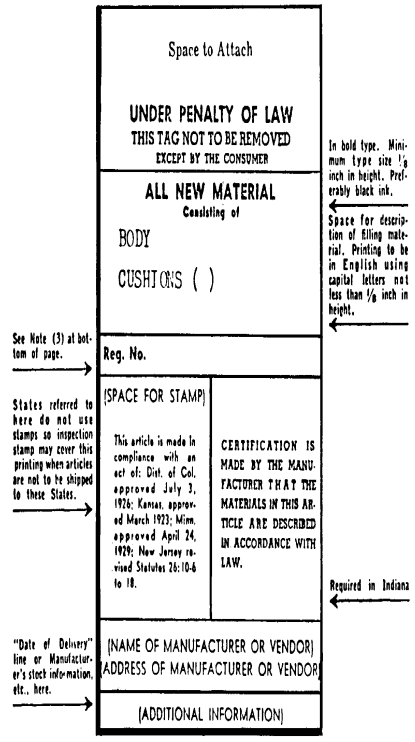
This policy is intended to benefit the registrant by requiring but one registration to be imprinted on the law labels used, regardless of where merchandise may be shipped.

The registration number shall be preceded by name of state (may be abbreviated) issuing REG. NO. and if factory is located in another state than that issuing REG. NO. then name of state in which factory is located shall follow the registration number in parenthesis.

NO.2

LABEL FOR ALL NEW MATERIAL

For Filling Materials *NOT* Requiring Sterilization or Disinfection



Note: (1) All above printing preferably in black ink on white vellum cloth or a cloth of comparable quality, which shall not flake out when abraded.

(2) Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size of the tag shall be not less than six (6) square inches, but may be greater as the need demands.

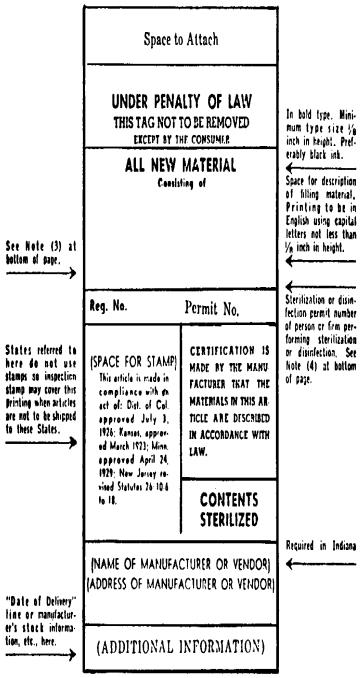
(3) Indiana approves and recognizes the uniform registry number and will accept the registration number issued by another State if registrant so desires, providing such registration follows the policy of uniform registration.

This policy is intended to benefit the registrant by requiring but one registration to be imprinted on the law labels used, regardless of where merchandise may be shipped.

The registration number shall be preceded by name of state (may be abbreviated) issuing REG. NO. and if factory is located in another state than that issuing REG. NO. then name of state in which factory is located shall follow the registration number in parenthesis.

NO. 3
LABEL FOR ALL NEW MATERIAL

For Animal and Fowl and Any Other Filling Material Requiring Sterilization or Disinfection



Note: (1) All above printing preferably in black ink on white vellum cloth or a cloth of comparable quality, which shall not flake out when abraded.

(2) Size of label. Exclusive of the portion required to affix the tag to the article, the minimum size of the tag shall be not less than six (6) square inches, but may be greater as the need demands.

(3) Indiana approves and recognizes the uniform registry number and will accept the registration number issued by another State if registrant so desires, providing such registration follows the policy of uniform registration.

This policy is intended to benefit the registrant by requiring but one registration to be imprinted on the law labels used, regardless of where merchandise may be shipped.

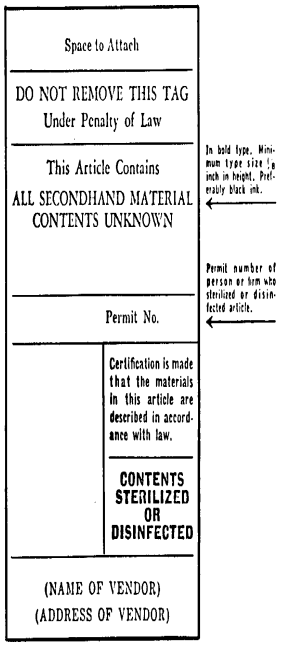
The registration number shall be preceded by name of state (may be abbreviated) issuing REG. NO. and if factory is located in another state than that issuing REG. NO. then name of state in which factory is located shall follow the registration number in parenthesis.

(4) Indiana will accept the PERMIT NO. Issued by another State if applicant so desires, providing approval is granted and an Indiana Sterilization or Disinfection Permit is issued to applicant bearing such number.

NO. 4

YELLOW LABEL FOR ARTICLES CONTAINING ALL SECONDHAND MATERIAL OFFERED FOR SALE BY SECONDHAND DEALERS "AS IS."

REQUIRED TO BE STERILIZED OR DISINFECTED



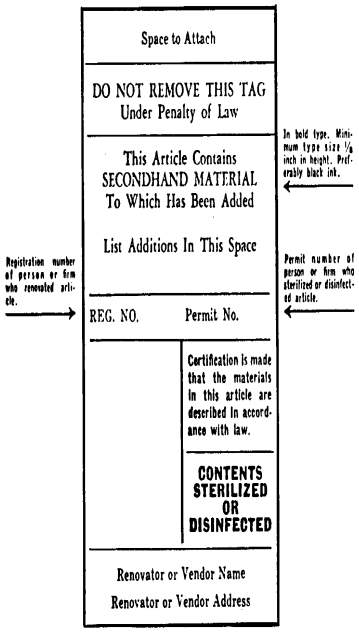
Note: (1) All above printing preferably in black ink on yellow vellum cloth or a cloth of comparable quality, which shall not flake out when abraded.

(2) Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size of the tag shall be not less than six (6) square inches, but may be greater as the need dictates.

NO. 5

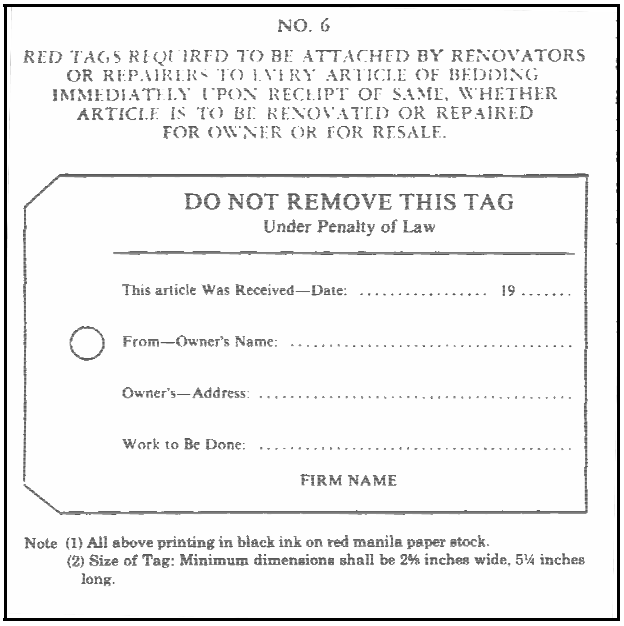
YELLOW LABEL FOR ARTICLES WHICH HAVE BEEN RENOVATED FOR RESALE AND WHICH CONTAIN SECONDHAND MATERIAL IN WHOLE OR IN PART.

REQUIRED TO BE STERILIZED OR DISINFECTED



Note: (1) All above printing preferably in black ink on yellow cotton cloth or a cloth of comparable quality, which shall not fade out when abraded.

(2) Size of label: Exclusive of the portion required to affix the tag to the article, the minimum size of the tag shall be not less than six (6) square inches, but may be greater as the need demands.



NO. 6

RED TAGS REQUIRED TO BE ATTACHED BY RENOVATORS OR REPAIRERS TO EVERY ARTICLE OF BEDDING IMMEDIATELY UPON RECEIPT OF SAME, WHETHER ARTICLE IS TO BE RENOVATED OR REPAIRED FOR OWNER OR FOR RESALE.

DO NOT REMOVE THIS TAG
Under Penalty of Law

This article Was Received—Date: ..... 19 .....

From—Owner's Name: .....

Owner's—Address: .....

Work to Be Done: .....

FIRM NAME

Note (1) All above printing in black ink on red manila paper stock.
(2) Size of Tag: Minimum dimensions shall be 2⅝ inches wide, 5¼ inches long.

(Indiana State Department of Health; Reg HSB 3R; filed Oct 5, 1971, 8:30 am: Rules and Regs. 1972, p. 124; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 13-1-6 Sterilization or disinfection; permits; procedures

Authority: IC 16-19-3-5; IC 16-41-32-14
Affected: IC 16-41-32

Sec. 6. Sterilization or Disinfection. (A) Each establishment using, or selling secondhand articles of bedding or filling materials therefor shall either have a permit for its own sterilization or disinfection equipment, or have its sterilization or disinfection performed by anyone having such a permit.

(B) Every applicant for permission to operate a sterilizing or disinfecting process shall furnish with such application, detailed plans and specifications in duplicate (2 copies) of the proposed equipment. A permit is valid for one year from date of issue and is renewable prior to expiration date on payment of $10.00. If renewed after expiration date, it is renewable only upon payment of the initial permit fee of $25.00.

(C) All unsterilized or undisinfected secondhand articles of bedding or materials therefor shall be separately stored and carefully segregated from new or clean articles of bedding or materials therefor. No new or clean materials shall be stored within a room or space used for sterilizing or disinfecting secondhand materials. Sterilizing or disinfecting chambers shall not be used for storage purposes.

(D) A sterilization or disinfection permit number shall not be misused.

(E) All sterilization or disinfection processes shall follow the method approved for that type process.

(F) All sterilization or disinfection equipment shall be maintained in good condition, no leaky joints, faulty construction, etc.

(G) All sterilization or disinfection permits must be kept posted conspicuously, preferably on the outside wall of the sterilization or disinfection chamber.

(H) The required written record of sterilization or disinfection performed shall be kept in a bound ledger, and such records shall be available for examination at any time by the Board.

The record shall show the date on which sterilization or disinfection was performed, and the articles of bedding or materials that were sterilized or disinfected and the name and address of the owner. EXAMPLE:

Date	Articles	Owners Name and Address
3-24-50	4 mattresses	Acme Furn. Store, 919 First Ave., Indianapolis.

1 bed davenport with three loose cushions	John Doe, 6120 Evans St., Indianapolis.

(I) The Board shall approve or disapprove an application for each separate installation and shall approve or disapprove each process. Processes to be approved shall either thoroughly sterilize or disinfect the article of bedding or materials thereof, to be processed. Such process shall not be placed in commercial operation until a numbered permit has been issued by the Board. Processes which comply with the following requirements will be approved upon application and inspection.

(I)(1) STEAM PRESSURE: A Steam pressure process, when approved by the Board, may be used to sterilize or disinfect any article of bedding or filling material.

SATISFACTORY COMPLIANCE: Articles of bedding or filling materials therefor sterilized or disinfected by this process shall be subjected to treatment by live steam for thirty (30) minutes at a pressure of fifteen (15) pounds and at a temperature of 250 degrees Fahr., or for twenty (20) minutes at a pressure of twenty (20) pounds and at a temperature of 260 degrees Fahr. Chamber must be steam tight, sufficiently strong to withstand the pressure applied, be equipped with visible pressure and temperature gauges and necessary safety devices. Chamber must be provided with wire or lattice work shelving which provides a minimum clearance of one (1) inch from bottom, top, sides and between articles of bedding being sterilized or disinfected.

(I)(2) DRY HEAT. Dry hot air, when approved by the Board, may be used to sterilize or disinfect articles of bedding or filling materials thereof.

SATISFACTORY COMPLIANCE: Sterilization or disinfection by the dry heat method requires developing and holding a temperature of 230 degrees Fahr. for a minimum period of two (2) hours after the temperature of 230 degrees Fahr. plus or minus 5 degrees is attained in an approved chamber. Steam, electricity or flue gases may be used to produce the heat but gas will not be approved for heating unless an indirect system is used where there could be no possibility of igniting the materials being sterilized or disinfected. A thermostat shall be connected with the heating device to provide and maintain a reasonably uniform temperature of 230 degrees Fahr. plus or minus 5 degrees Fahr. A recording thermometer shall be used to automatically record the temperature and time of each sterilization or disinfection period. The operator shall initial and date each sterilization or disinfection period on the recording thermometer charts and such charts shall be kept carefully filed for examination at any time by the Board.

(I)(3) FORMALDEHYDE AND MOISTURE. Formaldehyde gas in the presence of moisture, when approved by the Board, may be used to sterilize or disinfect articles of bedding or filling materials thereof which is not compressed to a degree in excess of the usual compression of cotton felt. Articles of bedding or filling materials shall be so spaced in approved sterilizing or disinfecting chamber as to allow free circulation of gas; not less than 4 inches on all sides and between articles. The exhaust from the sterilization or disinfection chamber shall discharge above the roof of building in such manner as will not create a health hazard. Formaldehyde being a toxic gas, provisions must be made to preclude any danger to employees in workroom. A minimum temperature shall be maintained in sterilization or disinfection chamber of not less than 70 degrees Fahr.

SATISFACTORY COMPLIANCE: Articles of bedding or filling materials thereof to be sterilized or disinfected by this method shall be treated with formaldehyde in a moist atmosphere not less than 70 degrees Fahr. for a period of at least ten (10) hours. Formaldehyde gas shall be generated from the use of one (1) pint of formaldehyde solution (37%) to each 1,000 cubic feet of air space in sterilizing or disinfecting chamber or through the use of any commercial fumigators which generate an equivalent quantity of gas. The minimum quantity of solution permitted is two (2) ounces regardless of how small the sterilizing or disinfecting chamber is. The solution must be heated or boiled to release the gas. Chamber must be gas tight and equipped with air inlet and outlet. Tight closure gate valves shall be provided on both air inlet and outlet. Shelving shall be of wire or lattice type construction or mattresses may be suspended from suitable hangers with proper spacing. Formaldehyde will not sterilize or disinfect unless moisture is present and the gas is used for the full period required, a minimum of ten (10) hours. Care must be taken that no fire hazard is present if a flame is used to vaporize the formaldehyde. This process is a germicidal treatment only and is not recommended as an insecticide.

(I)(4) FEATHERS or DOWN.

(1) New Feathers or Down: Sterilization or disinfection application must indicate that feathers or down are thoroughly washed and rinsed, that live steam and dry heat are applied and that feathers or down are free of dust or dirt on completion of the process.

(2) Secondhand Feathers or Down: Secondhand feather or down articles of bedding will be considered as having been

sterilized or disinfected when the contents and ticking are kept intact without opening and washed by a commercial laundry method with subsequent drying to remove moisture; or when processed by a method for which approval has been obtained from the Board.

(I)(5) HAIR.

(1) New Hair: Sterilization or disinfection application must indicate the entire process used for washing and curling (if curled), and that at some point during the process the hair remains in boiling water a sufficient period (not less than 1 hour) to kill all pathogenic organisms.

(2) Secondhand Hair: Secondhand articles of bedding will be considered as having been sterilized or disinfected when the hair is removed from the ticking and washed by a commercial laundry method and subsequently dried to remove all moisture, and when the ticking is also washed and subsequently dried; or when processed by a method for which approval has been obtained from the Board.

(I)(6) WOOL.

(1) New Wool: Sterilization or disinfection application must indicate whether raw wool or previously scoured and carbonized wool is to be treated. The processing of raw wool must be set forth in detail and indicate that at some point during the scouring and carbonizing, the wool is subjected to wet or dry heat or acid treatment sufficient to kill all pathogenic spores and micro-organisms. Wool fibers reclaimed from new fabric need not be re-sterilized or re-disinfected.

(2) Secondhand Wool: Secondhand wool articles of bedding will be considered as having been sterilized or disinfected when the contents and cover are kept intact without opening and washed or dry cleaned by a commercial laundering or dry cleaning method; or when processed by a method for which approval has been obtained from the Board.

(I)(7) DRY CLEANING: Dry cleaning, when approved by the Board, may be used to sterilize or disinfect articles of bedding or filling materials thereof.

SATISFACTORY COMPLIANCE: Sterilization or disinfection by dry cleaning shall be deemed to have been met when bedding articles or materials have been subjected to a commercial dry cleaning process.

(I)(8) OTHER METHOD: Articles of bedding or filling materials thereof may be sterilized or disinfected by any other method which is safe to use, and is adequately proficient to thoroughly sterilize or disinfect the product or material to be processed, and for which approval has been given by the Board.

(Indiana State Department of Health; Reg HSB 4; filed Apr 26, 1950, 3:15 pm: Rules and Regs. 1951, p. 136; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

ARTICLE 14. HOSPITAL AND HEALTH CENTER PLANNING AND CONSTRUCTION

Rule 1. Application for Aid for Hospital or Health Center Construction Projects, Hearing and Review

410 IAC 14-1-1 Initial decision by designated hearing member

Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 1. The initial decision in any hearing upon an application for aid for a hospital or health center construction project under the provisions of Chapter 101 of the Acts of 1945, as amended by Chapter 173 of the Acts of 1947, may be recommended by such hearing member of the Indiana State Board of Health or officer or employee of the Indiana State Board of Health as shall be so designated by the Indiana State Board of Health. *(Indiana State Department of Health; Reg HPC 1; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 306; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-2 Submission of hearing member's recommendation

Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 2. The recommendation of the person so designated as hearing member shall be submitted to the State Board of Health and adopted or rejected at the next meeting of the Indiana State Board of Health. *(Indiana State Department of Health; Reg HPC 2; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 306; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-3 Applicant's opportunity for hearing and review

Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 3. Any applicant who is aggrieved by an initial decision of the State Board of Health shall be given an opportunity for a hearing and review of the decision before the Board or such section of the Board, not less than three in number, as shall be designated by a resolution of the Board for that purpose. *(Indiana State Department of Health; Reg HPC 3; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 306; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-4 Grounds for review and hearing

Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 4. The following grounds will be sufficient to entitle an applicant to a review and hearing:
(a) Denial of opportunity to make formal application.
(b) Rejection or disapproval of application.
(c) Refusal to reconsider an application.
(Indiana State Department of Health; Reg HPC 4; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 306; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 14-1-5 Filing of request for review

Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 5. Requests for review of decisions or actions of the Indiana State Board of Health must be made by the applicant, in writing, within 30 days from the date of the adverse decision by the Indiana State Board of Health. *(Indiana State Department of Health; Reg HPC 5; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 307; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-6 Notice of hearing

Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 6. The applicant who has requested a review and hearing will be notified in writing of the time and place of hearing by the Indiana State Board of Health, such time and place to be reasonably convenient for the applicant. *(Indiana State Department of Health; Reg HPC 6; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 307; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-7 Representation at hearing; admissibility of evidence

Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 7. The applicant who has requested a review and hearing is entitled to be represented by friends or counsel, if he so desires. The applicant and other persons interested and concerned with the Indiana State Board of Health's decision are entitled to present pertinent evidence in the way desired subject to reasonable procedures of admissibility and methods of presentation. *(Indiana State Department of Health; Reg HPC 7; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 307; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-8 Right to examination of evidence and witnesses

Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 8. The applicant is entitled to examine all evidence and to question opposing witnesses. *(Indiana State Department of Health; Reg HPC 8; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 307; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-9 Presiding officer
Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 9. Whenever practicable, the presiding officer will be an official in a responsible position who did not participate in the action from which the appeal is made. *(Indiana State Department of Health; Reg HPC 9; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 307; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-10 Decision of board
Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 10. The decision of the Indiana State Board of Health will be made in writing within 30 days from the date of the hearing, and will be based on the evidence presented at the hearing. *(Indiana State Department of Health; Reg HPC 10; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 307; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 14-1-11 Transcript of hearing
Authority: IC 16-19-3-5
Affected: IC 16-45

Sec. 11. A stenographic record of the hearing will be made, and, upon request of the applicant, will be transcribed and made available for examination. *(Indiana State Department of Health; Reg HPC 11; filed Aug 5, 1947, 11:30 am: Rules and Regs. 1948, p. 308; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 15. HOSPITAL LICENSURE RULES

Rule 1. Hospital Operation, Management, Construction, Equipment Requirements (Repealed)

(Repealed by Indiana State Department of Health; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1280; errata filed Jan 5, 1995, 4:20 p.m.: 18 IR 1290)

Rule 1.1. Definitions

410 IAC 15-1.1-1 Applicability
Authority: IC 16-21-1-7; IC 16-21-1-8; IC 16-21-1-9
Affected: IC 16-21-1

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 15-1.1-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-2 "Ambulatory outpatient surgical center" defined
Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-21-1; IC 16-25-1

Sec. 2. "Ambulatory outpatient surgical center" means a center as defined in IC 16-18-2-14. *(Indiana State Department of Health; 410 IAC 15-1.1-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-3 "Authenticate" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. "Authenticate" means the author or responsible individual has reviewed the clinical content of the order and validated an entry in the record by:

(1) a full signature, including first initial, last name, and discipline;
(2) written initials if full signature appears on the same page;
(3) a unique identifier such as a number or computer key; or
(4) a signature stamp.

(Indiana State Department of Health; 410 IAC 15-1.1-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.1-4 "Commissioner" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. "Commissioner" means the state health commissioner or the state health commissioner's designee. *(Indiana State Department of Health; 410 IAC 15-1.1-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-5 "Council" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-84; IC 16-21-1

Sec. 5. "Council" means the body defined in IC 16-18-2-84(1). *(Indiana State Department of Health; 410 IAC 15-1.1-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-6 "Department" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 6. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 15-1.1-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-7 "Division" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. "Division" means the division of acute care of the department. *(Indiana State Department of Health; 410 IAC 15-1.1-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-8 "Donor" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 29-2-16-1

Sec. 8. "Donor" means an individual as defined in IC 29-2-16-1. *(Indiana State Department of Health; 410 IAC 15-1.1-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-9 "Executive board" defined
Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-18-2-120; IC 16-21-1

Sec. 9. "Executive board" means the board as defined in IC 16-18-2-120. *(Indiana State Department of Health; 410 IAC 15-1.1-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-10 "Governing board" defined
Authority: IC 16-21-1-7
Affected: IC 16-18-2-149; IC 16-21-1

Sec. 10. "Governing board" means the body defined in IC 16-18-2-149. *(Indiana State Department of Health; 410 IAC 15-1.1-10; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-11 "Health care provider" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 11. "Health care provider" means a provider as defined in IC 27-12-2-14 *[IC 27-12 was repealed by P.L.1-1998, SECTION 221, effective July 1, 1998.]*. *(Indiana State Department of Health; 410 IAC 15-1.1-11; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-12 "Health care worker" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1-6

Sec. 12. "Health care worker" means a person who provides services whether as an individual health care provider, volunteer, or student at or employee of a hospital. *(Indiana State Department of Health; 410 IAC 15-1.1-12; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-13 "Hospital" defined
Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-18-2-179

Sec. 13. "Hospital" means an organization as defined in IC 16-18-2-179. *(Indiana State Department of Health; 410 IAC 15-1.1-13; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-14 "Licensed health professional" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1-27.1

Sec. 14. "Licensed health professional" means an individual as defined in IC 25-23-1-27.1. *(Indiana State Department of Health; 410 IAC 15-1.1-14; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-15 "Medical staff" defined
Authority: IC 16-21-1-7
Affected: IC 16-18-2-149; IC 16-21-2-7

Sec. 15. "Medical staff" means a group as defined in IC 16-21-2-7. *(Indiana State Department of Health; 410 IAC 15-1.1-15; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-16 "Pharmacist" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-26-13

Sec. 16. "Pharmacist" means an individual licensed under IC 25-26-13. *(Indiana State Department of Health; 410 IAC 15-1.1-16; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-17 "Physician" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-22.5-5

Sec. 17. "Physician" means an individual licensed under IC 25-22.5-5. *(Indiana State Department of Health; 410 IAC 15-1.1-17; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-18 "Practitioner" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-1-9-2

Sec. 18. "Practitioner" means an individual as defined in IC 25-1-9-2. *(Indiana State Department of Health; 410 IAC 15-1.1-18; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.1-19 "Registered nurse" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1

Sec. 19. "Registered nurse" means an individual licensed under IC 25-23-1. *(Indiana State Department of Health; 410 IAC 15-1.1-19; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 1.2. Compliance with Rules

410 IAC 15-1.2-1 Compliance with rules

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) All hospitals shall be licensed by the department and shall comply with all applicable federal, state, and local laws and rules.

(b) Components required for licensure as a hospital are the following:

(1) Governing board.
(2) Quality assessment and improvement program.
(3) Dietary service.
(4) Infection control program.
(5) Laboratory service.
(6) Medical record service.
(7) Medical staff.
(8) Nursing service.
(9) Pharmaceutical service.
(10) Physical environment service.
(11) Plant maintenance service.
(12) Radiologic service.

(c) Optional services, not required for licensure, shall comply with all rules for that service.

(d) The hospital shall have a plan to address the internal review and reporting of unusual occurrences and disasters. This plan

shall cover, but not be limited to, the following:

(1) Patient injuries or marked deterioration of patient condition occurring under unanticipated or unexpected circumstances.

(2) Chemical poisoning occurring within the hospital resulting in a negative patient outcome.

(3) Unexplained loss of or theft of a controlled substance.

(4) Missing patient whose whereabouts are unknown for over twenty-four (24) hours.

(e) The hospital shall report the following incidents to the division:

(1) Verbal reports within twenty-four (24) hours of occurrence on:

(A) murder, suicide, or kidnapping of patient occurring after admission;

(B) reportable infection outbreaks or food poisonings as required by federal, state, and local law; and

(C) a disruption, exceeding four (4) hours, in the continued safe operation of the hospital or in the provision of patient care, caused by internal or external disasters, strikes by health care workers, or unscheduled termination of vital services.

(2) Written reports on occurrences listed in subdivision (1), if requested, shall be submitted to the division within a reasonable period of time and document all information required by the department, including, but not limited to, the following:

(A) An explanation of the circumstances surrounding the incident.

(B) Summaries of all findings, conclusions, and recommendations associated with the review of the incident.

(C) A summary of actions taken to resolve identified problems, to prevent recurrence of the incident, and to improve overall patient care.

(3) This subsection does not replace other reporting requirements. Copies of these required reports will be acceptable in satisfying subdivision (2).

(f) In the event of flood, fire, or other disaster, the governing board, or the governing board's designee, or the commissioner shall close all or that part of the hospital as may be necessary to ensure the safety and well-being of patients. The commissioner shall approve reopening. *(Indiana State Department of Health; 410 IAC 15-1.2-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 1.3. Licensure Requirements

410 IAC 15-1.3-1 Issuance of license

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The hospital shall file an application for licensure on a yearly basis with the division, prior to the expiration of the current license.

(b) A license is not transferable or assignable and shall be issued only for the premises named in the application.

(c) If multiple buildings are licensed under a single license, the licensee shall operate these buildings as a single integrated system as follows:

(1) All buildings or portions of buildings under a single license shall be governed by a single governing body and under administrative control of a single administrator.

(2) All hospital facilities operating under a single license shall have a single medical staff.

(d) Reapplication shall be filed when a change of fifty percent (50%) or greater ownership occurs.

(e) An application for license from a newly constructed hospital shall be obtained from the division and submitted after the physical plant plans have been approved under 410 IAC 15-1.5-8. Upon receipt of a design release from the state building commissioner, an application shall be submitted to the division on the form provided, along with the documents required by the application form.

(f) Any full or partial replacement of the physical plant of a hospital, any addition or renovation to the physical plant of a hospital, or any acquisitions of additional buildings under the current license of an existing hospital, shall meet the provisions of 410 IAC 15-1.5-8. *(Indiana State Department of Health; 410 IAC 15-1.3-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1263; filed Jun 3, 1996, 9:00 a.m.: 19 IR 2876; errata filed Jun 10, 1996, 2:00 p.m.: 19 IR 2884; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.3-2 Posting of license

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. The license shall be conspicuously posted on the hospital premises in an area open to patients and public. A copy shall be conspicuously posted in an area open to patients and public on the premises of each separate hospital building of a multiple hospital building system. *(Indiana State Department of Health; 410 IAC 15-1.3-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1263; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.3-3 Suspension or revocation of license

Authority: IC 16-21-1-7
Affected: IC 4-21.5; IC 16-21-1

Sec. 3. (a) The commissioner may take any of the following actions on any of the grounds listed in subsection (b):
(1) Issue a letter of correction.
(2) Issue a probationary license.
(3) Conduct a resurvey.
(4) Deny renewal of a license.
(5) Revoke a license.
(6) Impose a civil penalty in an amount not to exceed ten thousand dollars ($10,000).
(b) The commissioner may take action under subsection (a) on any of the following grounds:
(1) Violation of any of the provisions of this article.
(2) Permitting, aiding, or abetting the commission of any illegal act in an institution.
(3) Conduct or practice found by the council to be detrimental to the welfare of the patients of an institution.
(c) IC 4-21.5 applies to an action under this section.
(d) A licensee or an applicant for a license aggrieved by an action under this rule may request review under IC 4-21.5.
(e) The state department shall appoint an appeals panel consisting of three (3) members as follows:
(1) One (1) member of the executive board.
(2) One (1) attorney admitted to the practice of law in Indiana.
(3) One (1) individual with qualifications determined by the state department.
(f) An employee of the department may not be a member of the panel.
(g) The panel shall conduct proceedings for review of an order issued by an administrative law judge under this rule. The panel is the ultimate authority under IC 4-21.5. *(Indiana State Department of Health; 410 IAC 15-1.3-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1264; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.3-4 Complaint investigation

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. (a) The division shall investigate all complaints that come under the department's jurisdiction, regardless of the method of communication.

(b) The complaints will be assigned a priority based on the seriousness of the complaint, according to division policy, and the priority will dictate the immediacy of the investigation.

(c) The complaint investigations will be unannounced and may:
(1) occur at the time of the annual licensure inspection; and
(2) evolve into a full survey.

(d) The results of the investigation will be given in writing to the hospital.

(e) The hospital will have a reasonable period of time to respond in writing with an acceptable plan of correction for noncompliance with state rules noted as a result of the investigation before this information is made available to the public.

(f) The results will be reviewed and upon recommendation of the division forwarded to the commissioner for action under section 3 of this rule.

(g) The completed complaint and survey results will become part of the hospital's public file. *(Indiana State Department of Health; 410 IAC 15-1.3-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1264; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 1.4. Governing Board Responsibilities

410 IAC 15-1.4-1 Governing board

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The governing board is legally responsible for the conduct of the hospital as an institution. The governing board shall do the following:

(1) Function as the supreme authority of the hospital.

(2) Ensure that the hospital:

(A) meets all rules and regulations for licensure and certification, if applicable; and

(B) makes available to the commissioner upon request all reports, records, minutes, documentation, information, and files required for licensure.

(3) Adopt bylaws and function accordingly.

(4) Review the bylaws at least triennially.

(5) Maintain a liaison with the medical staff.

(6) Review, at least quarterly, reports of management operations, medical staff actions, and quality monitoring, including patient services provided, results attained, recommendations made, actions taken, and follow-up.

(7) Ensure that there is a hospital-wide, quality assessment and improvement program to evaluate the provision of patient care.

(b) The governing board is responsible for the conduct of the medical staff. The governing board shall do the following:

(1) Determine, with the advice and recommendation of the medical staff, and in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(2) Ensure that:

(A) the requests of practitioners, for appointment or reappointment to practice in the hospital, are acted upon, with the advice and recommendation of the medical staff;

(B) reappointments are acted upon at least biennially;

(C) practitioners are granted privileges consistent with their individual training, experience, and other qualifications; and

(D) this process occurs within a reasonable period of time, as specified by the medical staff bylaws.

(3) Ensure that the medical staff has approved bylaws and rules and that the bylaws and rules are reviewed and approved at least triennially. Governing board approval of medical staff bylaws and rules shall not be unreasonably withheld.

(4) Ensure that the medical staff is accountable and responsible to the governing board for the quality of care provided to patients.

(5) Ensure that criteria for selection for medical staff membership are individual character, competence, education, training, experience, and judgment.

(6) Ensure that the granting of medical staff membership or professional privileges in the hospital is not solely dependent upon certification, fellowship, or membership in a specialty body or society.

(c) The governing board is responsible for managing the hospital. The governing board shall do the following:

(1) Develop criteria, which include, but are not limited to, defining educational and experience requirements for the chief executive officer. These criteria would apply to all chief executive officers appointed after the effective date of this article.

(2) Appoint a qualified chief executive officer who is delegated the authority and responsibility for managing the hospital and report to the division the name of the chief executive officer within ten (10) days after the appointment.

(3) Delineate in writing the responsibility and authority of the chief executive officer.

(4) Require that the chief executive officer or designee attends meetings of the governing board and its committees and act as its representative at medical staff meetings.

(5) Require that the chief executive officer has designated in writing an administrative officer to serve during his or her absence.

(6) Require that the chief executive officer develops policies and programs for the following:

(A) Ensuring the employment of personnel, in accordance with state and federal rules, whose qualifications are commensurate with anticipated job responsibilities.

(B) Orientation of all new employees, including contract and agency personnel, to applicable hospital, department, service, and personnel policies.

(C) Ensuring that all health care workers, including contract and agency personnel, for whom a license, registration, or certification is required, maintain current license, registration, or certification and keep documentation of same so that it can be made available within a reasonable period of time.

(D) Annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.

(E) Establishing criteria for each service manager, department director, or supervisor that includes, but is not limited to, the following:

(i) Definition of educational requirements.

(ii) Experience requirements.

(iii) Professional certification, licensing, or registration, where appropriate.

(F) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and hospital policy for all health care workers, including contract and agency personnel, who provide direct patient care.

(G) Providing employee health services and a post offer physical examination in consultation with the infection control committee.

(H) Requiring all services to have written policies and procedures that are updated as needed and reviewed at least triennially.

(I) Establishing a policy and procedure for communicating with physicians concerning an inpatient emergency in accordance with 410 IAC 15-1.5-5(b)(3)(L).

(J) Maintaining a current roster of members of the medical staff and their service categories.

(K) Maintaining personnel records for each employee of the hospital which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin test or chest x-ray, as applicable.

(L) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-servicing in special procedures.

(M) Coordinating with local, regional, and state health planning groups and other hospital services providers so that effective disaster preparedness, emergency service communication, and transportation systems are established and maintained.

(N) Annual implementation of internal and external disaster preparedness plans with documentation of outcome.

(O) Development, implementation, and monitoring of a safety management program under the direction of a safety officer, qualified by experience or education.

(P) Safe, appropriate, and adequate transport of patients.

(d) The governing board is responsible for assuring that quality patient care is provided. In accordance with hospital policy, the governing board shall do the following:

(1) Ensure all patients are admitted to the hospital only by a licensed practitioner who has been granted admitting privileges in accordance with the credentialing process of the hospital.

(2) Ensure a qualified licensed physician member of the medical staff is responsible for the care and treatment of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that does not specifically fall within the scope of practice or the medical staff privileges of the admitting practitioner.

(3) Provide the following for any patients requiring emergency care:

(A) In hospitals with at least one hundred (100) acute care staffed beds, a licensed physician on the premises at all times who has the responsibility to respond to patients requiring emergency care as defined in 410 IAC 15-1.5-5(b)(3)(L)(i).

(B) In hospitals of less than one hundred (100) acute care staffed beds:

(i) a licensed physician on the premises as in clause (A); or

(ii) a licensed physician who has the responsibility to respond to patients requiring emergency care as defined in 410 IAC 15-1.5-5(b)(3)(L)(i) and who is on call at all times and immediately available by phone and then available on the premises within thirty (30) minutes, if necessary, and in accordance with hospital and medical

staff policies.

(4) Ensure either of the following:

(A) If the hospital does provide community emergency services to the public, it shall provide that service in compliance with 410 IAC 15-1.6-2.

(B) If the hospital does not provide community emergency services to the public, it shall do the following:

(i) Have written medical staff policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(ii) Provide immediate lifesaving measures within the scope of services available to all persons who appear for emergency care which includes, but is not limited to, the following:

(AA) Timely assessment.

(BB) Stabilization.

(CC) Treatment prior to transfer.

(iii) Arrange for transfer of the patient, with copies of records of treatments provided, to another hospital which does provide appropriate clinical services.

(5) Ensure policies are established to cover physician limited practice problems that may include, but are not necessarily limited to, the following:

(A) Impaired physicians.

(B) Criminal checks.

(C) Disciplinary action.

(6) Ensure that the hospital does the following:

(A) Establish written protocols to identify potential organ and tissue donors.

(B) Has written policies and procedures for the facilitation of organ and tissue donations, including procurement.

(C) Inform families or authorized persons of potential organ and tissue donors of the option of donation on admission or at the time of death of a potential donor.

(D) Use discretion and sensitivity in contacts with potential organ donor families.

(E) Notify the appropriate procurement organization of potential organ donors.

(F) Establish membership in the organ procurement and transplantation network if the hospital performs transplants.

(e) The governing board is responsible for the overall institutional plan as follows:

(1) The institutional plan shall:

(A) be reviewed and updated annually; and

(B) be prepared, under the direction of the governing board, by a committee with representatives from:

(i) the governing board;

(ii) the administration, which includes, but is not limited to:

(AA) nursing;

(BB) finance; and

(CC) medical staff of the hospital.

(2) The plan shall include, but not be limited to, the programs and services provided and an annual operating budget prepared according to generally accepted accounting principles.

(f) The governing board is responsible for services delivered in the hospital whether or not they are delivered under contracts. The governing board shall ensure the following:

(1) That a contractor of any service furnishes those services in such a manner as to permit the hospital to comply with all applicable statutes and rules.

(2) That the services performed under a contract are provided in a safe and effective manner and are included in the hospital's quality assessment and improvement program.

(3) That the hospital maintains a list of all contracted services, including the scope and nature of the services provided.

(Indiana State Department of Health; 410 IAC 15-1.4-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1264; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.4-2 Quality assessment and improvement

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 2. (a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge planning.

(B) Infection control.

(C) Medication therapy.

(D) Response to emergencies as defined in 410 IAC 15-1.5-5(b)(3)(L)(i).

(3) All medical and surgical services performed in the hospital with regard to appropriateness of diagnosis and treatments related to a standard of care and anticipated or expected outcomes.

(b) The hospital shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action shall be documented.

(2) The outcome of the action shall be documented as to its effectiveness, continued follow-up, and impact on patient care.

(Indiana State Department of Health; 410 IAC 15-1.4-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 1.5. Required Hospital Services

410 IAC 15-1.5-1 Dietetic services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The hospital shall have organized food and dietary services that are directed and staffed by adequate, qualified personnel, or a contract with an outside food management company that meets the minimum standards specified in this section.

(b) The food and dietetic service shall have the following:

(1) A full-time employee who:

(A) serves as director of the food and dietetic services; and

(B) is responsible for the daily management of the dietary services.

(2) A qualified dietitian, full-time, part-time, or on a consulting basis. If a consultant is used, he or she shall:

(A) submit periodic written reports on the dietary services provided; and

(B) provide the number of on-site dietitian hours commensurate with:

(i) the type of dietary supervision required;

(ii) the bed capacity; and

(iii) the complexity of the patient care services.

(3) Administrative and technical personnel competent in their respective duties.

(c) The dietary service shall do the following:

(1) Provide for liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(2) Correlate and integrate dietary care functions with those of other patient care personnel which include, but are not limited to, the following:

(A) Patient nutritional assessment and intervention.

(B) Recording pertinent information on the patient's chart.

(C) Conferring with and sharing specialized knowledge with other members of the patient care team.

(d) Menus shall meet the needs of the patients as follows:

(1) Therapeutic diets shall be prescribed by the practitioner responsible for the care of the patient.

(2) Nutritional needs shall be met in accordance with recognized dietary standards of practice and in accordance with the orders of the responsible practitioner.

(3) A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing, and food service personnel.

(Indiana State Department of Health; 410 IAC 15-1.5-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001,

2:23 p.m.: 24 IR 4234)

410 IAC 15-1.5-2 Infection control

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) The hospital shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.

(b) There shall be an active, effective, and written hospital-wide infection control program. Included in this program shall be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.

(c) The infection control program shall have a method for identifying and evaluating trends or clusters of nosocomial infections or communicable diseases.

(d) A person qualified by training or experience shall be designated as responsible for the ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases.

(e) The chief executive officer, medical staff, and executive nurse shall do the following:

(1) Be responsible for the implementation of successful corrective action plans in affected problem areas.

(2) Provide for appropriate infection control input into plans for renovation and new construction to ensure awareness of federal, state, and local rules that affect infection control practices as well as plan for appropriate protection of patients and employees during construction or renovation.

(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows:

(1) The infection control committee shall be a hospital or medical staff committee that meets at least quarterly, with membership that includes, but is not limited to, the following:

(A) The person directly responsible for management of the infection surveillance, prevention, and control program.

(B) A representative from the medical staff.

(C) A representative from nursing service.

(D) A representative from administration.

(E) Consultants from other appropriate services within the hospital, as needed.

(2) The chairman should be a person with interest or experience in infection control.

(3) The infection control committee responsibilities shall include, but not be limited to, the following:

(A) Establishing techniques and systems for identifying, reviewing, and reporting infections in the hospital.

(B) Recommending corrective action plans on identified problems, reviewing outcomes, and assuring resolution.

(C) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.

(D) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:

(i) Sanitation.

(ii) Universal precautions, including infectious waste management.

(iii) Cleaning, disinfection, and sterilization.

(iv) Aseptic technique, invasive procedures, and equipment usage.

(v) Reuse of disposables.

(vi) An isolation system.

(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.

(viii) An employee health program to determine the communicable disease history of new personnel as required by state and federal agencies.

(ix) Requirements for personal hygiene and attire appropriate for work settings.

(x) A program of food preparation and storage for all personnel involved in food handling which includes, but is not limited to, the following:

(AA) Storage of employee food in patient refrigerators.

(BB) Medications in nutrition refrigerators.

(CC) Refrigerator and freezer temperature monitoring.

(xi) A program of linen management for personnel involved in linen handling.

(Indiana State Department of Health; 410 IAC 15-1.5-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.5-3 Laboratory services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. (a) The hospital shall have, or make available, those pathology and medical laboratory services and consultation to meet the needs of patients served as determined by the medical staff which include the following:

(1) Emergency laboratory services shall be available twenty-four (24) hours a day as determined by the medical staff.

(2) The laboratory performs tests and examines specimens on the written request of individuals and practitioners allowed to order such evaluations and receive the results of the evaluations to the extent permitted by law and authorized by the governing body.

(3) A written description of available laboratory services, reference values, critical values, and expected turnaround time shall be available to the medical and nursing staff.

(4) Frozen section shall be provided where surgical procedures are performed which require immediate pathological examination.

(b) The hospital shall assure that all laboratory services provided to its inpatients and outpatients are performed in a facility possessing a valid certificate, in accordance with 42 CFR 493 (excluding Subparts F, R, Q, and T) authorizing the performance of testing in the specialty or subspecialty of service for level of complexity in which the test is categorized.

(c) The medical staff and a pathologist shall determine which tissue specimens require a macroscopic examination only and which require both macroscopic and microscopic examinations. Categories of specimens removed during surgical procedures which are determined to require only macroscopic examination shall be specified in the laboratory policies and the medical staff rules. The medical staff and a pathologist shall determine the qualified licensed health professional responsible for macroscopic examination.

(d) Laboratory supervisory and testing personnel qualifications shall be consistent with the work assignments and in compliance with 42 CFR 493.

(e) All nursing and other hospital personnel performing out-of-laboratory testing shall have annually updated performance certification maintained in the employee file for the procedures being performed.

(f) If sufficient or suitable outside facilities are not provided by undertakers or others, the hospital shall have a morgue or a low temperature body holding room. Policies covering appropriate refrigeration requirements and length of holding bodies shall be approved by the medical staff. If autopsies are performed in the hospital, there shall be a refrigerated storage unit designed for holding bodies, along with hand washing facilities and other necessary personal hygiene facilities available.

(g) The hospital shall maintain a minimum supply of blood and blood products or have an agreement with licensed blood sources which are in compliance with state law to obtain blood and blood products as quickly as needed.

(h) If donor blood is drawn in the hospital, the blood center shall be:

(1) in compliance with state law;

(2) appropriately licensed or registered by the Food and Drug Administration (FDA); and

(3) in compliance with 21 CFR 640 and 21 CFR 606.

(Indiana State Department of Health; 410 IAC 15-1.5-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1268; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.5-4 Medical record services

Authority: IC 16-21-1-7
Affected: IC 16-18-2-149

Sec. 4. (a) The medical record service has administrative responsibility for the medical records that shall be maintained for every individual evaluated or treated within those services that come under the hospital's license.

(b) The organization of the medical record service shall be appropriate to the scope and complexity of the services provided as follows:

(1) The service shall be directed by a registered record administrator (RRA) or an accredited record technician (ART). If a full-time or part-time RRA or ART is not employed, then a consultant RRA or ART shall be provided to assist the person in charge. Documentation of the findings and recommendations of the consultant shall be maintained.

(2) The medical record service shall be provided with the necessary direction, staffing, and facilities to perform all required functions in order to ensure prompt completion, filing, and retrieval of records.

(c) An adequate medical record shall be maintained with documentation of service rendered for each individual who is evaluated or treated as follows:

(1) Medical records are documented accurately and in a timely manner, are readily accessible, and permit prompt retrieval of information.

(2) A unit record system of filing should be utilized. When this is not possible, a system shall be established by the hospital to retrieve when necessary all divergently located record components.

(3) The hospital shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry shall be authenticated in accordance with the hospital and medical staff policies.

(4) Medical records shall be retained in their original or legally reproduced form as required by federal and state law.

(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the hospital policies.

(6) The hospital shall have a system of coding and indexing medical records which allows for timely retrieval of records by diagnosis and procedure in order to support continuous quality assessment and improvement activities.

(7) The hospital shall ensure the confidentiality of patient records which includes, but is not limited to, the following:

(A) A procedure for releasing information from or copies of records only to authorized individuals in accordance with federal and state laws.

(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.

(d) The medical record shall contain sufficient information to:

(1) identify the patient;

(2) support the diagnosis;

(3) justify the treatment; and

(4) document accurately the course of treatment and results.

(e) All entries in the medical record shall be:

(1) legible and complete;

(2) made only by individuals given this right as specified in hospital and medical staff policies; and

(3) authenticated and dated promptly, within forty-eight (48) hours in accordance with subsection (c)(3).

(f) All inpatient records, except those in subsection (g), shall document and contain, but not be limited to, the following:

(1) Identification data.

(2) The medical history and physical examination of the patient done within the timeframes as prescribed by the medical staff rules and section 5(b)(3)(M) of this rule.

(3) A statement of the diagnosis or impressions drawn from the admission history and physical examination.

(4) Diagnostic and therapeutic orders.

(5) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.

(6) Clinical observations, including results of therapy, documented in a timely manner.

(7) Progress notes.

(8) Operative note in accordance with 410 IAC 15-1.6-9(c)(7).

(9) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(10) Nursing notes, nursing plan of care, and entries by other health care providers that contain pertinent, meaningful observations and information.

(11) Reports of pathology and clinical laboratory examinations, radiology and nuclear medicine examinations or treatment, anesthesia records, and any other diagnostic or therapeutic procedures and their results.

(12) Documentation of complications and unfavorable reactions to drugs and anesthesia.

(13) A discharge summary authenticated by the physician. A final progress note may be substituted for the discharge summary

in the case of a normal newborn infant and uncomplicated obstetric delivery. The final progress note should include any instruction given to the patient and family.

(14) Final diagnosis.

(g) A short stay record form used for inpatients hospitalized for less than forty-eight (48) hours, observation patients, ambulatory care patients, and ambulatory surgery patients shall document and contain, but not be limited to, the following:

(1) Identification data.

(2) Medical history and description of the patient's condition and pertinent physical findings.

(3) Diagnostic and therapeutic orders.

(4) Care based on identified standard of care and standard of practice.

(5) Data necessary to support the diagnosis and the treatment given, with reports of procedures and tests, and their results, clinical observations, including the results of therapy, and anesthesia given, if applicable.

(6) Operative note in accordance with 410 IAC 15-1.6-9(c)(7), if applicable.

(7) Final progress note, including instructions to the patient and family with dismissal diagnosis and disposition of patient.

(8) Authentication by the physician and other responsible personnel in attendance.

(h) Outpatient records shall document and contain, but not be limited to, the following:

(1) Identification data.

(2) Diagnostic and therapeutic orders.

(3) Description of treatment given, procedures performed, and documentation of patient response to intervention, if applicable.

(4) Results of diagnostic tests and examinations done, if applicable.

(i) Emergency service records shall document and contain, but not be limited to, the following:

(1) Identification data.

(2) Time of arrival, means of arrival, time treatment is initiated, and time examined by the physician, if applicable.

(3) Pertinent history of illness or injury, description of the illness or injury, and examination, including vital signs.

(4) Diagnostic and therapeutic orders.

(5) Description of treatment given or prescribed, clinical observations, including the results of treatment, and the reports of procedures and test results, if applicable.

(6) Authentication by the practitioner or licensed health professional who rendered treatment or prescribed for the patient in accordance with hospital policy.

(7) Instruction given to patient on release, prescribed follow-up care, signature of patient or responsible other, and name of person giving instructions.

(8) Diagnostic impression and condition on discharge documented by the practitioner, and disposition of the patient and time of dismissal.

(9) Copy of transfer form, if patient is referred to the inpatient service of another hospital. If care is not furnished to a patient or if the patient is referred elsewhere, the reasons for such action shall be recorded.

(Indiana State Department of Health; 410 IAC 15-1.5-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1269; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.5-5 Medical staff

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-22.5

Sec. 5. (a) The hospital shall have an organized medical staff that operates under bylaws approved by the governing board and is responsible to the governing board for the quality of medical care provided to patients. The medical staff shall be composed of two (2) or more physicians and other practitioners as appointed by the governing board and do the following:

(1) Conduct outcome oriented performance evaluations of its members at least biennially.

(2) Examine credentials of candidates for appointment and reappointment to the medical staff by using sources in accordance with hospital policy and applicable state and federal law.

(3) Make recommendations to the governing board on the appointment or reappointment of the applicant for a period not to exceed two (2) years.

(4) Maintain a file for each member of the medical staff which includes, but is not limited to, the following:

(A) A completed, signed application.

(B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.

(C) A copy of their current Indiana license showing date of licensure and current number or an available certified list provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the medical licensing board.

(D) A copy of their current Indiana controlled substance registration showing number, as applicable.

(E) A copy of their current Drug Enforcement Agency registration showing number, as applicable.

(F) Documentation of experience in the practice of medicine.

(G) Documentation of specialty board certification, as applicable.

(H) Category of medical staff appointment and delineation of privileges approved.

(I) A signed statement to abide by the rules of the hospital.

(J) Documentation of current health status as established by hospital and medical staff policy and procedure and federal and state requirements.

(K) Other items specified by the hospital and medical staff.

(b) The medical staff shall adopt and enforce bylaws and rules to carry out its responsibilities. These bylaws and rules shall:

(1) be approved by the governing board;

(2) be reviewed at least triennially;

(3) include, but not be limited to, the following:

(A) A description of the medical staff organizational structure. If the organization calls for an executive committee, a majority of the members shall be physicians on the active medical staff.

(B) Meeting requirements of the staff.

(C) A provision for maintaining records of all meetings of the medical staff and its committees.

(D) A procedure for designating an individual physician with current privileges as chief, president, or chairperson of the staff.

(E) A statement of duties and privileges for each category of the medical staff.

(F) A description of the medical staff applicant qualifications.

(G) Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(H) A process for review of applications for staff membership, delineation of privileges in accordance with the competence of each practitioner, and recommendations on appointments to the governing board.

(I) A process for appeals of decisions regarding medical staff membership and privileges.

(J) A process for medical staff performance evaluations based on clinical performances indicated in part by the results of quality assessment and improvement activities.

(K) A process for reporting practitioners who fail to comply with state professional licensing law requirements as found in IC 25-22.5, and for documenting appropriate enforcement actions against practitioners who fail to comply with the hospital and medical staff bylaws and rules.

(L) A provision for physician coverage of emergency care which addresses at least:

(i) a definition of emergency care to include, but not be limited to:

(AA) inpatient emergencies;

(BB) emergency services emergencies; and

(ii) a timely response.

(M) A requirement that a complete physical examination and medical history be performed:

(i) on each patient admitted by a practitioner who has been granted such privileges by the medical staff;

(ii) within seven (7) days prior to date of admission and documented in the record with a durable, legible copy of the report and changes noted in the record on admission; or

(iii) within forty-eight (48) hours after an admission.

(N) A requirement that all physician orders shall be in writing or acceptable computerized form and shall be authenticated within forty-eight (48) hours by the responsible individual.

(O) A requirement that the final diagnosis be documented along with completion of the medical record within thirty (30) days following discharge.

(c) The medical staff should attempt to secure autopsies in all cases of unusual deaths and educational interest. There shall

be the following:

(1) A mechanism for documenting in writing the following:

(A) That permission to perform an autopsy was obtained.

(B) The source of the permission.

(2) A system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed. *(Indiana State Department of Health; 410 IAC 15-1.5-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1271; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.5-6 Nursing service

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1-11

Sec. 6. (a) The hospital shall have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse. The service shall have the following:

(1) An organizational plan which delineates the responsibilities for patient care.

(2) A nurse executive who is:

(A) licensed under IC 25-23-1-11; and

(B) responsible for the following:

(i) The operation of the services, including, but not limited to, determining the types and numbers of nursing personnel and staff necessary to provide care for all patient care areas of the hospital.

(ii) Maintaining a current nursing service organization chart.

(iii) Maintaining current job descriptions with reporting responsibilities for all nursing staff positions.

(iv) Ensuring that all nursing personnel meet annual in-service requirements as established by hospital and medical staff policy and procedure, and federal and state requirements.

(v) Establishing the standards of nursing care and practice in all settings in which nursing care is provided in the hospital.

(b) The nursing service shall have the following:

(1) Adequate numbers of licensed registered nurses, licensed practical nurses, and other ancillary personnel necessary for the provision of appropriate care to all patients, as needed, to include the immediate availability of a registered nurse.

(2) The service shall have a procedure to ensure that hospital nursing personnel, including nurse registry personnel for whom licensure is required, have valid and current licensure.

(3) A registered nurse shall supervise and evaluate the care planned for and provided to each patient.

(4) The nursing staff shall develop and utilize an ongoing individualized plan of care based on standards of care for each patient.

(5) A registered nurse shall assign the care of each patient to nursing personnel in accordance with the patient's need and the specialized qualifications and competence of the nursing staff available.

(6) All nursing personnel shall demonstrate and document competency in fulfilling assigned responsibilities.

(c) Drugs and biologicals shall be prepared for administration and administered as follows:

(1) By, or under the supervision of, a registered nurse or other qualified personnel.

(2) In accordance with current federal and state laws.

(3) In accordance with medical staff rules.

(4) In accordance with the signed written orders of the practitioner or practitioners responsible for the patient's care. When verbal or telephone orders are used, they shall be accepted only by personnel that are authorized to do so by the medical staff rules.

(5) In accordance with currently acceptable standards of practice.

(6) As specified under section 7 of this rule.

(d) Blood transfusions and intravenous medications shall be administered in accordance with state law and approved medical staff policies and procedures. If the blood transfusions and intravenous medications are administered by personnel other than physicians, the personnel shall have special training for these procedures in accordance with subsection (b)(6).

(e) Emergency equipment and emergency drugs shall be available for use on all nursing units. *(Indiana State Department of Health; 410 IAC 15-1.5-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1272; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.5-7 Pharmaceutical services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. (a) The hospital shall have a pharmaceutical service that meets the needs of the patient and complies with requirements set forth by the Indiana board of pharmacy.

(b) The hospital shall have a pharmacy service directed by a pharmacist, as follows:

(1) A full-time, part-time, or consulting pharmacist shall be responsible for developing, supervising, coordinating, and implementing the written policies and procedures to ensure appropriate distribution, control, therapeutic monitoring, and accountability of all drugs used in the hospital.

(2) The pharmacy service shall be administered in accordance with accepted professional standards and federal and state laws.

(3) The pharmacy service shall have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(c) In order to provide patient safety, the director of pharmacy shall develop and implement written policies and procedures for the appropriate selection, control, labeling, storage, use, monitoring, and quality assurance of all drugs and biologicals.

(d) Written policies and procedures shall be developed and implemented that include the following:

(1) Establish a formulary system with specifications for the selection and procurement of all drugs and biologicals at reasonable costs and as approved by the medical staff.

(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following:

(A) Separation of drugs designed for external use from drugs intended for internal use.

(B) Appropriate storage conditions.

(C) Detection and quarantine of outdated or otherwise unusable drugs and biologicals from general inventory pursuant to their return to the manufacturer, distributor, or destruction.

(D) Documentation and accountability for an accurate accounting of controlled substances from the time of receipt in the institution through the administration to the patient or subsequent removal from general stock and reporting of all abuses and losses of controlled substances.

(E) Security of and authorized access to all drug storage areas within the hospital, as approved by the medical staff, when the pharmacist is absent.

(F) Availability of information relating to drug interactions and information on the following:

(i) Drug therapy.
(ii) Side effects.
(iii) Toxicology.
(iv) Dosage.
(v) Indications for use.
(vi) Routes of administration.

(3) Review the use of medications with the standards developed by the medical staff, which include stop orders for scheduled drugs and biologicals not specifically prescribed as to time or number of doses.

(4) Allow for adequate drug therapy monitoring procedures to exist.

(5) Minimize medication errors and document, monitor, evaluate, and report adverse drug reactions and medication errors.

(6) Provide for the maintenance of drug and poison information materials.

(Indiana State Department of Health; 410 IAC 15-1.5-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1272; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.5-8 Physical plant, maintenance, and environmental services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 8. (a) The hospital shall be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for services authorized under the hospital license as follows:

(1) The plant operations and maintenance service, equipment maintenance, and environmental service shall be:

(A) staffed to meet the scope of the services provided; and

(B) under the direction of a person or persons qualified by education, training, or experience.

(2) There shall be a safety officer designated to assume responsibility for the safety program.

(3) The hospital shall provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the state department of fire and building services, including 675 IAC 22, Indiana fire prevention codes, and 675 IAC 13, Indiana building codes.

(b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:

(1) No condition in the facility or on the grounds shall be maintained which may be conducive to the harborage or breeding of insects, rodents, or other vermin.

(2) No condition shall be created or maintained which may result in a hazard to patients, public, or employees.

(3) There shall be emergency power and lighting in accordance with National Fire Protection Association (NFPA) 99.

(4) There shall be a plan for emergency fuel and water supply.

(5) Provision shall be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:

(A) Operation, maintenance, and spare parts manuals shall be available, along with training or instruction of the appropriate personnel, in the maintenance and operation of the fixed and movable equipment.

(B) Operational and maintenance control records shall be established and analyzed periodically. These records shall be readily available on the premises.

(C) Maintenance and repairs shall be carried out in accordance with applicable codes, rules, standards, and requirements of local jurisdictions, the administrative building council, the state fire marshal, and the department.

(c) In new construction, renovations, and additions, the hospital site and facilities, or nonlicensed facilities acquired for the purpose of providing hospital services, shall meet the following:

(1) The 2001 edition of the national "Guideline for Construction and Equipment of Hospital and Medical Facilities" (Guidelines).

(2) All building, fire safety, and handicapped accessibility codes and rules adopted and administered by the state building commissioner shall apply to all facilities covered by this rule and take precedence over any building, fire safety, or handicapped accessibility requirements of the Guidelines.

(3) When renovation or replacement work is done within an existing facility, all new work or addition, or both, shall comply, insofar as practical, with applicable sections of the Guidelines and for certification with appropriate parts of National Fire Protection Association (NFPA) 101.

(4) Proposed sites shall be located away from detrimental nuisances, well drained, and not subject to flooding. A site survey and recommendations shall be obtained from the department prior to site development.

(5) Water supply and sewage disposal services shall be obtained from municipal or community services. Outpatient facilities caring for patients less than twenty-four (24) hours that do not provide surgery, laboratory, or renal dialysis services may be served by approved private on-site septic tank absorption field systems.

(6) Site utility installations for water, sprinkler, sanitary, and storm sewer systems, and wells for potable emergency water supplies shall comply with applicable sections of Bulletin S.E. 13, "On-Site Water Supply and Waste-water Disposal for Public and Commercial Establishments", 1988 edition.

(7) As early in the construction, addition, or renovation project as possible, the functional and operational description shall be submitted to the division. This submission shall consist of, but not be limited to, the following:

(A) Functional program narrative as established in the Guidelines.

(B) Schematics, based upon the functional program, consisting of drawings (as single-line plans), outline specifications, and other documents illustrating the scale and relationship of project components.

(8) Prior to the start of construction, addition, and/or renovation projects, detailed architectural and operational plans for construction shall be submitted to the plan review division of the department of fire and building services and to the division of sanitary engineering of the department, as follows:

(A) Working drawings, project manual, and specifications shall be included.

(B) Prior to submission of final plans and specifications, recognized standards and codes, including infection control standards, shall be reviewed as required in section 2(f)(2) of this rule.

(C) All required approvals shall be obtained from the state building commissioner and final approval from the division

of sanitary engineering of the department prior to issuance of the occupancy letter by the division.

(9) All back flow prevention devices shall be installed as required by 327 IAC 8-10 and the current edition of the Indiana plumbing code. Such devices shall be listed as approved by the department.

(10) Upon receipt of a design release from the state building commissioner and documentation of a completed plan review by the division of sanitary engineering of the department, a licensure application shall be submitted to the division on the form approved and provided by the department.

(11) Documentation from the state building commissioner that the hospital is in compliance with the fire safety rules of the fire prevention and building safety commission shall be furnished to the division with the licensure application.

(12) Plans for constructing, expanding, or remodeling x-ray or gamma ray facilities shall be accompanied by an evaluation of the radiation protection features by a radiation qualified expert as required by 410 IAC 5. After completion of the x-ray or gamma ray installation and prior to use, a radiation safety survey shall be performed by a radiation qualified expert to insure that the facility meets all applicable requirements of 410 IAC 5 and National Council on Radiation Protection and Measurements (NCRP) Reports Number 49 and 102.

(13) Outpatient facilities, rehabilitation facilities, psychiatric facilities, and mobile, transportable, and relocatable units which are included under the hospital license may comply with appropriate sections of the Guidelines. If not, they shall comply with the hospital section of the Guidelines.

(d) The equipment requirements are as follows:

(1) All equipment shall be in good working order and regularly serviced and maintained.

(2) There shall be sufficient equipment and space to assure the safe, effective, and timely provision of the available services to patients, as follows:

(A) All mechanical equipment (pneumatic, electric, or other) shall be on a documented maintenance schedule of appropriate frequency and with the manufacturer's recommended maintenance schedule.

(B) There shall be evidence of preventive maintenance on all equipment.

(C) Appropriate records shall be kept pertaining to equipment maintenance, repairs, and current leakage checks.

(3) Defibrillators shall be discharged at least in accordance with manufacturers recommendations and a discharge log with initialed entries shall be maintained.

(4) Electrical safety shall be practiced in all areas.

(e) The building(s), including fixtures, walls, floors, ceiling, and furnishings throughout, shall be kept clean and orderly in accordance with current standards of practice as follows:

(1) Environmental services shall be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of:

(A) asepsis;

(B) cross-infection; and

(C) safe practice.

(2) Refuse and garbage shall be collected, transported, sorted, and disposed of by methods which will minimize nuisances or hazards.

(f) The safety management program shall include, but not be limited to, the following:

(1) An ongoing hospital-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the safety committee.

(2) A safety committee appointed by the chief executive officer which includes representatives from administration, patient services, and support services.

(3) The safety program which includes, but is not limited to, the following:

(A) Patient safety.

(B) Health care worker safety.

(C) Public and visitor safety.

(D) Hazardous materials and wastes management in accordance with federal and state rules.

(E) A written fire control plan that contains provisions for the following:

(i) Prompt reporting of fires.

(ii) Extinguishing of fires.

(iii) Protection of patients, personnel, and guests.

(iv) Evacuation.

(v) Cooperation with firefighting authorities.

(F) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies.

(G) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.

(Indiana State Department of Health; 410 IAC 15-1.5-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1273; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1135)

410 IAC 15-1.5-9 Radiologic services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 9. (a) The hospital shall have on-site, or available by arrangement, the diagnostic imaging services required by the needs of the patients served and within the scope of the service provided, that are in compliance with federal and state rules, as follows:

(1) If radiation emitting or nonionizing services, either diagnostic or therapeutic, are provided, the applicable requirements of this section apply. The services may include, but not be limited to the following:

(A) Mammography.

(B) Computerized tomography.

(C) Magnetic resonance imaging.

(D) Ultrasound.

(E) Catheterization lab.

(F) Interventional radiology.

(2) If therapeutic or diagnostic nuclear medicine services are provided, they shall comply with the applicable requirements of this section and with 410 IAC 15-1.6-4.

(b) The services that use ionizing radiation shall not compromise the health, safety, and welfare of patients or personnel in accordance with federal and state rules, as follows:

(1) Proper safety precautions shall be maintained against radiation hazards in accordance with the hospital's radiation and safety program as developed by the radiation safety officer. This includes, but is not limited to, the following:

(A) Adequate shielding for patients, personnel, and facilities.

(B) Procedures for monitoring:

(i) skin dosage;

(ii) radionuclide contamination;

(iii) quality control;

(iv) technique charts, where applicable; and

(v) handling of hazardous materials.

(C) Appropriate storage, use, and disposal of radioactive materials.

(2) Equipment shall be inspected, tested, and calibrated at least annually by qualified personnel with appropriate documentation reasonably available.

(3) Hazards and faulty equipment identified shall be promptly corrected in accordance with current standards of practice and applicable federal and state rules to include, but not be limited to, collimation and filtration, and evaluation of equipment performance.

(4) Written preventive maintenance policies and procedures, in accordance with manufacturer's recommendations and hospital policy, shall be maintained and compliance shall be documented.

(c) Procedures and treatments are performed on the written request of individuals and practitioners allowed to order such procedures and treatments and receive the results of the evaluations to the extent permitted by law and authorized by the governing body.

(d) A full-time, part-time, or consulting radiologist or physician qualified by education and experience in the service provided as determined by the medical staff shall do the following:

(1) Supervise the service provided.

(2) Ensure that only personnel use the equipment and administer procedures who:

(A) have been designated as qualified by the medical staff; and

(B) are allowed to do so in accordance with current standards of practice and state rules.

(3) Interpret those tests that are determined by the medical staff to require a radiologist's or appropriately credentialed

physician's specialized knowledge.

(4) Be available for consultation for the quality and necessity of diagnostic imaging, nuclear medicine, and therapeutic procedures, if applicable.

(e) Records shall be maintained as follows:

(1) The radiologist or other practitioner shall authenticate reports of his or her interpretations.

(2) The hospital shall maintain the following for at least five (5) years:

(A) Copies of reports and printouts.

(B) Films, scans, and other image records.

(C) If clauses (A) and (B) are maintained in the medical record, these items shall be maintained in accordance with state and federal law.

(Indiana State Department of Health; 410 IAC 15-1.5-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1275; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.5-10 Utilization review and discharge planning services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 10. (a) The hospital shall have and implement a written plan, approved by the medical staff and governing body, that describes the utilization review program and governs its operation.

(b) The utilization review program shall address appropriate utilization of patient care resources.

(c) Concurrent review shall focus on those diagnoses problems, procedures, or practitioners with identified or suspected utilization-related problems.

(d) The hospital's utilization review program shall be reviewed and evaluated at least annually and be revised, as appropriate, to reflect the findings of the hospital's utilization review activities.

(e) To facilitate discharge as soon as an acute level of care is no longer required, the hospital shall have effective, ongoing discharge planning that:

(1) facilitates the provision of follow-up care;

(2) is initiated in a timely manner as established by written hospital policy;

(3) transfers or refers patients, along with necessary medical information and records, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care. The information shall include, but not be limited to, the following:

(A) medical history;

(B) current medications;

(C) activities status;

(D) nutritional needs;

(E) outpatient service needs;

(F) follow-up care needs; and

(4) utilizes available community and hospital resource to provide appropriate referrals or make available social, psychological, and educational services to meet the needs of the patient.

(f) If required by Medicare, the hospital has a current memorandum of understanding covering binding review that complies with federal peer review rules. *(Indiana State Department of Health; 410 IAC 15-1.5-10; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1276; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 1.6. Optional Hospital Services

410 IAC 15-1.6-1 Anesthesia services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) If the hospital furnishes anesthesia services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and be under the direction of a qualified physician. The

service is responsible for all anesthesia administered in the hospital.

(b) Anesthesia shall only be administered by those privileged by the medical staff who are:

(1) an anesthesiologist;

(2) a qualified physician with appropriate training, experience, and privileges;

(3) a dentist, oral surgeon, or a podiatrist who is qualified to administer anesthesia under state law; or

(4) a certified registered nurse anesthetist (CRNA) who is under the direction of the operating practitioner or of a qualified physician who is immediately available if needed.

(c) Anesthesia services shall be consistent with needs and resources, as follows:

(1) There shall be written policies and procedures on monitored anesthesia care (MAC), general anesthesia, and regional anesthesia which include, but are not limited to, the following:

(A) The delineation of preanesthesia and postanesthesia responsibilities.

(B) The completion, within forty-eight (48) hours prior to surgery, of a preanesthesia evaluation for each patient by an individual(s) qualified to administer anesthesia.

(C) The requirement of an intra-operative anesthesia record on each patient.

(D) The completion, within forty-eight (48) hours after surgery, of a postanesthesia follow-up report on each inpatient by the individual who administered the anesthesia.

(E) The completion of a postanesthetic evaluation for proper anesthesia recovery of each outpatient in accordance with written policies and procedures approved by the medical staff.

(F) The requirement that all postoperative patients shall be discharged from the postanesthetic care unit by the practitioner in subsection (b) responsible for the patient's care in accordance with hospital policy.

(2) There shall be written policies and procedures on local anesthesia.

(3) There shall be intra-operative monitoring in accordance with current acceptable standards of practice.

(4) Anesthesia equipment shall be checked for operational readiness and safety prior to patient administration. Documentation to that effect shall be included in the patient's medical record.

(Indiana State Department of Health; 410 IAC 15-1.6-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1276; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.6-2 Emergency services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) If a hospital provides a community emergency service, the service shall meet the emergency needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and be under the direction of a physician qualified by education or experience.

(b) The emergency service shall have the following:

(1) A scope of service that is clearly defined.

(2) Written policies and procedures governing medical care provided in the emergency service are established by and are a continuing responsibility of the medical staff. The policies shall include, but not be limited to, the following:

(A) Provision for the care of the disturbed patient.

(B) Provision for immediate assessment of all patients presenting for emergency and obstetrical care.

(C) Provision for transfer of patients when care is needed which cannot be provided.

(3) Integration with other hospital services.

(4) Laboratory and x-ray services available at all times.

(5) Adequate qualified medical and nursing personnel available to meet the needs anticipated by the facility in accordance with 410 IAC 15-1.4-1 and 410 IAC 15-1.5-6, which includes, but is not limited to, the following:

(A) A registered nurse on duty and available to patients presenting with an emergency condition, on a twenty-four (24) hours per day, seven (7) day per week basis.

(B) A physician available at all times in accordance with 410 IAC 15-1.4-1(d)(3) and attending to patients with an emergency condition.

(6) A physician on-call roster available in the emergency service department which lists medical specialists in addition to scheduled medical staff.

(7) A patient control register.

(Indiana State Department of Health; 410 IAC 15-1.6-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1277; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.6-3 Nuclear medicine services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. (a) If the hospital provides nuclear medicine services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and comply with applicable requirements of 410 IAC 15-1.5-9.

(b) Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice, and federal and state law, as follows:

(1) In-house preparation of radio-pharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or physician.

(2) There is proper storage and disposal of radioactive material.

(3) If clinical laboratory tests are performed in the nuclear medicine service, the service shall meet the requirements for laboratory services, in this article, with respect to the following:

(A) Management.
(B) Adequacy of facilities.
(C) Proficiency testing.
(D) Quality control.

(c) Equipment and supplies shall:

(1) be appropriate for the types of nuclear medicine services offered;

(2) be maintained in safe operating condition; and

(3) be inspected, tested, and calibrated at least annually by qualified personnel.

(d) The hospital shall maintain the following:

(1) Signed and dated reports of nuclear medicine interpretations, consultation, and procedures in accordance with applicable requirements of 410 IAC 15-1.5-9(e).

(2) Records of the receipt and disposition of radio-pharmaceuticals in accordance with federal and state rules.

(Indiana State Department of Health; 410 IAC 15-1.6-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1277; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.6-4 Outpatient care services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. (a) If the hospital provides outpatient care services, the service shall meet the needs of the patients, within the scope of the service offered, in accordance with acceptable standards of practice. The service shall be under the direction of a qualified person or persons.

(b) Outpatient care services shall be appropriately organized and integrated with inpatient services, as follows:

(1) Assign a qualified registered nurse to supervise the nursing care in outpatient care services.

(2) Have appropriate personnel available.

(3) Ensure a record is maintained in accordance with 410 IAC 15-1.5-4 and hospital policy.

(c) Outpatient care services may include, but are not limited to, the following:

(1) Observation care.

(2) Ambulatory care.

(3) Other care programs designated by the hospital.

(Indiana State Department of Health; 410 IAC 15-1.6-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.6-5 Psychiatric services

Authority: IC 16-21-1-7
Affected: IC 12-22-2-3; IC 16-21-1

Sec. 5. (a) If the hospital provides psychiatric services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice.

(b) The service shall be under the direction of a physician qualified by training or experience.

(c) The service shall be staffed in accordance with hospital policies and with applicable state and federal rules.

(d) If the service provided includes a psychiatric unit exempt from the Medicare prospective payment system, it shall comply with 42 CFR Part 412, Subpart B, section 412.25 and CFR Part 412, Subpart B, section 412.27 for the purposes of licensure.

(e) If the service provided includes a subacute short term stabilization program provided in a group home setting as provided for in IC 12-22-2-3, this article will apply with the exception of 410 IAC 15-1.5-8. *(Indiana State Department of Health; 410 IAC 15-1.6-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.6-6 Rehabilitation services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 6. (a) If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, speech pathology, or other therapy services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice.

(b) The services shall be under the direction of a physician qualified by training or experience and supervised by a qualified person or persons.

(c) Available services shall be provided on the written request of individuals and practitioners allowed by law to order such services and as authorized by the governing body, and furnished in accordance with a written plan of treatment, if appropriate.

(d) The services shall have appropriate personnel available.

(e) If the services provided include an inpatient rehabilitation unit or the hospital itself is exempt from the Medicare prospective payment system, it shall comply with 42 CFR Part 412, Subpart B, section 412.25, 42 CFR Part 412, Subpart B, section 412.29, and 42 CFR Part 412, Subpart B, section 412.30 for purposes of licensure. *(Indiana State Department of Health; 410 IAC 15-1.6-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-1.6-7 Respiratory care services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. (a) If the hospital provides respiratory care services, the service shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.

(b) The service shall be under the direction of a physician who is a pulmonologist or a physician qualified by training or experience, and supervised by a qualified person.

(c) The respiratory care service shall meet the following requirements:

(1) Have certified respiratory care practitioners or other personnel who meet the qualifications specified by the medical staff.

(2) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.

(d) Respiratory care services shall be:

(1) delivered in accordance with medical staff directives;

(2) documented in the medical record; and

(3) provided only on the orders of a physician or appropriately credentialed practitioner.

(e) If blood gases or other clinical laboratory tests are performed by the respiratory care service, 410 IAC 15-1.5-3 applies. *(Indiana State Department of Health; 410 IAC 15-1.6-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; readopted filed Jul 11, 2001,*

2:23 p.m.: 24 IR 4234)

410 IAC 15-1.6-8 Surgical services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 8. (a) If the hospital provides inpatient or ambulatory surgical services, the services shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice and safety.

(b) The organization of the surgical services shall be appropriate, according to the scope of the services offered, as follows:

(1) The surgical service shall be under the direction of a physician qualified by experience and training.

(2) An experienced registered nurse shall supervise all nursing personnel in surgical services and postanesthesia care units (PACU), as follows:

(A) Licensed practical nurses, operating room technicians (ORTs), obstetrical technicians (OB Techs), and surgical technologists may serve as scrub personnel under the supervision of a qualified registered nurse.

(B) Circulating duties in the operating room shall be performed by a qualified registered nurse. Licensed practical nurses and surgical technologists may assist in circulating duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies, in accordance with applicable state law and approved written medical staff policies and procedures.

(c) Surgical services shall have policies governing surgical care designed to assure the achievement and maintenance of standards of medical practice and patient care, as follows:

(1) A mechanism shall be maintained which specifies the delineated surgical privileges of each practitioner.

(2) There shall be a history and physical workup in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note in the chart by the admitting physician, which includes vital signs, allergies, and appropriate data.

(3) A properly executed informed consent form for the operation shall be in the patient's chart before surgery, except in extreme emergencies.

(4) The following equipment shall be available to the operating room suites and PACU:

(A) Cardiac monitor.
(B) Resuscitation equipment.
(C) Defibrillator.
(D) Aspirator.
(E) Oximeter.
(F) Tracheotomy set.

(5) There shall be adequate provision for immediate postoperative care.

(6) The operating room register shall be complete and up-to-date.

(7) An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and authenticated by the surgeon.

(8) A list of tissues excluded from microscopic examination, if applicable, shall be maintained in surgery services.

(9) There shall be no explosive anesthetic agents, flammable, or potentially flammable, liquids or agents stored or used in the surgical services area.

(Indiana State Department of Health; 410 IAC 15-1.6-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1279; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 15-1.6-9 Other services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 9. (a) If the hospital provides other services not covered in specific sections of this article, the service shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.

(b) The services shall be under the direction of a qualified person or persons.

(c) The services shall be staffed in accordance with written hospital policies and comply with the applicable state and federal

rules. *(Indiana State Department of Health; 410 IAC 15-1.6-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1279; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 1.7. Incorporation by Reference

410 IAC 15-1.7-1 Incorporation by reference

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) When used in this article, references to the following publications shall mean the version of that publication listed below. The following publications are hereby incorporated by reference:

(1) Guidelines for Construction and Equipment of Hospital and Medical Facilities (2001 Edition). Copies are available from the American Institute of Architects, 1735 New York Ave. Northwest, Washington, D.C. 20006.

(2) Bulletin S.E. 13, "On-site Water Supply and Waste-water Disposal for Public and Commercial Establishments" (1988 Edition). Copies are available from the Indiana State Department of Health, 1330 West Michigan Street, P.O. Box 1964, Indianapolis, IN 46206-1964.

(3) National Fire Protection Association (NFPA) 99, Health Care Facilities (1993 Edition). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9904.

(4) National Fire Protection Association (NFPA) 101, Life Safety Code Handbook (1985 Edition for Medicare/Medicaid certified nonaccredited hospitals, and the 1991 Edition for Medicare/Medicaid certified hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9904.

(5) National Committee on Radiation Protection (NCRP) Reports, Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to 10 MeV", (September 15, 1976 Edition). Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.

(6) National Committee on Radiation Protection (NCRP) Reports, Number 102, "Medical X-ray, Electron Beam and Gamma Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance and Use)", (June 30, 1989 Edition). Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.

(7) 42 CFR Part 412, Subpart B, section 412.25, 42 CFR Part 412, Subpart B, section 412.27, 42 CFR Part 412, Subpart B, section 412.29, 42 CFR Part 412, Subpart B, section 412.30 (October 1, 1993 Edition).

(8) 42 CFR Part 493 (October 1, 1993 Edition).

(9) 21 CFR Part 606 (April 1, 1994 Edition).

(10) 21 CFR Part 640 (April 1, 1994 Edition).

(b) Federal rules which have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. All incorporated material is available for public review at the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 15-1.7-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1280; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1137)*

Rule 2. Ambulatory Outpatient Surgical Centers, Operation, Building and Equipment (Repealed)

(Repealed by Indiana State Department of Health; filed Dec 1, 1999, 3:44 p.m.: 23 IR 796)

Rule 2.1. Definitions

410 IAC 15-2.1-1 Applicability

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 15-2.1-1; filed*

Dec 1, 1999, 3:44 p.m.: 23 IR 781; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)

410 IAC 15-2.1-2 "Ambulatory outpatient surgical center" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-21-1

Sec. 2. "Ambulatory outpatient surgical center" means a center as defined in IC 16-18-2-14. *(Indiana State Department of Health; 410 IAC 15-2.1-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)*

410 IAC 15-2.1-3 "Authenticate" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. "Authenticate" means the author or responsible individual has reviewed the clinical content of the order and validated an entry in the record by:

(1) a full signature, including first initial, last name, and discipline;
(2) written initials if full signature appears on the same page;
(3) a unique identifier such as a number or computer key; or
(4) a signature stamp.

(Indiana State Department of Health; 410 IAC 15-2.1-3; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)

410 IAC 15-2.1-4 "Center" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. "Center" means an ambulatory outpatient surgical center. *(Indiana State Department of Health; 410 IAC 15-2.1-4; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)*

410 IAC 15-2.1-5 "Commissioner" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 5. "Commissioner" means the state health commissioner or the state health commissioner's designee. *(Indiana State Department of Health; 410 IAC 15-2.1-5; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)*

410 IAC 15-2.1-6 "Council" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-84; IC 16-21-1

Sec. 6. "Council" means the body defined in IC 16-18-2-84(1). *(Indiana State Department of Health; 410 IAC 15-2.1-6; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)*

410 IAC 15-2.1-7 "Dentist" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. "Dentist" means any person holding an unlimited license to practice dentistry in the state of Indiana. *(Indiana State Department of Health; 410 IAC 15-2.1-7; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)*

410 IAC 15-2.1-8 "Department" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 8. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 15-2.1-8; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)*

410 IAC 15-2.1-9 "Division" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 9. "Division" means the division of acute care of the department. *(Indiana State Department of Health; 410 IAC 15-2.1-9; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)*

410 IAC 15-2.1-10 "Governing body" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-149; IC 16-21-1

Sec. 10. "Governing body" means:
(1) board of trustees;
(2) governing board;
(3) board of directors; or
(4) other body responsible for governing a center.
(Indiana State Department of Health; 410 IAC 15-2.1-10; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)

410 IAC 15-2.1-11 "Health care provider" defined

Authority: IC 16-21-1-7
Affected: IC 16-18-2-163; IC 16-21-1

Sec. 11. "Health care provider" means a provider as defined in IC 16-18-2-163. *(Indiana State Department of Health; 410 IAC 15-2.1-11; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781; filed Nov 13, 2000, 11:17 a.m.: 24 IR 990)*

410 IAC 15-2.1-12 "Health care worker" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 12. "Health care worker" means a person who provides services whether as an individual health care provider, volunteer, or student at or employee of a center. *(Indiana State Department of Health; 410 IAC 15-2.1-12; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782)*

410 IAC 15-2.1-13 "Licensed health professional" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1-27.1

Sec. 13. "Licensed health professional" means an individual as defined in IC 25-23-1-27.1. *(Indiana State Department of Health; 410 IAC 15-2.1-13; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782)*

410 IAC 15-2.1-14 "Medical staff" defined

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 14. "Medical staff" means a group that is responsible to the governing board for the following:
(1) The clinical and scientific work of the center.
(2) Advice regarding professional matters and policies.
(3) Review of the professional practices in the center for the purposes of reducing morbidity and mortality and for the improvement of the care of patients in the center, including the following:
(A) The quality and necessity of care provided.
(B) The preventability of complications and deaths occurring in the center.
(Indiana State Department of Health; 410 IAC 15-2.1-14; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782)

410 IAC 15-2.1-15 "Pharmacist" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-26-13

Sec. 15. "Pharmacist" means an individual licensed under IC 25-26-13. *(Indiana State Department of Health; 410 IAC 15-2.1-15; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782)*

410 IAC 15-2.1-16 "Physician" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-22.5-5

Sec. 16. "Physician" means an individual licensed under IC 25-22.5-5. *(Indiana State Department of Health; 410 IAC 15-2.1-16; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782)*

410 IAC 15-2.1-17 "Podiatrist" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 17. "Podiatrist" means any person holding an unlimited license to practice podiatry in the state of Indiana. *(Indiana State Department of Health; 410 IAC 15-2.1-17; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)*

410 IAC 15-2.1-18 "Practitioner" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-1-9-2

Sec. 18. "Practitioner" means an individual as defined in IC 25-1-9-2. *(Indiana State Department of Health; 410 IAC 15-2.1-18; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782)*

410 IAC 15-2.1-19 "Registered nurse" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 25-23-1

Sec. 19. "Registered nurse" means an individual licensed under IC 25-23-1. *(Indiana State Department of Health; 410 IAC 15-2.1-19; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782)*

410 IAC 15-2.1-20 "Supplier" defined
Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 20. "Supplier", for HCFA reimbursement only, means an agency for diagnosis and therapy, such as a laboratory, a clinic, and a physical therapist office, rather than sustained patient care. *(Indiana State Department of Health; 410 IAC 15-2.1-20; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)*

Rule 2.2. Compliance

410 IAC 15-2.2-1 Compliance with rules

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) All centers shall be licensed by the department and shall comply with all applicable federal, state, and local laws and rules.

(b) Components required for licensure as a center are the following:

(1) Governing body.
(2) Quality assessment and improvement.
(3) Infection control program.
(4) Laboratory services.
(5) Medical records, storage, and administration.
(6) Medical staff, anesthesia, and surgical service.
(7) Patient care services.
(8) Pharmaceutical services.
(9) Physical plant, equipment maintenance, and environmental services.
(10) Radiology services.

(c) Optional services, not required for licensure, must comply with all rules for that service.

(d) The center shall develop, implement, and maintain a written plan to address the internal review and reporting of unusual occurrences and disasters. This plan must cover, but not be limited to, the following:

(1) Patient injuries or marked deterioration of patient condition occurring under unanticipated or unexpected circumstances.
(2) Unexplained loss of or theft of a controlled substance.
(3) Deaths occurring within the center.

(Indiana State Department of Health; 410 IAC 15-2.2-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 782)

410 IAC 15-2.2-2 Survey procedures

Authority: IC 16-21-1-7
Affected: IC 16-21-1; IC 16-21-2-6

Sec. 2. (a) The center shall fully cooperate with licensure and complaint investigation inspections conducted by representatives of the department.

(b) The center shall maintain documents, registers, and reports which show ownership and compliance with local, state, and federal laws and regulations and adherence to bylaws and regulations of the facility.

(c) All documents in legally reproducible form must be maintained within the center for the period required by statutes of limitations and must be made available upon request for inspection, including copying by representatives of the department as follows:

(1) Items to include, but not be limited to, the following:
    (A) Documents showing ownership and a certified copy of articles of incorporation (if incorporated).
    (B) Constitution and bylaws of governing body.
    (C) Minutes of meetings of governing body and committees thereof.
    (D) Minutes of meetings of the medical staff and committees thereof.
    (E) All documents pertaining to quality assurance and improvement of patient care and medical care.
    (F) A current roster of members of the medical staff with designated privileges.
    (G) Personnel records.
    (H) Medical records.
    (I) Reports pursuant to IC 16-21-2-6.
(2) A written or electronic register must be kept of all patients treated which provides identification data, treatment rendered, attending surgeon, condition on discharge, transfers to hospital facility, and such other pertinent data deemed needed by the center.

(3) Reports on patient services rendered must be submitted to the department as specified by the commissioner on forms provided by the department.

(d) The center must file an acceptable plan of correction with the division within ten (10) days of receipt of a survey report that documents noncompliance with state rules. *(Indiana State Department of Health; 410 IAC 15-2.2-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 783; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)*

Rule 2.3. Licensure Requirements

410 IAC 15-2.3-1 Issuance of license

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The center shall file an application for licensure on a yearly basis with the division, prior to the expiration of the current license.

(b) A license is not transferable or assignable, and is issued only for the premises named in the application.

(c) If multiple buildings or sites (contracted, rented, or leased) are licensed under a single license, the licensee shall provide for these buildings as a single integrated system as follows:

(1) All buildings or portions of buildings under a single license must be governed by a single governing body and under the administrative control of a single chief executive officer.

(2) All facilities operating under a single license must have a single medical staff.

(d) All changes in ownership, name, and address must be reported in writing to the division. Reapplication must be filed when a change of fifty percent (50%) or greater ownership occurs.

(e) An application for licensure from a newly constructed center shall be obtained from the division and submitted on the form provided, along with the documents required by the application form, after the physical plant plans have been approved under 410 IAC 15-2.5-7 and upon receipt of a design release from the state building commissioner.

(f) Any full or partial replacement of the physical plant of a center, any addition or renovation to the physical plant of a center, or any acquisitions of additional buildings under the current license of an existing ambulatory surgical center shall meet the provisions of 410 IAC 15-2.5-7.

(g) Upon closure of the center, the license shall be returned to the division. *(Indiana State Department of Health; 410 IAC 15-2.3-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 783)*

410 IAC 15-2.3-2 Posting of license

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) The license must be conspicuously posted on the premises.

(b) A copy must be conspicuously posted in an area open to patients and the public on the premises of each separate building of a multiple building system. *(Indiana State Department of Health; 410 IAC 15-2.3-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 783)*

410 IAC 15-2.3-3 Suspension or revocation of license

Authority: IC 16-21-1-7
Affected: IC 4-21.5; IC 16-21-1

Sec. 3. (a) The commissioner may take any of the following actions on any of the grounds listed in subsection (b):

(1) Issue a letter of correction.

(2) Issue a probationary license.

(3) Conduct a resurvey.

(4) Deny renewal of a license.

(5) Revoke a license.

(6) Impose a civil penalty in an amount not to exceed ten thousand dollars ($10,000) per violation.

(b) The commissioner may take action under subsection (a) on any of the following grounds:

(1) Violation of any provision of this rule.
(2) Permitting, aiding, or abetting the commission of any illegal act in an institution.
(3) Conduct or practice found by the council to be detrimental to the welfare of the patients of an institution.
(c) IC 4-21.5 applies to an action under this section.
(d) A licensee or an applicant for a license aggrieved by an action under this rule may request review under IC 4-21.5.
(e) The department shall appoint an appeals panel consisting of three (3) members as follows:
(1) One (1) member of the executive board.
(2) One (1) attorney admitted to the practice of law in Indiana.
(3) One (1) individual with qualifications determined by the department.
(f) An employee of the department may not be a member of the panel.
(g) The panel shall conduct proceedings for review of an order issued by an administrative law judge under this rule. The panel is the ultimate authority under IC 4-21.5. *(Indiana State Department of Health; 410 IAC 15-2.3-3; filed Dec 1, 1999, 3:44 p.m.: 23 IR 784; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)*

410 IAC 15-2.3-4 Complaint investigation

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 4. (a) The division shall investigate all complaints that come under the department's jurisdiction, regardless of the method of communication.
(b) The complaints will be assigned a priority for investigation according to division policy.
(c) The complaint investigation will be unannounced and may evolve into a full survey.
(d) The division shall notify the center of the results of the investigation in writing.
(e) The center will have ten (10) days after notification of a noncompliance to respond in writing with an acceptable plan of correction for noncompliance with state rules noted as a result of the investigation before this information is made available to the public.
(f) Upon recommendation of the division, the survey report will be forwarded to the commissioner for action under section 3 of this rule. *(Indiana State Department of Health; 410 IAC 15-2.3-4; filed Dec 1, 1999, 3:44 p.m.: 23 IR 784; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)*

Rule 2.4. Governing Body

410 IAC 15-2.4-1 Governing body; powers and duties

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The governing body shall function as the supreme authority of the center. The governing body shall assume full legal responsibility for determining, implementing, and monitoring policies governing the center's total operation and for ensuring that these policies are followed so as to provide quality health care in a safe environment. The governing body is legally responsible for the conduct of the center as an institution. The governing body shall do the following:
(1) Ensure that the center:
(A) meets all rules and regulations for licensure and for certification, if applicable; and
(B) makes available to the commissioner or representatives of the department upon request all reports, records, minutes, documentation, information, and files required for licensure.
(2) Adopt bylaws and function accordingly.
(3) Review the bylaws at least triennially.
(4) Maintain a liaison with the medical staff.
(5) Review, at least quarterly, reports of management operations, including, but not limited to, quality assessment and improvement program, patient services provided, results attained, recommendations made, actions taken, and follow-up.
(b) The governing body is responsible for conduct of the medical staff activities related to the center. The governing body shall do the following:

(1) Determine, with the advice and recommendations of the medical staff and in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.
(2) Ensure the following:
(A) The requests of practitioners for appointment or reappointment to practice in the center are acted upon, with the advice and recommendation of the medical staff.
(B) Reappointments are acted upon at least biennially.
(C) Practitioners are granted privileges consistent with their individual training, experience, and other qualifications.
(D) This process occurs within a reasonable period of time, as specified by the medical staff bylaws.
(3) Ensure that the medical staff has approved bylaws and rules, and that the bylaws and rules are reviewed and approved at least triennially by the governing body.
(4) Ensure that the medical staff is accountable and responsible to the governing body for the quality of care provided to patients.
(5) Ensure that criteria for selection for medical staff membership are individual character, competence, education, training, experience, and judgment.
(6) Ensure that the granting of medical staff membership or professional privileges in the center is not solely dependent upon certification, fellowship, or membership in a specialty body or society.
(7) Ensure all patients are admitted to the center only upon the recommendation of a practitioner with admitting privileges for the purpose of performing surgical procedures and services.
(8) Ensure surgical procedures are performed only by a physician, dentist, or podiatrist who is privileged to perform such procedures according to medical staff by laws, regulations, and/or policies and procedures.
(9) Ensure surgical procedures performed are limited to procedures authorized by the governing body and not requiring a stay longer than twenty-four (24) hours.
(c) The governing body is responsible for managing the center. The governing body shall do the following:
(1) Develop criteria, which include, but are not limited to, defining educational and experience requirements for the chief executive officer.
(2) Delineate in writing the responsibility and authority of the chief executive officer.
(3) Require the chief executive officer or a designee to attend meetings of the governing body and its committees and act as its representative at medical staff meetings.
(4) Require that the chief executive officer designate in writing an administrative officer to serve during his or her absence.
(5) Require that the chief executive officer develop and implement policies and programs for the following:
(A) Ensuring the employment of personnel, in accordance with state and federal rules, whose qualifications are commensurate with anticipated job responsibilities.
(B) Ensuring that during the center's operational hours that staffing requirements are met for quality patient care and that employees do not provide services in an adjacent office, clinic, hospital, or other facility at the same time.
(C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.
(D) Ensuring that all health care workers, including contract and agency personnel, for whom a license, registration, or certification is required, maintain current license, registration, or certification and keep documentation of same so that it can be made available upon request.
(E) Maintenance of current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.
(F) Establishing criteria for each manager, including, but not limited to, the following:
(i) Definition of educational requirements.
(ii) Experience requirements.
(iii) Professional certification, licensing, or registration, where appropriate.
(G) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and center policy for all health care workers including contract and agency personnel who provide direct patient care.
(H) A post offer physical examination and employee health monitoring in accordance with the center's infection control program.
(I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.

(J) Establishing a policy and procedure for communication with physicians concerning a patient emergency.

(K) Establishing criteria to determine the delineation of privileges.

(L) Maintaining personnel records for each employee of the center which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin tests or chest x-rays, as applicable.

(M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying in-service in special procedures.

(N) Coordinating, reporting, and complying with authorized local, regional, and state planning groups and other center services suppliers so that effective data collection can be maintained.

(O) Annual implementation of internal and external disaster preparedness plans with documentation of outcome.

(P) Development, implementation, and monitoring of a safety management program to include, but not be limited to, the following:

(i) Periodic equipment inspections.

(ii) Insect, rodent, or other vermin control.

(iii) Instructions for operating and maintaining the building or building portion and equipment.

(iv) Chemical substances use and storage.

(v) Surgical waste and similar material disposal.

(vi) General housekeeping precautions.

(d) The governing body is responsible for assuring that quality patient care is provided. In accordance with center policy, the governing body shall do the following:

(1) Ensure a qualified licensed physician member of the medical staff is responsible for the care and treatment of each patient with respect to any medical problem that is present on admission or that develops during the surgical procedure that does not fall within the scope of practice or the medical staff privileges of the admitting practitioner.

(2) Ensure the following:

(A) The center develops, implements, and maintains written medical staff policies and procedures for emergencies, initial treatment, and transfer.

(B) The center provides immediate lifesaving measures within the scope of service available, to all persons in the center, to include, but not be limited to, the following:

(i) Timely assessment.

(ii) Basic life support.

(iii) Proper transfer mode.

(3) Ensure that the center develops, implements, and maintains policies that cover physician limited practice problems, including, but not limited to, the following:

(A) Impaired physicians.

(B) Criminal history check.

(C) Disciplinary action.

(4) Ensure that there is a center-wide, quality assessment and improvement program that evaluates the provision of patient care and outcome.

(e) The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:

(1) Ensure that a contractor of any service furnishes those services in such a manner as to permit the center to comply with all applicable statutes and rules.

(2) Ensure that the services performed under a contract are provided in a safe and effective manner and are included in the center's quality assessment and improvement program.

(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.

(4) Ensure that the center maintains a written transfer agreement with one (1) or more hospitals for immediate acceptance of patients who develop complications or require postoperative confinement, and that all physicians, dentists, and podiatrists performing surgery in the center maintain admitting privileges at one (1) or more hospitals in the same county or in an Indiana county adjacent to the county in which the center is located.

(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.

(Indiana State Department of Health; 410 IAC 15-2.4-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 784; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; filed Nov 13, 2000, 11:17 a.m.: 24 IR 990; errata filed May 4, 2001, 11:07 a.m.: 24 IR 2710)

410 IAC 15-2.4-2 Quality assessment and improvement

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:

(1) All services, including services furnished by a contractor.

(2) All functions, including, but not limited to, the following:

(A) Discharge and transfer.

(B) Infection control.

(C) Medication errors.

(D) Response to patient emergencies.

(3) All services performed in the center with regard to appropriateness of diagnoses and treatments related to a standard of care and anticipated or expected outcomes.

(b) The center shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows:

(1) The action must be documented.

(2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.

(Indiana State Department of Health; 410 IAC 15-2.4-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 786)

Rule 2.5. Required Ambulatory Outpatient Surgical Center Services

410 IAC 15-2.5-1 Infection control program

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) The center shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.

(b) The center shall maintain a written, active, and effective center-wide infection control program. Included in this program must be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.

(c) The infection control program must identify and evaluate trends or clusters of center generated infections or communicable diseases.

(d) The center shall designate a person qualified by training or experience as responsible for the ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases.

(e) The chief executive officer, medical staff, and nursing manager shall:

(1) be responsible for the implementation of successful corrective action plans in affected problem areas and ensure that infection control policies are followed; and

(2) provide for appropriate infection control input into plans for renovation and new construction to ensure awareness of federal, state, and local rules that affect infection control practices as well as plan for appropriate protection of patients and employees during construction or renovation.

(f) The center shall establish a committee to monitor and guide the infection control program in the center as follows:

(1) The infection control committee shall be a center or medical staff committee, that meets at least quarterly, with membership that includes, but is not limited to, the following:

(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).

(B) A representative from the medical staff.

(C) A representative from the nursing staff.

(D) Consultants from other appropriate services within the center as needed.

(2) The infection control committee responsibilities must include, but are not limited to, the following:

(A) Establishing techniques and systems for identifying, reviewing, and reporting infections in the center.

(B) Recommending corrective action plans, reviewing outcomes, and assuring resolution of identified problems.

(C) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.

(D) Written reports of quarterly meetings.

(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:

(i) Sanitation.

(ii) Universal precautions, including infectious waste management.

(iii) Cleaning, disinfection, and sterilization.

(iv) Aseptic technique, invasive procedures, and equipment usage.

(v) Reuse of disposables.

(vi) A patient isolation system.

(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.

(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.

(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.

(x) A program of linen management.

(g) Sterilization of equipment and supplies must be provided, within the scope of the service offered, in accordance with acceptable standards of practice or manufacturer's recommendations and applicable state laws and rules, 410 IAC 1-4. Sterilization services must be directed by a qualified person or persons and must provide for the following:

(1) Biological indicators must be used to check sterilization processes at least monthly. Chemical sterilizing indicators must be used to check the sterilizing process of individual packs.

(2) Written policies and procedures must be available and followed by personnel responsible for sterilizing equipment and supplies, including, but not limited to, the following:

(A) Minimum time and temperature for processing various size bundles and packs.

(B) Instructions for loading, operating, cleaning, and maintaining sterilizers.

(C) Instructions for cleaning, packaging, storing, labeling, and dispensing of sterile supplies.

(D) Procedure for maintaining and recording the particular sterilizing cycle.

(E) Sterilization of heat labile reusable equipment.

(3) Records of results must be maintained and evaluated periodically in accordance with 410 IAC 15-2.4-2 to include, but not be limited to, the following:

(A) Records of recording thermometers or a daily record of the sterilizing cycle (date, time, temperature, pressure, and contents) for each sterilizer load.

(B) Results of biological indicators used in testing the sterilizing processes.

(h) Environmental surfaces and equipment not requiring sterilization which have been contaminated by blood or other potentially infectious materials shall be cleaned then decontaminated in accordance with acceptable standards of practice and applicable state laws and rules, 410 IAC 1-4.

(i) The center, whether it operates its own laundry or uses outside laundry service, shall ensure that the laundry process complies with a recognized laundry standard as follows:

(1) Clean linen must be separated from soiled linen at all times as follows:

(A) Contaminated linens must be clearly identified and bagged.

(B) Clean linen must be covered during transit, and separate containers or carts must be provided for transporting thereof.

(2) Central clean linen storage space must be provided as follows:

(A) If commercial laundry services are utilized:

(i) a soiled linen collection room must be provided; and

(ii) a hand washing facility is required in each area where unbagged soiled linen is handled.

(B) If laundry is processed in the center:

(i) a laundry processing room must be provided;

(ii) clean linen storage and mending must be separated from soiled linen handling and storage; and

(iii) employee hand washing facilities shall be available in each room where clean or soiled linen is processed and handled.

(Indiana State Department of Health; 410 IAC 15-2.5-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 786; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)

410 IAC 15-2.5-2 Laboratory services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) The center shall provide, or make available, those pathology and medical laboratory services and consultation necessary to meet the needs of patients as determined by the medical staff.

(b) The laboratory performs tests, examines specimens, and reports the evaluation only upon the written request of individuals and practitioners authorized by law and with governing body approval.

(c) A written description of available laboratory services, reference values, critical values, and expected turnaround time shall be available to the patient care staff.

(d) Frozen section shall be provided where surgical procedures are performed which require immediate pathological examination and if performed on site must meet 42 CFR 493 for high complexity pathology testing.

(e) The medical staff and a pathologist shall determine, as specified by medical staff rules and laboratory policy, what tissue specimen examination will be utilized on each specimen as follows:

(1) Microscopic examination only.

(2) Macroscopic examination only.

(3) Both microscopic and macroscopic examinations.

(f) The center shall assure that all laboratory services provided to its patients are performed in a facility possessing a valid certificate, in accordance with 42 CFR 493 (excluding Subparts F, R, Q, and T) authorizing the performance of testing in the specialty or subspecialty of service for level of complexity in which the test is categorized.

(g) Laboratory supervisory and testing personnel qualifications must be consistent with the work assignments and in compliance with 42 CFR 493.

(h) All nursing and other center personnel performing laboratory testing shall have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed.

(i) The center shall maintain a minimum supply of blood and blood products in compliance with state and federal laws or have a written agreement with a licensed blood center or transfusion service that meets all state and federal laws pertaining to collection, storing, testing, and or transfusing.

(j) The center shall develop, implement, and maintain written quality control and quality assurance policies and procedures for complexity of testing performed that are consistent with and include all standards found in 42 CFR 493. *(Indiana State Department of Health; 410 IAC 15-2.5-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 788; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)*

410 IAC 15-2.5-3 Medical records, storage, and administration

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 3. (a) The medical record service has administrative responsibility for the medical records that must be maintained for every patient of the center.

(b) The organization of the medical record service must be appropriate to the scope and complexity of the services provided as follows:

(1) The services must be directed by a registered record administrator (RRA) or an accredited record technician (ART). If a full-time and/or part-time RRA or ART is not employed, then a consultant RRA or ART must be provided to assist the qualified person in charge. Documentation of the findings and recommendations of the consultant must be maintained.

(2) The medical record service must be provided with necessary direction, staffing, and facilities to perform all required

functions in order to ensure prompt completion, filing, and retrieval of records.

(c) An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:

(1) Medical records are documented accurately and in a timely manner, are readily accessible, and permit prompt retrieval of information.

(2) A unit record system of filing should be utilized. When this is not practicable, a system must be established by the center to retrieve, when necessary, all divergently located record components.

(3) The center shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry must be authenticated in accordance with the center and medical staff policies.

(4) Medical records must be retained in their original or legally reproduced form as required by federal or state law.

(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the center policies.

(6) The center shall have a system of coding and indexing medical records which allows for timely retrieval of records by diagnosis and procedure, physician, and condition on discharge, in order to support continuous quality assessment and improvement activities.

(7) The center shall ensure the confidentiality of patient records. The center must develop, implement, and maintain the following:

(A) A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.

(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.

(d) The medical record must contain sufficient information to:

(1) identify the patient;

(2) support the diagnosis;

(3) justify the treatment; and

(4) document accurately the course of the patient's stay in the center and the results.

(e) All entries in the medical record must be as follows:

(1) Legible and complete.

(2) Made only by authorized individuals as specified in center and medical staff policies.

(3) Authenticated and dated in accordance with section 4(b)(3)(N) of this rule.

(f) All patient records must document and contain, at a minimum, the following:

(1) Patient identification.

(2) Appropriate medical history and results of a physical examination completed within the time frames in section 4(b)(3)(M) of this rule.

(3) Preoperative diagnostic studies recorded in the record before surgery, if performed.

(4) Any allergies and abnormal drug reactions.

(5) Entries related to anesthesia administration.

(6) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.

(7) Discharge diagnosis.

(8) Medical history, chief complaint, and physical examination, including copies of laboratory, x-ray consultations, and other special reports or summary of those same findings by the admitting physician.

(9) A written or dictated report describing techniques, findings, and tissue removed or altered.

(10) Signatures of physicians and health care workers who treated or cared for the patient.

(11) Condition on discharge, disposition of the patient, and time of dismissal.

(12) Final progress note, including instructions to the patient and family, with dismissal diagnosis.

(13) A copy of the transfer form, if the patient is referred to a hospital or other facility.

(g) All original medical records or legally reproduced medical records must be maintained by the center for a period of seven (7) years in accordance with subsection (c)(6) and (c)(7), must be readily accessible, in accordance with the center policy, and must be kept in a fire resistive structure. *(Indiana State Department of Health; 410 IAC 15-2.5-3; filed Dec 1, 1999, 3:44 p.m.: 23 IR 788; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)*

410 IAC 15-2.5-4 Medical staff; anesthesia and surgical services

Authority: IC 16-21-1-7
Affected: IC 16-18-2-14; IC 16-21-1; IC 25-22.5

Sec. 4. (a) The medical staff of the center is accountable to the governing body of the center. The medical staff must be organized and operate under bylaws approved by the governing body. The medical staff is responsible to the governing board for the quality of medical care and surgical services provided to patients. The medical staff must be composed of one (1) physician, dentist, or podiatrist. The medical staff shall do the following:

(1) Conduct outcome-oriented performance evaluations of its member at least biennially.

(2) Examine credentials of candidates for appointment and reappointment to the medical staff by using sources in accordance with center policy and applicable state and federal law.

(3) Make recommendations to the governing body on the appointment or reappointment of the applicant for a period not to exceed two (2) years.

(4) Maintain a reasonably accessible hard copy or electronic file for each member of the medical staff, which includes, but is not limited to, the following:

(A) A completed, signed application.

(B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.

(C) A current copy of the individual's credentials as follows:

(i) Indiana license showing date of licensure and number or available data provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the appropriate licensing board.

(ii) Indiana controlled substance registration showing number as applicable.

(iii) Drug Enforcement Agency registration showing number as applicable.

(iv) Documentation of experience in the practice of medicine.

(v) Documentation of specialty board certification as applicable.

(vi) Documentation of privilege to perform surgical procedures in a hospital in accordance with IC 16-18-2-14(3)(C).

(D) Category of medical staff appointment and delineation of privileges approved.

(E) A signed statement to abide by the rules of the center.

(F) Documentation of current health status as established by center and medical staff policy and procedure and federal and state requirements.

(G) Other items specified by the center and medical staff.

(b) The medical staff shall adopt and enforce bylaws and rules to carry out its responsibilities. These bylaws and rules must be as follows:

(1) Be approved by the governing board.

(2) Be reviewed at least triennially.

(3) Include, at a minimum, the following:

(A) A description of the medical staff organization structure. If the organization calls for an executive committee, a majority of the members must be practitioners on the active medical staff.

(B) Meeting requirements of the medical staff to include, at a minimum, the following:

(i) Frequency, at least quarterly.

(ii) Attendance.

(C) A provision for maintaining records of all meetings of the medical staff and its committees.

(D) A procedure for designating an individual practitioner with current privileges as chief, president, or chairperson of the staff.

(E) A statement of duties and privileges for each category of the medical staff.

(F) A description of the medical staff applicant qualifications.

(G) Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(H) A process for review of applications for staff membership, delineation of privileges in accordance with the

competence of each practitioner, and recommendations on appointments to the governing body.

(I) A process for reporting practitioners who fail to comply with state professional licensing law requirements as found in IC 25-22.5, and for documenting enforcement actions against practitioners who fail to comply with the center and medical staff bylaws and rules.

(J) A requirement that each physician's services, dentist's services, and podiatrist's services are to be reviewed and analyzed at specified intervals at regular meetings, including, but not limited to, the following:

(i) Appropriateness of diagnoses and treatments rendered related to a standard of care and anticipated or expected results.

(ii) Performance evaluation based on clinical performance indicated in part by the results or outcome of surgical intervention.

(iii) Scope and frequency of procedures.

(K) A process for appeals of decisions regarding medical staff membership and privileges.

(L) A provision for physician coverage of emergency care which addresses at least the following:

(i) A definition of emergency care.

(ii) A timely response.

(M) A requirement that a medical history and physical examination be performed as follows:

(i) In accordance with medical staff requirements on history and physical examination consistent with the scope and complexity of the procedure to be performed.

(ii) On each patient admitted by a physician, dentist, or podiatrist who has been granted such privileges by the medical staff or by another member of the medical staff.

(iii) Within the time frame specified by the medical staff prior to date of admission and documented in the record with a durable, legible copy of the report and with an update and changes noted in the record on admission in accordance with center policy.

(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.

(O) A provision for personnel authorized to take a verbal order.

(P) A requirement that the final diagnosis be documented along with completion of the medical record within thirty (30) days following discharge.

(Q) A requirement for a center that permits patient care responsibilities by practitioners other than physicians, to have established policies and procedures, approved by the governing body, for overseeing and evaluating the nonphysician practitioners.

(R) A requirement that a physician shall be available to the center during the period any patient is present in the center.

(c) The anesthesia services of the center must meet the needs of the patient, within the scope of the services offered, in accordance with acceptable standards of practice, and must be under the direction of a licensed physician with specialized training or experience in the administration of anesthetics. The anesthesia service is responsible for all anesthesia administered in the center as follows:

(1) The medical staff shall write and implement policies and procedures and the governing body shall approve policies and procedures which include, but are not limited to, the following:

(A) A requirement that a licensed physician with specialized training or experience in the administration of an anesthetic supervise the administration of the anesthetic to a patient and remain present in the facility during the surgical procedure, except when only a local infiltration anesthetic is administered.

(B) The use of the following:

(i) Monitored anesthesia care (MAC).

(ii) General anesthesia.

(iii) Regional anesthesia.

(iv) Local anesthesia.

(v) Topical anesthesia.

(vi) Intravenous anesthesia.

(C) Personnel permitted to administer anesthesia. Anesthesia must only be administered by an individual privileged by the medical staff and who is a:

(i) qualified physician with appropriate training, experience, and privileges;

(ii) practitioner holding a current permit to administer a specific form of anesthesia or otherwise authorized to administer topical, local, regional, or general anesthesia by state law or rule; or

(iii) registered nurse acting under the direction of and in the immediate presence of the operating physician or other physician and who holds a certificate of completion of a course in anesthesia approved by the American Association of Nurse Anesthetists or a course approved by the appropriate licensing board.

(D) Safety rules to be followed.

(E) Safety training required of personnel.

(F) The delineation of preanesthesia, intra-operative, and postanesthesia responsibilities as follows:

(i) The completion, within forty-eight (48) hours before surgery, of a preanesthesia evaluation for each patient by an individual qualified to administer anesthesia for all types of anesthetics other than local and updated according to center policy (when more than forty-eight (48) hours) before surgery.

(ii) The completion by the practitioner administering anesthesia of intra-operative anesthesia monitoring and notations, to include vitals signs, on each patient in accordance with the center policy.

(iii) The completion of a postanesthetic evaluation for proper anesthesia recovery of each patient prior to discharge in accordance with written policies and procedures approved by the medical staff.

(iv) The requirement that all postoperative patients shall be discharged from the postanesthetic care unit by the practitioner described in clause (C) as responsible for the patient's care in accordance with center policy.

(2) A requirement that anesthesia equipment must be checked for operational readiness and safety prior to patient administration. Documentation to that effect shall be included in the patient's medical record.

(3) A requirement that all anesthetic agents, flammable and/or potentially flammable liquids or agents, will be stored or used in the center in accordance with current standards of practice and as required by NFPA.

(d) Surgical services must be organized according to scope of the services offered, to meet the needs of the patient, in accordance with acceptable standards of practice and safety. Requirements for surgical services include the following:

(1) Surgical services are under the direction of a physician, dentist, or podiatrist qualified by experience and training.

(2) Surgical services shall develop, implement, and maintain written policies governing surgical care designed to assure the achievement and maintenance of standards of medical and patient care as follows:

(A) A mechanism must be maintained which specifies the delineated surgical privileges of each practitioner.

(B) A requirement that an appropriate history and physical workup must be in the chart of every patient before surgery. If this has been dictated, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note in the chart by the admitting practitioner which includes, but is not limited to, vital signs, allergies, any significant risk factors, and date written.

(C) A provision for the following equipment and supplies to be available to the surgical and recovery areas:

(i) Emergency call system.

(ii) Oxygen.

(iii) Resuscitation equipment.

(iv) Defibrillator.

(v) Cardiac monitors.

(vi) Tracheostomy set.

(vii) Oximeter.

(viii) Suction equipment.

(ix) Other supplies and equipment specified by the medical staff.

(D) A requirement for adequate provision of immediate postoperative care.

(E) A requirement that the patient register is complete and up to date.

(F) A requirement for an operative report describing techniques, findings, and tissue removed or altered to be written or dictated immediately following surgery and authenticated by the surgeon in accordance with center policy and governing body approval.

(G) A requirement that a list of tissues excluded from microscopic examination, if applicable, be maintained in surgical services.

(Indiana State Department of Health; 410 IAC 15-2.5-4; filed Dec 1, 1999, 3:44 p.m.: 23 IR 789; errata filed Dec 14, 1999, 23 IR 814; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)

410 IAC 15-2.5-5 Patient care services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 5. (a) All patient care services must meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice. Patient care services must be under the direction of a qualified person or persons. Patient care services must require the following:

(1) That the patient care services rendered are reviewed and analyzed at regular meetings of patient care personnel and used as a basis for evaluating the quality of services provided.

(2) That personnel with appropriate training are available at all times to handle possible emergencies involving patients of the center.

(3) That a registered nurse serves as head nurse supervising patient care services personnel.

(4) That all registered nurses and licensed practical nurses must be currently licensed in Indiana.

(5) That an experienced registered nurse supervise all nursing personnel, including, but not limited to, registered nurses, licensed practical nurses, and surgical technologists, in surgical areas and recovery unit(s) as follows:

(A) Licensed practical nurses and surgical technologists may serve as scrub personnel under the supervision of a qualified registered nurse.

(B) Circulating duties in the operating room shall be performed by a qualified registered nurse. Licensed practical nurses and surgical technologists may assist in circulating duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies, in accordance with applicable state law and approved medical staff policies and procedures.

(6) A registered nurse must be in attendance in the postanesthesia recovery room during its operational period when patients are present.

(b) Written patient care policies and procedures shall be available to personnel and shall include, but not be limited to, the following:

(1) Provision that a reliable method of patient identification must be used. Particular attention must be given to identification of infants, young children, and others unable to identify themselves.

(2) A requirement that side rails be provided on recovery carts and kept in the upright position when occupied by sedated patients.

(3) A provision for instruction(s) to be given to the patient, responsible adult, and/or family regarding follow-up care and transportation needed by the patient on discharge.

(4) A provision that facilities, reusable equipment, and supplies shall be thoroughly cleaned and/or sterilized following use according to center policies and procedures.

(5) A provision that all nursing personnel meet annual inservice requirements as established by center and federal and state requirements.

(6) A provision that a registered nurse assigns the care of each patient to patient care personnel in accordance with the patient's need and the specialized qualifications and competence of the patient care personnel available.

(Indiana State Department of Health; 410 IAC 15-2.5-5; filed Dec 1, 1999, 3:44 p.m.: 23 IR 792; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)

410 IAC 15-2.5-6 Pharmaceutical services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 6. The center shall provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services. Pharmaceutical services must have the following:

(1) A designated professional person with prescriptive authority, or a pharmacist, who is responsible for the control of drug stocks in the center.

(2) Records of stock supplies of all scheduled substances, including an accounting for all items purchased and dispensed.

(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not

limited to, the following:

(A) Drug handling, storing, labeling, and dispensing.

(B) Drug administration according to established center policies and acceptable standards of practice.

(C) Intravenous medications administration as it relates to sedation.

(D) Reporting of adverse reactions and medication errors to the practitioner responsible for the patient and the appropriate committee, and documented in the patient's record.

(E) Drugs must be accurately and clearly labeled and stored in specially-designated, well-illuminated cabinets, closets, or storerooms and the following:

(i) Drug cabinets must be accessible only to authorized personnel.

(ii) Drug cabinets for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse must be permanently affixed compartments that are separately locked.

(iii) Drug carts with controlled drugs as designated in item (ii) must be securely affixed when not in use.

(F) Instructions to the patient on the use of take home medication is the responsibility of the prescribing practitioner.

(4) A formulary.

(5) A list of available emergency drugs.

(Indiana State Department of Health; 410 IAC 15-2.5-6; filed Dec 1, 1999, 3:44 p.m.: 23 IR 792; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657)

410 IAC 15-2.5-7 Physical plant, equipment maintenance, and environmental services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 7. (a) The center shall be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for services authorized under the center license as follows:

(1) The plant operations and maintenance service, equipment maintenance, and environmental services must be as follows:

(A) Staffed to meet the scope of the services provided.

(B) Under the direction of a person or persons qualified by education, training, or experience according to center policy, approved by the governing body.

(2) The center shall provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the state department of fire and building services, 675 IAC 22, Indiana fire prevention codes, and 675 IAC 13, Indiana building codes.

(3) There must be emergency power and lighting in accordance with National Fire Protection Association (NFPA) 99.

(4) In new construction, renovations, and additions, the center site and facilities, or nonlicensed facilities acquired for the purpose of providing center services shall meet the following:

(A) The 2001 edition of the national "Guidelines for Design and Construction of Hospital and Health Care Facilities" (Guidelines).

(B) All building, fire safety, and handicapped accessibility codes, and rules adopted and administered by the state building commission shall apply to all facilities covered by this rule and take precedence over any building, fire safety, or handicapped accessibility requirements of the Guidelines.

(C) When renovation or replacement work is done within an existing facility, all new work or additions, or both, shall comply, insofar as practical, with applicable sections of the Guidelines and for certification with appropriate parts of NFPA 101.

(D) Water supply and sewage disposal services shall be obtained from municipal or community services.

(E) As early in the construction, addition, and/or renovation project as possible, the functional and operational description shall be submitted to the division. This submission shall consist of, but not be limited to, the following:

(i) Functional program narrative as established in the Guidelines.

(ii) Schematics, based upon the functional program, consisting of drawings, (as single-line plans), outline specifications, and other documents illustrating the scale and relationship of project components.

(F) Prior to the start of construction, addition, and/or renovation projects, detailed architectural and operational plans for construction shall be submitted to the plan review division of the department of fire and building services and to the

division of sanitary engineering of the department as follows:

(i) Working drawings, project manuals, and specifications shall be included.

(ii) Prior to submission of final plans and specifications, recognized standards and codes, including infection control standards, shall be reviewed as required in section 1(e)(2) of this rule.

(iii) All required approvals shall be obtained from fire and building services and final approval from the division of sanitary engineering of the department prior to issuance of the occupancy letter by the division.

(G) Upon receipt of a plan release from the fire and building commissioner and documentation of a completed plan review by the division of sanitary engineering of the department, a licensure application shall be submitted to the division on the form approved and provided by the department.

(H) Documentation from the state building commissioner that the center is in compliance with the fire safety rules of the fire prevention and building safety commission shall be furnished to the division with the licensure application.

(b) The condition of the physical plant and the overall center environment must be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:

(1) No condition in the center or on the grounds may be maintained which may be conducive to the harboring or breeding of insects, rodents, or other vermin.

(2) No condition may be created or maintained which may result in a hazard to patients, public, or employees.

(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:

(A) Operation, maintenance, and spare parts manuals must be available, along with training and/or instruction of the appropriate center personnel, in the maintenance and operation of fixed and movable equipment.

(B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.

(C) Operational and maintenance control records must be established and analyzed at least triennially. These records must be readily available on the premises.

(D) Maintenance and repairs must be carried out in accordance with applicable codes, rules, standards, and requirements of local jurisdictions, administrative building council, the state fire marshal, and the department.

(4) The patient care equipment requirements are as follows:

(A) There must be sufficient patient care equipment and space to assure the safe, effective, and timely provision of the available services to patients.

(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:

(i) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.

(ii) There must be evidence of preventive maintenance on all patient care equipment.

(iii) Appropriate records must be kept pertaining to equipment maintenance, repairs, and electrical current leakage checks and analyzed at least triennially.

(iv) Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.

(5) The building(s), including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following:

(A) Environmental services must be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:

(i) Asepsis.

(ii) Cross-contamination prevention.

(iii) Safe practice.

(B) Refuse, biohazards, infectious waste, and garbage must be collected, transported, sorted, and disposed of by methods, which will minimize nuisances or hazards according to federal, state, and local laws and rules.

(c) A safety management program must include, but not be limited to, the following:

(1) A review of safety functions by a committee appointed by the chief executive officer which includes representatives from administration and patient care services.

(2) An ongoing center-wide process to evaluate and collect information about hazards and safety practices to be reviewed by

the committee.

(3) The safety program includes, but is not limited to, the following:

(A) Patient safety.

(B) Health care worker safety.

(C) Public and visitor safety.

(4) A written fire control plan that contains provisions for the following:

(A) Prompt reporting of fires.

(B) Extinguishing of fires.

(C) Protection of patients, personnel, and guests.

(D) Evacuation.

(E) Cooperation with firefighting authorities.

(F) Fire drills.

(5) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies in accordance with center policy and state and local regulations.

(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.

(Indiana State Department of Health; 410 IAC 15-2.5-7; filed Dec 1, 1999, 3:44 p.m.: 23 IR 793; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1657; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1133)

410 IAC 15-2.5-8 Radiology services

Authority: IC 16-21-1-7

Affected: IC 16-21-1

Sec. 8. (a) The center shall provide or make available diagnostic radiology services and reports required in connection with any surgery to be performed, necessary to meet the needs of the patients, as determined by the medical staff.

(b) Radiology services solely under arrangement must meet the needs of the patient and meet all state and federal requirements. If all radiology services are under arrangement, the remainder of this section does not apply.

(c) All centers shall comply with all regulations set forth in this rule and with 410 IAC 5, when radiology services are provided on-site by the center, including, but not limited to, the following:

(1) Radiology services must be supervised by a radiologist or radiation oncologist.

(2) All radiation therapy treatments, including all aspects of radium treatments, must be under the direct supervision of a radiation oncologist.

(3) If therapeutic or diagnostic nuclear medicine services are provided, they must comply with the applicable requirements of this section and with 410 IAC 15-1.6-3.

(4) All diagnostic radiographic procedures must be conducted by an individual meeting the requirements of 410 IAC 5-11.

(d) Written policies and procedures must be developed, implemented, and maintained and made available to personnel.

(e) Safeguards for patients, personnel, and public must be specified, including, but not limited to, the following:

(1) Proper safety precautions must be maintained against radiation hazards in accordance with the center's radiation and safety program(s).

(2) Hazards and faulty equipment identified must be promptly corrected in accordance with current standards of practice and applicable federal and state rules, including, but not limited to, collimation and filtration and evaluations of equipment performance.

(f) Procedures and treatments are performed on the written request of individuals and practitioners allowed to order such procedures and treatments and receive the results of the evaluations to the extent permitted by law as authorized by the governing body.

(g) All radiologic equipment must be registered and inspected prior to use and then periodically, according to 410 IAC 5 and all other applicable state and federal statutes and rules.

(h) All radioactive materials must be registered and/or licensed under all applicable state and federal statutes and rules.

(i) The use of fluoroscopes must be limited to physicians or others authorized to operate in accordance with 410 IAC 5.

(j) Records of the results of all radiological procedures must be kept on file and recorded on the patient's chart. The center shall maintain the following for at least five (5) years:

(1) Copies of reports and printouts.

(2) Films, scans, and other image records.

(3) If subdivisions (1) and (2) are maintained in the medical record, these items shall be maintained in accordance with state and federal law.

(Indiana State Department of Health; 410 IAC 15-2.5-8; filed Dec 1, 1999, 3:44 p.m.: 23 IR 794; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1658)

Rule 2.6. Optional Ambulatory Surgical Center Services

410 IAC 15-2.6-1 Dietary services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) If nourishment and other dietary needs of the patients are provided in the center, the center shall comply with 410 IAC 7-20.

(b) If nourishments are to be prepared, a nourishment area with hand washing lavatory and refrigeration must be provided.

(c) If prepackaged single service nourishments are provided, refrigeration storage must be provided in the clean area. *(Indiana State Department of Health; 410 IAC 15-2.6-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 795; filed Nov 13, 2000, 11:17 a.m.: 24 IR 992)*

410 IAC 15-2.6-2 Other services

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 2. (a) If the center provides other services not covered in specific sections of 410 IAC 15-2.1 through 410 IAC 15-2.5, this rule, and 410 IAC 15-2.7, the services must meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.

(b) The services shall be under the direction of a qualified person or persons.

(c) The services shall be staffed in accordance with written center policies and comply with the applicable state and federal rules. *(Indiana State Department of Health; 410 IAC 15-2.6-2; filed Dec 1, 1999, 3:44 p.m.: 23 IR 795)*

Rule 2.7. Incorporation by Reference

410 IAC 15-2.7-1 Incorporation by reference

Authority: IC 16-21-1-7
Affected: IC 16-21-1

Sec. 1. (a) When used in this article, references to the following publications shall mean the version of that publication listed and are hereby incorporated by reference:

(1) Guidelines for Design and Construction of Hospital and Health Care Facilities (2001 Edition). Copies are available from the American Institute of Architects, 1735 New York Avenue Northwest, Washington, D.C. 20006. Local purchase may be made from the Architectural Center Bookstore, 47 South Pennsylvania Avenue, Indianapolis, Indiana 46204.

(2) National Fire Protection Association (NFPA) 99, Health Care Facilities (1993 Edition). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P. O. Box 1901, Quincy, Massachusetts 02260-9904.

(3) National Fire Protection Association (NFPA) 101, Life Safety Code Handbook (1985 Edition for Medicare/Medicaid certified nonaccredited hospitals, and the 1991 Edition for Medicare/Medicaid certified hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P. O. Box 1901, Quincy, Massachusetts 02269-9904.

(4) National Committee on Radiation Protection (NCRP) Reports, Number 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to 10 MeV: (September 15, 1976, Edition). Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.

(5) National Committee on Radiation Protection (NRCP) Reports, Number 102, "Medical X-ray, Electron Beam and Gamma

Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance and Use)", June 30, 1989, Edition). Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.

(6) 42 CFR 493 (Effective October 1, 1993, Edition).

(7) 21 CFR 606 (April 1, 1994, Edition).

(8) 21 CFR 640 (April 1, 1994, Edition).

(b) Federal rules which have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. All incorporated material is available for public review at the department. *(Indiana State Department of Health; 410 IAC 15-2.7-1; filed Dec 1, 1999, 3:44 p.m.: 23 IR 795; errata filed Feb 15, 2000, 8:05 a.m.: 23 IR 1658; filed Nov 13, 2000, 11:17 a.m.: 24 IR 992; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1134)*

Rule 3. Hospital Financial Disclosure

410 IAC 15-3-1 Definitions

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 1. As used in 410 IAC 15-3: "Ancillary service charges" means the difference between total service charges per stay and the daily service charges.

"Average patient length of stay by patient diagnosis" means the arithmetic mean of the total of all patient lengths of stay for a given patient diagnosis for each major payor category reported in days.

"Daily service charge" means the charge billed to a patient for a day of stay in a facility without any ancillary services provided.

"Discharges by patient diagnosis" means the count of discharges from a given fiscal period for each patient diagnosis/major payor category combination, where the primary payor has been used to determine assignment of each discharge to the appropriate major payor category.

"Major payor category" means categories of payors for Medicare, Medicaid, and all other payors (including, but not limited to, commercial insurance, Blue Cross, CHAMPUS, self-insured groups, HMOs and other prepaid groups, other government programs, individuals, and all others).

"Patient diagnosis" means the principal diagnosis recorded for billing purposes at the discharge of a patient.

"Preoperative preparation time by surgical procedure" means the average length of time in days between admit date and date of the first surgical procedure performed on the patient as counted based on the hospital's policy for daily charge purposes.

"Primary payor" means the first category of major payor categories which receives the bill for a patient stay.

"Surgical procedure" means a procedure reported as surgery for the purposes of billing. *(Indiana State Department of Health; 410 IAC 15-3-1; filed Jan 31, 1985, 3:30 pm: 8 IR 592; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-3-2 Fiscal reports; filing

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 2. (a) Each facility shall report the financial data required under IC 16-10-5-2(a) *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* by submitting a copy of audited financial statements and financial reports prepared for the hospital. Facilities audited by the Indiana state board of accounts may file a copy of that report as a means of satisfying this requirement.

(b) Each facility shall report the patient utilization data required under IC 16-10-5-2(a) *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* using the diagnosis reported for billing purposes. These should be reported on the Hospital Financial Disclosure Report Forms contained in 410 IAC 15-3-6 or individual billing forms if approved by the board. *(Indiana State Department of Health; 410 IAC 15-3-2; filed Jan 31, 1985, 3:30 pm: 8 IR 592; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-3-3 Fiscal reports; extension of time for filing

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 3. (a) Each facility requesting an extension of time for filing the reports required under IC 16-10-5-2 *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* beyond the 120 days after the end of the facility's fiscal year must make such request in writing to the board prior to the deadline for submitting the reports.

(b) The board shall act upon a request for an extension of time in which the report must be filed within 30 days of receiving the written request by the facility. Failure to act within the required period shall be deemed as a grant of the extension. *(Indiana State Department of Health; 410 IAC 15-3-3; filed Jan 31, 1985, 3:30 pm: 8 IR 592; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-3-4 Fiscal reports; additional information to be supplied

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 4. (a) The board shall notify, in writing, a facility of the need to submit further fiscal information as necessary to verify the accuracy of any information contained in the reports filed under these rules *[410 IAC 15-3]* by each facility.

(b) The board shall specify the period of time the facility has to supply the additional information. An extension of this time may be granted by the board upon written request by the facility. *(Indiana State Department of Health; 410 IAC 15-3-4; filed Jan 31, 1985, 3:30 pm: 8 IR 593; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-3-5 Commissioner's findings and recommendations

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 5. Each year, the state health commissioner or his designee shall make a compilation of the data obtained in these reports and report his findings and recommendations regarding changes in the financial status and patient utilization of facilities. *(Indiana State Department of Health; 410 IAC 15-3-5; filed Jan 31, 1985, 3:30 pm: 8 IR 593; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 15-3-6 Hospital financial disclosure report forms

Authority: IC 16-21-6-9
Affected: IC 16-21-6

Sec. 6.

INDIANA HOSPITAL FINANCIAL DISCLOSURE REPORT FORM A

Hospital _____ Fiscal Year Start _____ End _____ Payor Category _____

Net Patient Revenue _____ Total Inpatient Days _____

Patient Days for Patients Aged: 0-14 _____; 15-64 _____; 65 and Over _____

	Patients Ages 0-14				Patients Ages 15-64				Patients Age 65 and Over			
Diagnosis (xxx.x)	Number of Discharges	ALOS	Average Daily Charge	Average Ancillary Charge	Number of Discharges	ALOS	Average Daily Charge	Average Ancillary Charge	Number of Discharges	ALOS	Average Daily Charge	Average Ancillary Charge
Total Discharges by Age Group												

INDIANA HOSPITAL FINANCIAL DISCLOSURE REPORT FORM B

Hospital _____ Fiscal Year Start _____ End _____ Payor Category _____

	Patients Ages 0-14			Patients Ages 15-64			Patients Age 65 and Over		
Diagnosis (xxx.x)	Surgical Procedure (xx.xx)	Number of Procedures	Pre-Operative Preparation Time	Surgical Procedure (xx.xx)	Number of Procedures	Pre-Operative Preparation Time	Surgical Procedure (xx.xx)	Number of Procedures	Pre-Operative Preparation Time
Total Procedures by Age Group									

(Indiana State Department of Health; 410 IAC 15-3-6; filed Jan 31, 1985, 3:30 pm: 8 IR 593; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

ARTICLE 16. HEALTH FACILITIES COUNCIL (REPEALED)

(Repealed by Indiana State Department of Health; filed Jun 16, 1981, 2:55 pm: 4 IR 1476, eff one hundred eighty (180) days after filing with secretary of state)

ARTICLE 16.1. LICENSING AND OPERATIONAL STANDARDS FOR HEALTH FACILITIES (REPEALED)

(Repealed by Indiana State Department of Health; filed May 2, 1984, 2:50 pm: 7 IR 1502)

ARTICLE 16.2. HEALTH FACILITIES; LICENSING AND OPERATIONAL STANDARDS

Rule 0.5. Preamble

410 IAC 16.2-0.5-1 Preamble

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 1. (a) This article is intended for:
(1) the operation of health facilities in Indiana in meeting the long term care needs of residents;
(2) state surveyors in determining compliance with this article for the purpose of licensure; and
(3) the state survey agency in the application of remedies.
(b) This article includes provisions dealing with the following:
(1) Residents' rights.
(2) The administration and management of health facilities.
(3) Sanitation and safety standards.
(4) Assessment of residents' needs.
(5) Medical and nursing services.
(6) Food and nutrition services.
(7) Infection control.
(8) Activities and social services programs.
(9) Clinical records.
(c) This article was developed in the spirit of focusing on potential and actual outcomes of care. This article is intended to focus on achieving the best practicable health and happiness of residents, and preventing systemic, adverse events.
(d) The department recognizes that creative and innovative methods not contemplated by this article can be developed by health facilities in caring for residents. This article is not intended to stifle or discourage such creative and innovative methods of caregiving when it can be shown that residents' needs are being met. *(Indiana State Department of Health; 410 IAC 16.2-0.5-1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1518, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 1. Definitions

410 IAC 16.2-1-0.5 Applicability

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 0.5. The definitions in this rule apply throughout this article, except as noted. *(Indiana State Department of Health; 410 IAC 16.2-1-0.5; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1518, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-1 Abuse defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 1. "Abuse" means any physical or mental injury or sexual assault inflicted on a resident in the facility, other than by accidental means. *(Indiana State Department of Health; 410 IAC 16.2-1-1; filed May 2, 1984, 2:50 pm: 7 IR 1451; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-2 Activities of daily living defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 2. "Activities of daily living" includes, but is not limited to, bodily hygiene, eating, elimination, dressing, and ambulation. *(Indiana State Department of Health; 410 IAC 16.2-1-2; filed May 2, 1984, 2:50 pm: 7 IR 1451; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-2.1 "Administrator" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 25-19-1

Sec. 2.1. "Administrator" means a person holding a valid license under IC 25-19-1. *(Indiana State Department of Health; 410 IAC 16.2-1-2.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1518, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-2.2 "Ambulation" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 2.2. "Ambulation" means walking, once in a standing position. *(Indiana State Department of Health; 410 IAC 16.2-1-2.2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1518, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-3 Assessment defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 3. "Assessment" means the identification of an individual's present level of strengths, abilities and needs; and the conditions that impede the individual's development or functioning. *(Indiana State Department of Health; 410 IAC 16.2-1-3; filed May 2, 1984, 2:50 pm: 7 IR 1451; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-3.5 "Bathing" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 3.5. "Bathing" means washing and drying the body (excluding the back and shampooing the hair), including:
(1) full-body bath;
(2) sponge bath;
(3) preparatory activities; and
(4) transferring into and out of the tub and shower.
(Indiana State Department of Health; 410 IAC 16.2-1-3.5; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1518, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-4 Board defined (Repealed)

Sec. 4. *(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)*

410 IAC 16.2-1-5 "Certification" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 5. "Certification" means that the federal Department of Health and Human Services has determined a facility to be in compliance with applicable statutory or regulatory requirements and standards for the purposes of participation as a provider of care and service for Title XVIII or XIX, or both, of the federal Social Security Act. *(Indiana State Department of Health; 410 IAC 16.2-1-5; filed May 2, 1984, 2:50 p.m.: 7 IR 1451; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1519, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-6 "Children" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 6. "Children" means individuals who:
(1) are less than eighteen (18) years of age and not legally emancipated; or
(2) if older:
(A) require by the reason of physical or mental handicap, care of the type usually accepted as pediatric; or
(B) are suffering from a handicap or ailment which, in the judgment of the attending physician, indicates that the child care facility is more appropriate to their needs than an adult care facility.

(Indiana State Department of Health; 410 IAC 16.2-1-6; filed May 2, 1984, 2:50 p.m.: 7 IR 1452; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1519, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-6.5 "Comfortable and safe temperature levels" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 6.5. "Comfortable and safe temperature levels" means that the ambient temperature should be in a relatively narrow range, seventy-one degrees Fahrenheit (71°F) to eighty-one degrees Fahrenheit (81°F), that minimizes residents' susceptibility to the loss of body heat and risk of hypothermia or susceptibility to respiratory ailments and colds. *(Indiana State Department of Health; 410 IAC 16.2-1-6.5; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1519, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-7 "Communicable disease" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 7. "Communicable disease" means communicable disease as defined in 410 IAC 1-2.1-1(c). *(Indiana State Department of Health; 410 IAC 16.2-1-7; filed May 2, 1984, 2:50 p.m.: 7 IR 1452; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1519, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-8 "Comprehensive care facility" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 8. "Comprehensive care facility" means a health facility that provides nursing care, room, food, laundry, administration of medications, special diets, and treatments, and that may provide rehabilitative and restorative therapies under the order of an attending physician. *(Indiana State Department of Health; 410 IAC 16.2-1-8; filed May 2, 1984, 2:50 p.m.: 7 IR 1452; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1519, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-9 "Construction type" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 9. "Construction type" means the type of construction as established by the rules of the fire prevention and building safety commission (675 IAC). *(Indiana State Department of Health; 410 IAC 16.2-1-9; filed May 2, 1984, 2:50 p.m.: 7 IR 1452; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1519, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-10 Council defined (Repealed)

Sec. 10. *(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)*

410 IAC 16.2-1-10.1 "Convenience" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 10.1. "Convenience" means any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest. *(Indiana State Department of Health; 410 IAC 16.2-1-10.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1520, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-10.2 "Department" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 10.2. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 16.2-1-10.2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1520, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-11 "Developmentally disabled" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 11. "Developmentally disabled" means a personal disability which:

(1) is attributable to:

(A) mental retardation, cerebral palsy, epilepsy, or autism;

(B) any other condition found to be closely related to mental retardation because this condition results in similar impairment of general intellectual functioning or adaptive behavior, or requires similar treatment and services; or

(C) dyslexia resulting from a disability described in this subsection;

(2) originates before the person is eighteen (18) years of age; and

(3) has continued or is expected to continue indefinitely and constitutes a substantial handicap to the person's ability to function normally in society.

(Indiana State Department of Health; 410 IAC 16.2-1-11; filed May 2, 1984, 2:50 p.m.: 7 IR 1452; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1520, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-12 Dietitian defined (Repealed)

Sec. 12. *(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)*

410 IAC 16.2-1-12.5 "Discipline" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 12.5. "Discipline" means any action taken by the facility for the express purpose of punishing or penalizing residents. *(Indiana State Department of Health; 410 IAC 16.2-1-12.5; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1520, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-13 Distinct part defined (Repealed)

Sec. 13. *(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)*

410 IAC 16.2-1-14 "Division" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 14. "Division" means the part of the Indiana state department of health responsible for survey, licensure, and enforcement of health facilities. *(Indiana State Department of Health; 410 IAC 16.2-1-14; filed May 2, 1984, 2:50 p.m.: 7 IR 1453; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1520, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-14.1 "Dressing" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 14.1. "Dressing" means selecting, obtaining, putting on, fastening, and taking off all items of clothing, including donning or removing braces and artificial limbs. *(Indiana State Department of Health; 410 IAC 16.2-1-14.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1520, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-14.2 "Eating" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 14.2. "Eating" means how a resident ingests and drinks, regardless of self-feeding skills. *(Indiana State Department of Health; 410 IAC 16.2-1-14.2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1520, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-15 "Emergency" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 15. "Emergency" means a situation or physical condition that presents imminent danger of death or serious physical or mental harm to one (1) or more residents of a facility. *(Indiana State Department of Health; 410 IAC 16.2-1-15; filed May 2, 1984, 2:50 p.m.: 7 IR 1453; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1520, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-15.1 "Exercising rights" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 15.1. "Exercising rights" means that the residents have autonomy and choice, to the maximum extent possible, about how they wish to live their everyday lives and receive care, subject to the facility's rules, as long as those rules do not violate a regulatory requirement. *(Indiana State Department of Health; 410 IAC 16.2-1-15.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1521, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-15.2 "Functional furniture appropriate to resident's needs" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 15.2. "Functional furniture appropriate to resident's needs" means, at a minimum, the following:
(1) A structurally sound dresser or chest of drawers (may be built in).
(2) A night table.
(3) Seating.

(Indiana State Department of Health; 410 IAC 16.2-1-15.2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1521, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-15.3 "Grooming" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 15.3. "Grooming" means maintaining personal hygiene, including the following:
(1) Preparatory activities.
(2) Combing hair.
(3) Washing and drying face, hands, and perineum.
(4) Brushing teeth.
(5) If applicable, shaving or applying makeup.

(Indiana State Department of Health; 410 IAC 16.2-1-15.3; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1521, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-16 "Habilitation" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 16. "Habilitation" means programs and activities designed to help a resident develop and maintain a level of independence and self-sufficiency consistent with individual capabilities and performance levels. *(Indiana State Department of Health; 410 IAC 16.2-1-16; filed May 2, 1984, 2:50 pm: 7 IR 1453; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-17 "Health care facilities for children" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 17. "Health care facilities for children" means those facilities which provide nursing care, habilitative and rehabilitative procedures, room, food, and laundry for children who, because of handicaps, require such care. *(Indiana State Department of Health; 410 IAC 16.2-1-17; filed May 2, 1984, 2:50 pm: 7 IR 1453; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-18 "Health facility license" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-2

Sec. 18. "Health facility license" means any instrument issued pursuant to IC 16-28-2 by the Indiana state department of health to any person or persons demonstrating compliance with the laws and rules governing such issuance. *(Indiana State Department of Health; 410 IAC 16.2-1-18; filed May 2, 1984, 2:50 p.m.: 7 IR 1453; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1521, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-18.1 "Highest practicable" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 18.1. "Highest practicable" means the highest level of functioning and well-being possible, limited by the individual's present functional status, and potential for improvement or reduced rate of functional decline. *(Indiana State Department of Health; 410 IAC 16.2-1-18.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1521, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-18.2 "Infectious" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 18.2. "Infectious" means capable of spreading infection. *(Indiana State Department of Health; 410 IAC 16.2-1-18.2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1521, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-19 "Intermediate care facility for the mentally retarded" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 19. "Intermediate care facility for the mentally retarded (or persons with related conditions)" means a health facility that provides active treatment for each developmentally disabled resident. In addition, the facility provides nursing care, room, food, laundry, administration of medications, modified diets, and treatments. A facility is only for developmentally disabled residents, and the facility shall be designed to enhance the development of these individuals, to maximize achievement through an interdisciplinary approach based on development principles, and to create the least restrictive environment. *(Indiana State Department of Health; 410 IAC 16.2-1-19; filed May 2, 1984, 2:50 p.m.: 7 IR 1453; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1521, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-19.1 "Legal representative" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 16-36-1-5

Sec. 19.1. "Legal representative" means a person who is:
(1) a guardian;
(2) a health care representative;
(3) an attorney in fact; or
(4) a person authorized by IC 16-36-1-5 to give health care consent.
(Indiana State Department of Health; 410 IAC 16.2-1-19.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1522, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-20 "Licensed practical nurse" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 25-23-1-12

Sec. 20. "Licensed practical nurse (LPN)" means an individual as defined in IC 25-23-1-12. *(Indiana State Department of Health; 410 IAC 16.2-1-20; filed May 2, 1984, 2:50 p.m.: 7 IR 1453; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1522, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-21 "Licensee" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-2

Sec. 21. "Licensee" means the individual, partnership, corporation, association, company, and legal successor thereof who holds a valid license issued pursuant to IC 16-28-2. *(Indiana State Department of Health; 410 IAC 16.2-1-21; filed May 2, 1984, 2:50 p.m.: 7 IR 1453; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1522, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-22 "Medical records practitioner" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 22. "Medical records practitioner" means a person who is certified as or is eligible for certification as a registered record administrator (RRA) or an accredited record technician (ART) by the American Health Information Management Association under its requirements. *(Indiana State Department of Health; 410 IAC 16.2-1-22; filed May 2, 1984, 2:50 p.m.: 7 IR 1453; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1522, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-22.1 "Medication error" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 22.1. "Medication error" means a discrepancy between what the physician ordered and what was or was not administered. *(Indiana State Department of Health; 410 IAC 16.2-1-22.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1522, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-22.2 "Misappropriation of property" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 22.2. "Misappropriation of property" means the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent. *(Indiana State Department of Health; 410 IAC 16.2-1-22.2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1522, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-23 "Mobile" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 23. "Mobile" means able to move from place to place by ambulation or with the assistance of a wheelchair or other device. *(Indiana State Department of Health; 410 IAC 16.2-1-23; filed May 2, 1984, 2:50 p.m.: 7 IR 1454; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1522, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-24 "Modified diet" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 24. "Modified diet" means an adjustment of the regular diet which alters the calorie value, nutritive content, or consistency of the food. *(Indiana State Department of Health; 410 IAC 16.2-1-24; filed May 2, 1984, 2:50 pm: 7 IR 1454; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-25 "Neglect" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 25. "Neglect" means:

(1) an act or omission which places a resident in a situation that may endanger the resident's life or health;
(2) abandoning or cruelly confining the resident;
(3) depriving the resident of necessary support, including food, clothing, shelter, and medical care; or
(4) depriving the resident of education as required by statute.

(Indiana State Department of Health; 410 IAC 16.2-1-25; filed May 2, 1984, 2:50 p.m.: 7 IR 1454; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1523, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-26 "Nurse aide" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 26. "Nurse aide" means an individual as defined in 42 CFR 483.75(e)(1). *(Indiana State Department of Health; 410 IAC 16.2-1-26; filed May 2, 1984, 2:50 p.m.: 7 IR 1454; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1523, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-26.1 "Nurse practitioner" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 25-23-1

Sec. 26.1. "Nurse practitioner" means an individual as defined in IC 25-23-1. *(Indiana State Department of Health; 410 IAC 16.2-1-26.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1523, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-27 "Nursing care" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 27. "Nursing care" means those activities including:
(1) identifying human responses to actual or potential health conditions;
(2) deriving a nursing diagnosis;
(3) executing a nursing treatment regimen based on the nursing diagnosis;
(4) teaching health care practices;
(5) advocating provision of necessary health care services through collaboration with other health service personnel;
(6) executing regimens as prescribed by a physician, licensed chiropractor, dentist, optometrist, podiatrist, or nurse practitioner; and
(7) administering, supervising, delegating, and evaluating nursing activities.

(Indiana State Department of Health; 410 IAC 16.2-1-27; filed May 2, 1984, 2:50 p.m.: 7 IR 1454; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1523, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-27.1 "Nursing staff" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 27.1. "Nursing staff" means, at a minimum, licensed nurses and nurse aides. Nurse aides must meet the training and competency requirements required by the state. *(Indiana State Department of Health; 410 IAC 16.2-1-27.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1523, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-28 "Pharmacist" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 25-26-13

Sec. 28. "Pharmacist" means an individual as defined in IC 25-26-13. *(Indiana State Department of Health; 410 IAC 16.2-1-*

28; filed May 2, 1984, 2:50 p.m.: 7 IR 1454; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1523, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-29 "Physician" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 25-22.5-1-1.1

Sec. 29. "Physician" means an individual as defined in IC 25-22.5-1-1.1. *(Indiana State Department of Health; 410 IAC 16.2-1-29; filed May 2, 1984, 2:50 p.m.: 7 IR 1454; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1523, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-29.1 "Physician orders" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 29.1. "Physician orders" means those orders facility staff need to provide essential care to the resident, consistent with the resident's mental and physical status. At a minimum, these orders include dietary, medications, and routine care to maintain or improve the resident's functional abilities. *(Indiana State Department of Health; 410 IAC 16.2-1-29.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1524, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-30 "Policy manual" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 30. "Policy manual" means a document which details the administrative and operating plan of the facility. *(Indiana State Department of Health; 410 IAC 16.2-1-30; filed May 2, 1984, 2:50 pm: 7 IR 1454; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-31 "Psychologist" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 25-33-1

Sec. 31. "Psychologist" means a person as defined in IC 25-33-1. *(Indiana State Department of Health; 410 IAC 16.2-1-31; filed May 2, 1984, 2:50 p.m.: 7 IR 1454; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1524, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-31.1 "Qualified medication aide" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 31.1. "Qualified medication aide" means an individual who has satisfactorily completed the state qualified medication aide course and test. *(Indiana State Department of Health; 410 IAC 16.2-1-31.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1524, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-32 "Qualified mental retardation professional" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 25-22.5-5; IC 25-23-1-11; IC 25-27; IC 25-35.6-3

Sec. 32. "Qualified mental retardation professional (QMRP)" means a person who has specialized training or one (1) year of experience in treating the mentally retarded, and is one (1) of the following:

(1) A psychologist with a master's degree from an accredited program.

(2) A licensed doctor of medicine or osteopathy.
(3) An educator with a degree in education from an accredited program.
(4) A social worker with a bachelor's or master's degree in social work from an accredited program or a bachelor's or master's degree in a field other than social work and at least three (3) years of social work experience under the supervision of a qualified social worker.
(5) An occupational therapist who:
(A) is a graduate of an occupational therapy curriculum accredited jointly by the council on medical education of the American Medical Association and the American Occupational Therapy Association;
(B) is eligible for certification by the American Occupational Therapy Association under its requirements in effect on September 29, 1978; or
(C) has two (2) years of appropriate experience as an occupational therapist and has achieved a satisfactory grade on the approved proficiency examination, except that such determinations of proficiency shall not apply with respect to persons initially licensed by the state or seeking initial qualifications as an occupational therapist after December 31, 1977.
(6) A speech pathologist or audiologist licensed pursuant to IC 25-35.6-3.
(7) A registered nurse licensed pursuant to IC 25-23-1-11.
(8) A therapeutic recreation specialist who is a graduate of an accredited program.
(9) A rehabilitative counselor who is certified by the Committee of Rehabilitation Counselor Certification.
(10) A physical therapist who is licensed pursuant to IC 25-27.

(Indiana State Department of Health; 410 IAC 16.2-1-32; filed May 2, 1984, 2:50 p.m.: 7 IR 1455; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1524, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-32.1 "Range of motion" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 32.1. "Range of motion" means the extent of movement of a joint. *(Indiana State Department of Health; 410 IAC 16.2-1-32.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1524, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-32.2 "Recreation area" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 32.2. "Recreation area" means:
(1) an area where residents can enjoy fresh air, either inside or outside the facility, for example:
(A) balcony;
(B) porch;
(C) patio;
(D) courtyard; or
(E) solarium; and
(2) an inside area used primarily for activities organized by the facility.

(Indiana State Department of Health; 410 IAC 16.2-1-32.2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1524, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-33 "Registered nurse" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28; IC 25-23-1-11

Sec. 33. "Registered nurse (RN)" means an individual as defined in IC 25-23-1-11. *(Indiana State Department of Health; 410 IAC 16.2-1-33; filed May 2, 1984, 2:50 p.m.: 7 IR 1455; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1525, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-34 "Rehabilitation" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 34. "Rehabilitation" means programs and activities implemented as a component of a treatment plan or in support of a plan to restore a resident to his optimal level of physical and psychosocial functions. *(Indiana State Department of Health; 410 IAC 16.2-1-34; filed May 2, 1984, 2:50 pm: 7 IR 1455; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-35 "Resident" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 35. "Resident" means a person residing and receiving care in a health facility. For purposes of exercising the resident's rights, such rights may be exercised by the resident or his or her legal representative. *(Indiana State Department of Health; 410 IAC 16.2-1-35; filed May 2, 1984, 2:50 p.m.: 7 IR 1455; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1525, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-36 "Residential care facility" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 36. "Residential care facility" means a facility that provides room, food, laundry, and occasional assistance in daily living for residents who need less service than the degree of service provided by a comprehensive care facility. There is an overall general supervision of health care, medications, and diets as defined in the written policies of the facility. *(Indiana State Department of Health; 410 IAC 16.2-1-36; filed May 2, 1984, 2:50 pm: 7 IR 1455; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-37 "Respite care" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 37. "Respite care" means the provision by a facility of room, board, and care up to the level ordinarily provided for permanent residents of the facility to a person for not more than one (1) month for each stay in the facility. *(Indiana State Department of Health; 410 IAC 16.2-1-37; filed May 2, 1984, 2:50 pm: 7 IR 1455; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-38 "Restraint" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 38. "Restraint" means a device or method, including chemical means, used to limit the activity or aggressiveness of a resident where such activity or aggressiveness could be harmful to the resident or others. *(Indiana State Department of Health; 410 IAC 16.2-1-38; filed May 2, 1984, 2:50 pm: 7 IR 1455; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-39 "Seclusion" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 39. "Seclusion" means any circumscribed area in which a person is maintained alone and under surveillance, with the area so equipped that the person may not leave without assistance. *(Indiana State Department of Health; 410 IAC 16.2-1-39; filed May 2, 1984, 2:50 pm: 7 IR 1456; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-39.1 "Significant change" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 39.1. "Significant change" means a major improvement or decline in the resident's physical, mental, or psychosocial status. *(Indiana State Department of Health; 410 IAC 16.2-1-39.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1525, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-40 Sponsor defined (Repealed)

Sec. 40. *(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)*

410 IAC 16.2-1-41 Standing order defined (Repealed)

Sec. 41. *(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)*

410 IAC 16.2-1-41.1 "Sufficient space" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 41.1. "Sufficient space" means the resident can access the area unless it is functionally off-limits, and the resident's functioning is not restricted once access to the space is gained. *(Indiana State Department of Health; 410 IAC 16.2-1-41.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1525, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-42 "Supervise" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 42. "Supervise " means to instruct an employee or subordinate in his duties and to oversee or direct work, but does not necessarily require immediate presence of the supervisor. *(Indiana State Department of Health; 410 IAC 16.2-1-42; filed May 2, 1984, 2:50 pm: 7 IR 1456; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-43 Surrogate defined (Repealed)

Sec. 43. *(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)*

410 IAC 16.2-1-44 "Therapist" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 44. "Therapist" means a person who holds a valid license issued pursuant to Indiana statute or is certified or registered by the appropriate body to practice and who has completed the approved educational curriculum. *(Indiana State Department of Health; 410 IAC 16.2-1-44; filed May 2, 1984, 2:50 p.m.: 7 IR 1456; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1525, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-45 "Toileting" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 45. "Toileting" means how the resident:
(1) uses the toilet room (or bedpan, bedside commode, or urinal);

(2) transfers on and off the toilet;
(3) cleanses self after elimination;
(4) changes sanitary napkins or incontinence pads or external catheters; and
(5) adjusts clothing prior to and after using the toilet.

(Indiana State Department of Health; 410 IAC 16.2-1-45; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1525, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-46 "Total health status" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 46. "Total health status" includes the following:
(1) Functional status.
(2) Medical care.
(3) Nursing care.
(4) Nutritional status.
(5) Rehabilitation and restorative potential.
(6) Activities potential.
(7) Cognitive status.
(8) Oral health status.
(9) Psychosocial status.
(10) Sensory and physical impairments.

(Indiana State Department of Health; 410 IAC 16.2-1-46; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1525, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-1-47 "Transfer" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 47. "Transfer" means moving between two (2) surfaces, to or from a:
(1) bed;
(2) chair;
(3) wheelchair; or
(4) standing position.

The term does not include transfer to or from the bath or toilet. This section does not apply to transfer and discharge of residents pursuant to 410 IAC 16.2-3.1 and 410 IAC 16.2-5. *(Indiana State Department of Health; 410 IAC 16.2-1-47; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1526, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-1-48 "Written" defined

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 48. "Written" means handwritten, typewritten, or contained on electronic media. *(Indiana State Department of Health; 410 IAC 16.2-1-48; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1526, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. General Provisions (Repealed)

(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)

Rule 3. Comprehensive Care Facilities (Repealed)

(Repealed by Indiana State Department of Health; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997)

Rule 3.1. Comprehensive Care Facilities

410 IAC 16.2-3.1-1 Applicability of rule

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 1. This rule applies to all comprehensive care facilities. *(Indiana State Department of Health; 410 IAC 16.2-3.1-1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1526, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-2 Licenses

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-18-2-167; IC 16-28-1-10; IC 16-28-2-2; IC 16-28-2-4; IC 16-28-5-7

Sec. 2. (a) Any person, in order to lawfully operate a health facility as defined in IC 16-18-2-167, shall first obtain an authorization to occupy the facility or a license from the director. The applicant shall notify the director, in writing, before the applicant begins to operate a facility that is being purchased or leased from another licensee. Failure to notify the director precludes the issuance of a full license.

(b) An application shall be submitted on the prescribed form in accordance with IC 16-28-2-2. The application shall include identification of direct or indirect ownership interest of five percent (5%) or more and of corporate officers or partners.

(c) Any change in direct or indirect corporate ownership of five percent (5%) or more, which occurs during the licensure period, shall be reported to the director, in writing, at the time of the change. The facility must also provide written notice at the time the change occurs in the officers, directors, agents, or managing employees, or the corporation, association, or other company responsible for the management of the facility.

(d) A license for a new facility, an existing facility that proposes a change in the number of beds, or a facility that has changed ownership is obtained as follows:

(1) Prior to the start of construction, detailed architectural and operational plans shall be submitted through the office of the state building commissioner to the division for consideration and approval. The plans shall state the licensure classification sought. Plans for projects involving less than thirty thousand (30,000) cubic feet require suitable detailed plans and sketches. Plans for projects involving more than thirty thousand (30,000) cubic feet require certification by an architect or an engineer registered in Indiana. A plan of operation, in sufficient detail to facilitate the review of functional areas, that is, nursing unit, laundry, and kitchen, shall accompany the submitted plan.

(2) Upon receipt of a design release from the state building commissioner and the state fire marshal, an application shall be submitted to the director on the form provided and approved by the department, with the documents required by the application form.

(3) Information and supporting documents that the facility will be operated in reasonable compliance with this article and applicable statutes shall be furnished.

(4) A report by the state fire marshal that the facility is in reasonable compliance with the fire safety rules of the fire prevention and building safety commission (675 IAC) shall be furnished.

(5) If new construction or remodeling is involved, information verified by the appropriate building official that the building is in reasonable compliance with the building rules of the fire prevention and building safety commission (675 IAC) shall be furnished.

(6) A plan of operation shall be submitted to the director. The plan shall include, but is not limited to, the following:

(A) Corporate or partnership structure.
(B) Policies and procedures, including personnel, operations, and resident care.
(C) A disaster plan.
(D) A copy of agreements and contracts.

(7) The appropriate licensure fee shall be submitted.

(e) The director may approve occupancy and use of the structure pending a final licensure decision.

(f) The director may issue a provisional license to a new facility or to a facility under new ownership in accordance with IC 16-28-2-4(2).

(g) For the renewal of a license, the director may issue a full license for any period up to one (1) year or a probationary license,

or the director may refuse to issue a license as follows:

(1) The facility shall submit a renewal application to the director at least forty-five (45) days prior to the expiration of the license. The renewal application shall be on a form provided and approved by the division, which includes identification of direct or indirect ownership interest of five percent (5%) or more and of corporate officers or partners.

(2) The licensure fee shall be included with the renewal application.

(3) The director shall verify that the facility is operated in reasonable compliance with IC 16-28-2 and this article.

(4) The state fire marshal shall verify that the facility is in reasonable compliance with the applicable fire safety statutes and rules (675 IAC).

(h) If the director issues a probationary license, the license may be granted for a period of three (3) months. However, no more than three (3) probationary licenses may be issued in a twelve (12) month period. Although the license fee for a full twelve (12) month period has been paid, a new fee shall be required prior to the issuance of a probationary license.

(i) If the director denies renewal, reduces, revokes, or issues a probationary license, then a hearing officer will be appointed to hold a hearing. However, a facility may waive its right to a hearing and accept the director recommendation.

(j) For a good cause shown, waiver of any nonstatutory provisions of this rule may be granted by the executive board for a specified period in accordance with IC 16-28-1-10.

(k) A licensure survey finding or complaint allegation does not constitute a breach for the purposes of IC 16-28-2 until or unless the commissioner makes a specific determination that a breach has occurred. Moreover, the director shall issue a citation only upon a determination by the commissioner that a breach has occurred. Regardless of whether the commissioner makes a determination that a breach has occurred, a licensure survey finding or complaint allegation may be used as evidence as to whether a violation actually occurred for the purposes of licensure hearings or any other proceedings initiated under IC 16-28-2 or this article.

(l) The classification of rules into the categories that are stated at the end of each section of this rule and 410 IAC 16.2-5 through 410 IAC 16.2-7 shall be used to determine the corrective actions and penalties, if appropriate, to be imposed by the commissioner upon a determination that a breach has occurred, as follows:

(1) An offense presents a substantial probability that death or a life-threatening condition will result. For an offense, the commissioner shall issue an order for immediate correction of the offense. In addition, the commissioner shall:

(A) impose a fine not to exceed ten thousand dollars ($10,000); or

(B) order the suspension of new admissions to the health facility for a period not to exceed forty-five (45) days;

or both. If the offense is immediately corrected, the commissioner may waive up to fifty percent (50%) of any fine imposed and reduce the number of days for suspension of new admissions by one-half (½). The commissioner may also impose revocation by the director of the facility's license or issuance of a probationary license.

(2) A deficiency presents an immediate or direct, serious adverse effect on the health, safety, security, rights, or welfare of a resident. For a deficiency, the commissioner shall issue an order for immediate correction of the deficiency. In addition, the commissioner may:

(A) impose a fine not to exceed five thousand dollars ($5,000); or

(B) order the suspension of new admissions to the health facility for a period not to exceed thirty (30) days;

or both. For a repeat of the same deficiency within a fifteen (15) month period, the commissioner shall order immediate correction of the deficiency and impose a fine not to exceed ten thousand dollars ($10,000) or suspension of new admissions to the facility for a period not to exceed forty-five (45) days, or both. If the deficiency is immediately corrected, the commissioner may waive up to fifty percent (50%) of any fine imposed and reduce the number of days for suspension of new admissions by one-half (½). The commissioner may also impose revocations by the director of the facility license or issuance of a probationary license.

(3) A noncompliance presents an indirect threat on the health, safety, security, rights, or welfare of a resident. For a noncompliance, the commissioner shall require the health facility to comply with any plan of correction approved or directed under IC 16-28-5-7. If the facility is found to have a pattern of noncompliance, the commissioner may suspend new admissions to the health facility for a period not to exceed fifteen (15) days or impose a fine not to exceed one thousand dollars ($1,000), or both. Additionally, if the health facility is found to have a repeat of the same noncompliance in any fifteen (15) month period, the commissioner shall issue an order for immediate correction of the noncompliance. The commissioner may impose a fine not to exceed five thousand dollars ($5,000) or suspension of new admissions to the health facility for a period not to exceed thirty (30) days, or both.

(4) A nonconformance is any other classified rule that does not fall in the three (3) categories established in subdivisions (1) through (3). For a nonconformance, the commissioner shall require the health facility to comply with any plan of correction

approved or directed in accordance with IC 16-28-5-7. For a repeat of the same nonconformance within a fifteen (15) month period, the commissioner shall require the health facility to comply with any plan of correction approved or directed in accordance with IC 16-28-5-7. For a repeat pattern of nonconformance the commissioner may suspend new admissions to the health facility for a period not to exceed fifteen (15) days or impose a fine not to exceed one thousand dollars ($1,000), or both.

(m) For Medicare and Medicaid certified facilities, or both, the department shall not collect both a civil money penalty under 42 CFR 488 and a fine under IC 16-28 and this article. *(Indiana State Department of Health; 410 IAC 16.2-3.1-2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1526, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; filed May 16, 2001, 2:09 p.m.: 24 IR 3022; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-3 Residents' rights

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 3. (a) The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

(1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of the following:

(A) Interference.

(B) Coercion.

(C) Discrimination.

(D) Reprisal from or threat of reprisal from the facility in exercising his or her rights.

(b) The resident has the right to the following:

(1) Examination of the results of the most recent annual survey of the facility conducted by federal or state surveyors and any plan of correction in effect with respect to the facility, and any subsequent surveys. The results must be available for examination in the facility in a place readily accessible to residents, and a notice posted of their availability.

(2) Receipt of information from agencies acting as client advocates, and the opportunity to contact these agencies.

(c) In the case of a resident adjudged incompetent under the laws of the state by a court of competent jurisdiction, the rights of the residents are exercised by the person appointed under state law to act on the resident's behalf.

(d) In the case of an incompetent resident who has not been adjudicated incompetent by a state court, any legal representative may exercise the resident's rights to the extent provided by state law.

(e) The resident has the right to:

(1) refuse to perform services for the facility;

(2) perform services for the facility, if he or she chooses, when:

(A) the facility has documented the need or desire for work in the care plan;

(B) the plan specifies the nature of the services performed and whether the services are voluntary or paid;

(C) compensation for paid services is at or above the prevailing rates; and

(D) the resident agrees to the work arrangement described in the care plan.

(f) The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard.

(g) A resident has the right to organize and participate in resident groups in the facility.

(h) A resident's family has the right to meet in the facility with the families of other residents in the facility.

(i) The facility must provide a resident or family group, if one exists, with private space.

(j) Staff or visitors may attend meetings only at the group's invitation.

(k) The facility must provide a designated staff person responsible for providing assistance and responding to written requests that result from group meetings.

(l) When a resident or family group exists, the facility must listen to the views and act upon the grievances and recommendations of residents and families and report back at a later time in accordance with facility policy.

(m) A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of

other residents in the facility.

(n) The resident has the right to the following:

(1) Choose a personal attending physician or other provider of services. If a physician, or other provider of services, of the resident's choosing fails to fulfill a given federal or state requirement to assure the provisions of appropriate and adequate care and treatment, the facility will have the right, after consulting with the resident, the physician, or other provider of services, to seek alternate physician participation, or services from another provider.

(2) Be fully informed in advance about care and treatment, and of any changes in that care and treatment, that may affect the resident's well-being.

(3) Participate in planning care and treatment or changes in care and treatment unless adjudged incompetent or otherwise found to be incapacitated under state law.

(o) The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

(p) Personal privacy includes the following:

(1) Accommodations.

(2) Medical treatment.

(3) Written and telephone communications.

(4) Personal care.

(5) Visits.

(6) Meetings of family and resident groups.

This does not require the facility to provide a private room for each resident.

(q) Except as provided in subsection (r), the resident may approve or refuse the release of personal and clinical records to any individual outside the facility.

(r) The resident's rights to refuse release of personal and clinical records does not apply when:

(1) the resident is transferred to another health care institution; or

(2) record release is required by law.

(s) The resident has the right to privacy in written communications, including the right to:

(1) send and promptly receive mail that is unopened unless the administrator has been instructed otherwise in writing by the resident;

(2) have access to stationery, postage, and writing implements at the resident's own expense; and

(3) receive any literature or statements of services that accompany mailings from Medicaid that the facility receives on behalf of the resident.

(t) The resident has the right to be cared for in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

(u) The resident has the right to the following:

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care.

(2) Interact with members of the community both inside and outside the facility.

(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

(v) A resident has the right to the following:

(1) Reside and receive services in the facility with reasonable accommodations of the individual's needs and preferences, except when the health or safety of the individual or other residents would be endangered.

(2) Receive notice before the resident's room or roommate in the facility is changed.

(w) The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms.

(x) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b)(1), (e), (n), (o), (p), (q), (r), (t), or (w) is a deficiency;

(2) subsection (b)(2), (c), (d), (f), (g), (l), (m), (s), (u), or (v) is a noncompliance; and

(3) subsection (h), (i), (j), or (k) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-3; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1528, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-4 Notice of rights and services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1; IC 16-36-1-3; IC 16-36-1-7; IC 16-36-4-7; IC 16-36-4-13; IC 30-5-7-4

Sec. 4. (a) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing. A copy of the resident's rights must be available in a publicly accessible area. The copy must be at least 12-point type.

(b) The resident has the right to the following:

(1) Immediate access to the current active clinical record.

(2) Upon an oral or written request to access all other records pertaining to himself or herself within twenty-four (24) hours.

(3) After receipt of his or her records for inspection, to purchase at a cost, not to exceed the community standard, photocopies of the records or any portions of them upon request and two (2) working days advance notice to the facility.

(c) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including, but not limited to, his or her medical condition.

(d) The resident has the right to refuse treatment. Any refusals of treatment must be accompanied by counseling on the medical consequences of such refusal.

(e) The resident has the right to refuse participation in experimental research. All experimental research must be conducted in compliance with state, federal, and local laws and professional standards.

(f) The facility must do the following:

(1) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or when the resident becomes eligible for Medicaid of the following:

(A) The items and services that are included in nursing facility services under the state plan and for which the resident may not be charged.

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of the charges.

(2) Inform each resident when changes are made to the items and services specified in this section.

(3) Inform each resident before, or at the time of admission, in writing and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

(4) Provide written information to each resident concerning the following:

(A) The resident's rights under IC 16-36-1-3 and IC 16-36-1-7 to make decisions concerning their care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives.

(B) The facility's written policies regarding the implementation of such rights, including a clear and precise statement of limitation if the facility or its agent cannot implement an advance directive on the basis of conscience pursuant to IC 16-36-4-13.

(5) Document in the resident's clinical record whether the resident has executed an advance directive and to include a copy of such advance directive in the clinical record.

(6) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.

(7) Ensure compliance with the requirements of state law regarding advance directives.

(8) Provide for education for staff on issues concerning advance directives.

(9) Provide for community education regarding advance directives either directly or in concert with other facilities or health care providers or other organizations.

(10) Distribute to each resident upon admission the state developed written description of the law concerning advance directives.

(g) A facility is not required to provide care that conflicts with an advance directive pursuant to IC 16-36-4-7.

(h) If a facility objects to implementation of an advance directive on the basis of conscience, they must comply with IC 30-5-7-4.

(i) Residents have the right to be informed by the facility, in writing, at least thirty (30) days in advance of the effective date,

of any changes in the rates or services that these rates cover.

(j) The facility must furnish on admission a written description of legal rights, including the following:

(1) A description of the manner of protecting personal funds under this section.

(2) A statement that the resident may file a complaint with the director concerning resident abuse, neglect, misappropriation of resident property, and other practices of the facility.

(3) The most recently known addresses and telephone numbers, including, but not limited to, the following:

(A) The department.

(B) The office of the secretary of family and social services.

(C) The ombudsman designated by the division of disability, aging, and rehabilitative services.

(D) The area agency on aging.

(E) The local mental health center.

(F) The protection and advocacy services commission.

(G) Adult protective services.

These shall be displayed in a prominent place in the facility.

(k) The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

(l) The facility must prominently display in the facility written information, and provide to residents and applicants for admission, oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(m) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (h) is an offense;

(2) subsection (d), (e), or (g) is a deficiency;

(3) subsection (a), (b), (c), (f)(1), (f)(2), (f)(3), (f)(4), (f)(5), (f)(8), (f)(10), (i), (j)(1), (k), or (l) is a noncompliance; and

(4) subsection (f)(6), (f)(7), (f)(9), (j)(2), or (j)(3) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-4; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1529, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; errata filed Jun 4, 1997, 1:47 p.m.: 20 IR 2789; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-5 Notification of changes

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 5. (a) A facility must immediately inform the resident, consult with the resident's physician, and, if known, notify the resident's legal representative or an interested family member when there is:

(1) an accident involving the resident that results in injury and has the potential for requiring physician intervention;

(2) a significant change in the resident's physical, mental, or psychosocial status, that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications;

(3) a need to alter treatment significantly, that is, a need to discontinue an existing form of treatment due to adverse consequences or to commence a new form of treatment; or

(4) a decision to transfer or discharge the resident from the facility.

(b) The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member, when there is:

(1) a change in room or roommate assignment; or

(2) a change in resident rights under federal or state law or regulation.

(c) The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.

(d) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) is a deficiency;

(2) subsection (b)(2) or (c) is a noncompliance; and

(3) subsection (b)(1) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-5; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1531, eff Apr 1, 1997; errata filed

Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-6 Protection of resident funds

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 6. (a) The resident has the right to manage his or her financial affairs, and the facility may not require residents to deposit their personal funds with the facility.

(b) Upon written authorization of the resident, the facility must hold, safeguard, manage, and account for personal funds of the resident deposited with the facility.

(c) Unless otherwise required by federal law, the facility must deposit any residents' personal funds in excess of fifty dollars ($50) in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on the resident's funds to his or her account. (In pooled accounts, there must be a separate accounting for each resident's share.)

(d) The facility must maintain residents' personal funds that do not exceed fifty dollars ($50) in a noninterest bearing account, interest bearing, or petty cash fund.

(e) The facility must establish and maintain a system that assures a full, complete, and separate accounting according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf. The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(f) The facility must:

(1) provide reasonable access during normal business hours to the funds in the account;

(2) return to the resident in not later than fifteen (15) calendar days, upon written request, all or any part of the resident's funds given to the facility for safekeeping; and

(3) provide reasonable access during normal business hours, to the written records of all financial transactions involving the individual resident's funds upon request.

(g) The individual financial record must be provided to the resident or his or her legal representative upon request of the resident and through quarterly statements.

(h) Upon the death of a resident with a personal fund deposited with the facility, the facility must convey within thirty (30) days the resident's funds, and a final accounting of those funds, to the individual or the probate jurisdiction administering the resident's estate.

(i) The facility must purchase surety bond insurance, or otherwise provide assurance satisfactory to the state survey agency, to assure the security of all personal funds of residents deposited with the facility.

(j) The facility may not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare.

(k) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b), (c), (d), (e), (f), (g), (h), or (j) is a noncompliance; and

(2) subsection (i) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-6; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1531, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-7 Grievances

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 7. (a) A resident has the right to the following:

(1) Voice a grievance without discrimination or reprisal. Such grievances include those with respect to treatment which has been furnished as well as that which has not been furnished.

(2) Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(3) Recommend changes in policy and procedure, and receive reasonable responses to their requests without fear of reprisal

or interference.

(b) Each facility shall develop and implement policies for investigating and responding to complaints and grievances made by an individual resident, a resident group, a family member, or family group or other individuals.

(c) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a)(1) is a deficiency; and

(2) subsection (a)(2), (a)(3), or (b) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-7; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1531, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-8 Access and visitation rights

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 8. (a) Residents have the right to choose with whom they associate. The facility shall provide reasonable visiting hours which should include at least nine (9) hours a day. The hours shall be posted in a prominent place in the facility and made available to each resident. Policies shall also provide for emergency visitation at other than posted hours.

(b) The resident has the right and the facility must provide immediate access to any resident by the following:

(1) Individuals representing state or federal agencies.

(2) Any authorized representative of the state.

(3) The resident's individual physician.

(4) The state and area long term care ombudsman.

(5) The agency responsible for the protection and advocacy system for developmentally disabled individuals.

(6) The agency responsible for the protection and advocacy system for mentally ill individuals.

(7) Immediate family or other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time.

(8) Subject to the resident's right to deny or withdraw consent at any time, the resident's legal representative or spiritual advisor.

(9) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

(c) The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, and other services to the resident, subject to the resident's right to deny or withdraw consent at any time.

(d) The facility must allow representatives of the state ombudsman to examine a resident's clinical records with the permission of the resident or the resident's legal representative, and consistent with state law.

(e) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (b) or (c) is a deficiency; and

(2) subsection (a) or (d) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-8; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1532, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-9 Personal property

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 9. (a) The resident has the right to retain and use personal possessions, including some furnishings and appropriate clothing as space permits unless to do so would infringe upon the rights or health and safety of other residents.

(b) The facility shall exercise reasonable care for the protection of the resident's property from loss or theft.

(c) The administrator or the administrator's designee is responsible for investigating reports of lost or stolen residents' property.

(d) The facility will have written policies and procedures outlining the steps to be taken in the event an item is reported lost or stolen.

(e) The policies will include a mechanism to report the results of the investigation to the resident or his or her legal representative in the event the lost or stolen item is not recovered.

(f) If the resident's clothing is laundered by the facility, the facility shall identify the clothing in a suitable manner. The facility

is only responsible for marking those items that are recorded on the resident's inventory sheet.

(g) The facility must inventory, upon admission and discharge, the personal effects, money, and valuables declared by the resident at the time of admission. It is the resident's responsibility to maintain and update the inventory listing of the resident's personal property.

(h) Facilities shall, in writing, annually remind residents, legal representatives, or family members or all, of the need to update inventory records.

(i) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (b) is a deficiency; and

(2) subsection (a), (c), (d), (e), (f), (g), or (h) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-9; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1532, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-10 Living arrangements

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 10. (a) The resident has the right to share a room with his or her spouse when:

(1) married residents live in the same facility and both spouses consent to the arrangement; and

(2) a room is available for residents to share.

(b) The facility shall have written policy and procedures to address the circumstances in which persons of the opposite sex, other than husband and wife, will be allowed to occupy a bedroom, if such an arrangement is agreeable to the occupants.

(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-3.1-10; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1533, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-11 Self-administration of drugs

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 11. (a) An individual resident may self-administer drugs if the interdisciplinary team has determined that the practice is safe.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-3.1-11; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1533, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-12 Transfer and discharge rights

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 4-21.5; IC 16-28-5-1

Sec. 12. (a) The transfer and discharge rights of residents of a facility are as follows:

(1) As used in this section, "interfacility transfer and discharge" means the movement of a resident to a bed outside of the licensed facility. For Medicare and Medicaid certified facilities, an interfacility transfer and discharge means the movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not.

(2) As used in this section, "intrafacility transfer" means the movement of a resident to a bed within the same licensed facility. For Medicare and Medicaid certified facilities, an intrafacility transfer means the movement of a resident to a bed within the same certified facility.

(3) When a transfer or discharge of a resident is proposed, whether intrafacility or interfacility, provision for continuity of care shall be provided by the facility.

(4) Health facilities must permit each resident to remain in the facility and not transfer or discharge the resident from the facility unless:

(A) the transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(B) the transfer or discharge is appropriate because the resident's health has improved sufficiently so that the resident no longer needs the services provided by the facility;

(C) the safety of individuals in the facility is endangered;

(D) the health of individuals in the facility would otherwise be endangered;

(E) the resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility; or

(F) the facility ceases to operate.

(5) When the facility proposes to transfer or discharge a resident under any of the circumstances specified in subdivision (4)(A), (4)(B), (4)(C), (4)(D), or (4)(E), the resident's clinical records must be documented. The documentation must be made by the following:

(A) The resident's physician when transfer or discharge is necessary under subdivision (4)(A) or (4)(B).

(B) Any physician when transfer or discharge is necessary under subdivision (4)(D).

(6) Before an interfacility transfer or discharge occurs, the facility must, on a form prescribed by the department, do the following:

(A) Notify the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner that the resident understands. The health facility must place a copy of the notice in the resident's clinical record and transmit a copy to the following:

(i) The resident.

(ii) A family member of the resident if known.

(iii) The resident's legal representative if known.

(iv) The local long term care ombudsman program (for involuntary relocations or discharges only).

(v) The person or agency responsible for the resident's placement, maintenance, and care in the facility.

(vi) In situations where the resident is developmentally disabled, the regional office of the division of disability, aging, and rehabilitative services, who may assist with placement decisions.

(vii) The resident's physician when the transfer or discharge is necessary under subdivision (4)(C), (4)(D), (4)(E), or (4)(F).

(B) Record the reasons in the resident's clinical record.

(C) Include in the notice the items described in subdivision (9).

(7) Except when specified in subdivision (8), the notice of transfer or discharge required under subdivision (6) must be made by the facility at least thirty (30) days before the resident is transferred or discharged.

(8) Notice may be made as soon as practicable before transfer or discharge when:

(A) the safety of individuals in the facility would be endangered;

(B) the health of individuals in the facility would be endangered;

(C) the resident's health improves sufficiently to allow a more immediate transfer or discharge;

(D) an immediate transfer or discharge is required by the resident's urgent medical needs; or

(E) a resident has not resided in the facility for thirty (30) days.

(9) For health facilities, the written notice specified in subdivision (7) must include the following:

(A) The reason for transfer or discharge.

(B) The effective date of transfer or discharge.

(C) The location to which the resident is transferred or discharged.

(D) A statement in not smaller than 12-point bold type that reads, “You have the right to appeal the health facility's decision to transfer you. If you think you should not have to leave this facility, you may file a written request for a hearing with the Indiana state department of health postmarked within ten (10) days after you receive this notice. If you request a hearing, it will be held within twenty-three (23) days after you receive this notice, and you will not be transferred from the facility earlier than thirty-four (34) days after you receive this notice of transfer or discharge unless the facility is authorized to transfer you under subdivision (8). If you wish to appeal this transfer or discharge, a form to appeal the health facility's decision and to request a hearing is attached. If you have any questions, call the Indiana state department of health at the number listed below.”.

(E) The name of the director, address, telephone number, and hours of operation of the division.

(F) A hearing request form prescribed by the department.

(G) The name, address, and telephone number of the division and local long term care ombudsman.

(H) For facility residents with developmental disabilities or who are mentally ill, the mailing address and telephone number of the protection and advocacy services commission.

(10) If the resident appeals the transfer or discharge, the facility may not transfer or discharge the resident within thirty-four (34) days after the resident receives the initial transfer or discharge notice, unless an emergency exists as provided under subdivision (8).
(11) If nonpayment is the basis of a transfer or discharge, the resident shall have the right to pay the balance owed to the facility up to the date of the transfer or discharge and then is entitled to remain in the facility.
(12) The department shall provide a resident who wishes to appeal the transfer or discharge from a facility the opportunity to file a request for a hearing postmarked within ten (10) days following the resident's receipt of the written notice of the transfer or discharge from the facility.
(13) If a facility resident requests a hearing, the department shall hold an informal hearing at the facility within twenty-three (23) days from the date the resident receives the notice of transfer or discharge. The department shall attempt to give at least five (5) days written notice to all parties prior to the informal hearing. The department shall issue a decision within thirty (30) days from the date the resident receives the notice. The facility must convince the department by a preponderance of the evidence that the transfer or discharge is authorized under subdivision (4). If the department determines that the transfer is appropriate, the resident must not be required to leave the facility within the thirty-four (34) days after the resident's receipt of the initial transfer or discharge notice unless an emergency exists under subdivision (8). Both the resident and the facility have the right to administrative or judicial review under IC 4-21.5 of any decision or action by the department arising under this section. If a hearing is to be held de novo, that hearing shall be held in the facility where the resident resides.
(14) An intrafacility transfer can be made only if:
    (A) the transfer is necessary for medical reasons as judged by the attending physician; or
    (B) the transfer is necessary for the welfare of the resident or other persons.
(15) If an intrafacility transfer is required, the resident must be given notice at least two (2) days before relocation, except when:
    (A) the safety of individuals in the facility would be endangered;
    (B) the health of individuals in the facility would be endangered;
    (C) the resident's health improves sufficiently to allow a more immediate transfer; or
    (D) an immediate transfer is required by the resident's urgent medical needs.
(16) The written notice of an intrafacility transfer must include the following:
    (A) Reasons for transfer.
    (B) Effective date of transfer.
    (C) Location to which the resident is transferred.
    (D) Name, address, and telephone number of the local and state long term care ombudsman.
    (E) For facility residents with developmental disabilities or who are mentally ill, the mailing address and telephone number of the protection and advocacy services commission.
(17) The resident has the right to relocate prior to the expiration of the two (2) day notice.
(18) Prior to any interfacility or involuntary intrafacility relocation, the facility shall prepare a relocation plan to prepare the resident for relocation and to provide continuity of care. In nonemergency relocations, the planning process shall include a relocation planning conference to which the resident, his or her legal representative, family members, and physician shall be invited. The planning conference may be waived by the resident or his or her legal representative.
(19) At the planning conference, the resident's medical, psychosocial, and social needs with respect to the relocation shall be considered and a plan devised to meet these needs.
(20) The facility shall provide reasonable assistance to the resident to carry out the relocation plan.
(21) The facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.
(22) If the relocation plan is disputed, a meeting shall be held prior to the relocation with the administrator or his or her designee, the resident, and the resident's legal representative. An interested family member, if known, shall be invited. The purpose of the meeting shall be to discuss possible alternatives to the proposed relocation plan.
(23) A written report of the content of the discussion at the meeting and the results of the meeting shall be reviewed by the administrator or his or her designee, the resident, the resident's legal representative, and an interested family member, if known, each of whom may make written comments on the report.
(24) The written report of the meeting shall be included in the resident's permanent record.
(25) Before a facility transfers a resident to a hospital or allows a resident to go on therapeutic leave of twenty-four (24) hours

duration or longer, the facility must provide written information to the resident and a family member or legal representative that specifies the following:

(A) The duration of the bed-hold policy under the Medicaid state plan during which the resident is permitted to return and resume residence in the facility.

(B) The facility's policies regarding bed-hold periods, which must be consistent with subdivision (27), permitting a resident to return.

(26) Except in an emergency, at the time of transfer of a resident for hospitalization or therapeutic leave, a facility must provide to the resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in subdivision (25).

(27) Medicaid certified facilities must establish and follow a written policy under which a resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the state plan, is readmitted to the facility immediately upon the first availability of a bed in a semiprivate room if the resident:

(A) requires the services provided by the facility; and

(B) is eligible for Medicaid nursing facility services.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-12; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1533, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-13 Administration and management

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1; IC 25-19-1

Sec. 13. (a) The licensee is responsible for compliance with all applicable laws and rules. The licensee has full authority and responsibility for the organization, management, operation, and control of the licensed facility. The delegation of any authority by the licensee does not diminish the responsibilities of the licensee.

(b) The licensee shall provide the number of staff as required to carry out all the functions of the facility, including:

(1) initial orientation of all employees;

(2) a continuing in-service education and training program for all employees; and

(3) provision of supervision for all employees.

(c) If a facility offers services in addition to those provided to its long term care residents, the administrator is responsible for assuring that such additional services do not adversely affect the care provided to its residents.

(d) The licensee shall notify the department within three (3) working days of a vacancy in the administrator's position. The licensee shall also notify the director of the name and license number of the replacement administrator.

(e) An administrator shall be employed to work in each licensed health facility. For purposes of this subsection, an individual can only be employed as an administrator in one (1) health facility or one (1) hospital based long term care unit at a time.

(f) In the administrator's absence, an individual shall be authorized, in writing, to act on the administrator's behalf.

(g) The administrator is responsible for the overall management of the facility, but shall not function as a departmental supervisor, for example, director of nursing or food service supervisor, during the same hours. The responsibilities of the administrator shall include, but are not limited to, the following:

(1) Immediately informing the division by telephone, followed by written notice within twenty-four (24) hours, of unusual occurrences that directly threaten the welfare, safety, or health of the resident or residents, including, but not limited to, any:

(A) epidemic outbreaks;

(B) poisonings;

(C) fires; or

(D) major accidents.

If the department cannot be reached, such as on holidays or weekends, a call shall be made to the emergency telephone number ((317) 383-6144) of the division.

(2) Promptly arranging for medical, dental, podiatry, or nursing care or other health care services as prescribed by the attending physician.

(3) Obtaining director approval prior to the admission of an individual under eighteen (18) years of age to an adult facility.

(4) Ensuring that the facility maintains, on the premises, time schedules and an accurate record of actual time worked that

indicates the employees' full names and the dates and hours worked during the past twelve (12) months. This information shall be furnished to the division staff upon request.

(5) Maintaining a copy of this article and making it available to all personnel and the residents.

(6) Maintaining reports of surveys conducted by the division in each facility for a period of two (2) years and making the reports available for inspection to any member of the public upon request.

(h) Each facility, except a facility that cares for children or an intermediate care facility for the mentally retarded, shall encourage all employees serving residents or the public to wear name and title identification.

(i) Each facility shall establish and implement a written policy manual to ensure that resident care and facility objectives are attained, to include the range of services offered, resident rights, personnel administration, and facility operations.

(j) The licensee shall approve the policy manual, and subsequent revisions, in writing. The policy manual shall be reviewed and dated at least annually. The resident care policies shall be developed by a group of professional personnel and approved by the medical director.

(k) The policies shall be maintained in a manual(s) accessible to employees and made available upon request to residents, the department, the sponsor or surrogate of a resident, and the public. Management/ownership confidential directives are not required to be included in the policy manual; however, the policy manual must include all of the facility's operational policies.

(l) To assure continuity of care of residents in cases of emergency, the facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, missing residents, and including situations that may require emergency relocation of residents. Facilities caring for children shall have a written plan outlining the staff procedures, including isolation and evacuation, in case of an outbreak of childhood diseases.

(m) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under a written agreement. Such agreements pertaining to services furnished by outside resources must specify, in writing, that the facility assumes responsibility for the following:

(1) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility.

(2) The timeliness of the services.

(3) Orientation to pertinent facility policies and residents to whom they are responsible.

(n) Each facility shall conspicuously post the license or a true copy thereof within the facility in a location accessible to public view.

(o) Each facility shall submit an annual statistical report to the department.

(p) The facility must have in effect, a written transfer agreement with one (1) or more hospitals that reasonably assures the following:

(1) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician.

(2) Medical and other information needed for care and treatment of residents, and when the transferring facility deems it appropriate, for determining whether such residents can be adequately cared for in a less expensive setting than either the facility or the hospital, will be exchanged between the institutions.

(3) Specification of the responsibilities assumed by both the discharging and receiving institutions for prompt notification of the impending transfer of the resident for:

(A) agreement by the receiving institution to admit the resident;

(B) arranging appropriate transportation and care of the resident during transfer; and

(C) the transfer of personal effects, particularly money and valuables, and of information related to such items.

(4) Specification of the restrictions with respect to the types of services available and/or the types of residents or health conditions that will not be accepted by the hospital or the facility, including any other criteria relating to the transfer of residents.

The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

(q) A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(r) The facility must operate and provide services in compliance with all applicable federal, state, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

(s) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility.

(t) The governing body shall appoint the administrator who is:

(1) licensed under IC 25-19-1; and

(2) responsible for the management of the facility.

(u) The facility must designate a physician to serve as medical director.

(v) The medical director shall be responsible for the following:

(1) Acting as a liaison between the administrator and the attending physicians to encourage physicians to write orders promptly and to make resident visits in a timely manner.

(2) Reviewing, evaluating, and implementing resident care policies and procedures and to guide the director of nursing services in matters related to resident care policies and services.

(3) Reviewing incidents and accidents that occur on the premises to identify hazards to health and safety.

(4) Reviewing employees preemployment physicals and health reports, and monitoring employees health status.

(5) The coordination of medical care in the facility.

(w) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (c), (g), (r), (t), (u), or (v) is a deficiency;

(2) subsection (b), (d), (e), (f), (i), (l), (p), (q), or (s) is a noncompliance; and

(3) subsection (h), (j), (k), (m), (n), or (o) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-13; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1535, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-14 Personnel

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1; IC 16-28-13-3

Sec. 14. (a) Each facility shall have specific procedures written and implemented for the screening of prospective employees. Specific inquiries shall be made for prospective employees. The facility shall have a personnel policy that considers references and any convictions in accordance with IC 16-28-13-3.

(b) A facility must not use any individual working in the facility as a nurse aide for more than four (4) months on a full time, part time, temporary, per diem, or other basis unless that individual:

(1) is competent to provide nursing and nursing-related services; and

(2) has completed a training and competency evaluation program approved by the division or a competency evaluation program approved by the division.

(c) Each nurse aide who is hired to work in a facility shall have successfully completed a nurse aide training program approved by the division or shall enroll in the first available approved training program scheduled to commence within sixty (60) days of the date of the nurse aide's employment. The program may be established by the facility or by an organization or institution. The training program shall consist of at least the following:

(1) Thirty (30) hours of classroom instruction within one hundred twenty (120) days of employment. At least sixteen (16) of those hours shall be in the following areas prior to any direct contact with a resident:

(A) Communication and interpersonal skills.

(B) Infection control.

(C) Safety/emergency procedures, including the Heimlich maneuver.

(D) Promoting resident's independence.

(E) Respecting residents' rights.

(2) The remainder of the thirty (30) hours of instruction shall include the following:

(A) Basic nursing skills as follows:

(i) Taking and recording vital signs.

(ii) Measuring and recording height and weight.

(iii) Caring for residents' environment.

(iv) Recognizing abnormal changes in body functioning and the importance of reporting such changes to a supervisor.

(v) Caring for residents when death is imminent.

(B) Personal care skills, including, but not limited to, the following:

(i) Bathing.

(ii) Grooming, including mouth care.

(iii) Dressing.

(iv) Toileting.

(v) Assisting with eating and hydration.

(vi) Proper feeding techniques.

(vii) Skin care.

(viii) Transfers, positioning, and turning.

(C) Mental health and social service needs as follows:

(i) Modifying aides' behavior in response to residents' behavior.

(ii) Awareness of developmental tasks associated with the aging process.

(iii) How to respond to residents' behavior.

(iv) Allowing the resident to make personal choices, providing and reinforcing other behavior consistent with the resident's dignity.

(v) Using the resident's family as a source of emotional support.

(D) Care of cognitively impaired residents as follows:

(i) Techniques for addressing the unique needs and behaviors of individuals with dementia (Alzheimer's and others).

(ii) Communicating with cognitively impaired residents.

(iii) Understanding the behavior of cognitively impaired residents.

(iv) Appropriate responses to the behavior of cognitively impaired residents.

(v) Methods of reducing the effects of cognitive impairments.

(E) Basic restorative services as follows:

(i) Training the resident in self-care according to the resident's abilities.

(ii) Use of assistive devices in transferring, ambulation, eating, and dressing.

(iii) Maintenance of range of motion.

(iv) Proper turning and positioning in bed and chair.

(v) Bowel and bladder training.

(vi) Care and use of prosthetic and orthotic devices.

(F) Residents' rights as follows:

(i) Providing privacy and maintenance of confidentiality.

(ii) Promoting residents' right to make personal choices to accommodate their needs.

(iii) Giving assistance in resolving grievances and disputes.

(iv) Providing needed assistance in getting to and participating in resident and family groups and other activities.

(v) Maintaining care and security of residents' personal possessions.

(vi) Promoting residents' right to be free from abuse, mistreatment, and neglect, and the need to report any instances of such treatment to appropriate facility staff.

(vii) Avoiding the need for restraints in accordance with current professional standards.

(3) Seventy-five (75) hours of supervised clinical experience, at least sixteen (16) hours of which must be in directly supervised practical training. As used in this subdivision, "directly supervised practical training" means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under direct supervision of a registered nurse or a licensed practical nurse. These hours shall consist of normal employment as a nurse aide under the supervision of a licensed nurse.

(4) Training that ensures the following:

(A) Students do not perform any services for which they have not trained and been found proficient by the instructor.

(B) Students who are providing services to residents are under the general supervision of a licensed nurse.

(d) A facility must arrange for individuals used as nurse aides as of the effective date of this rule, to participate in a competency evaluation program approved by the division, and preparation necessary for the individual to complete the program.

(e) Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has

met competency evaluation requirements unless:

(1) the individual is a full-time employee in a training and competency evaluation program approved by the division; or

(2) the individual can prove that he or she has recently successfully completed a training and competency evaluation program approved by the division and has not yet been included in the registry.

Facilities must follow up to ensure that such individual actually becomes registered.

(f) A facility must check with all state nurse aide registries it has reason to believe contain information on an individual before using that individual as a nurse aide.

(g) If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of twenty-four (24) consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

(h) The facility must complete a performance review of every nurse aide at least once every twelve (12) months and must provide regular in-service education based on the outcome of these reviews. The in-service training must be as follows:

(1) Sufficient to ensure the continuing competence of nurse aides, but must be no less than twelve (12) hours per year.

(2) Address areas of weakness as determined in nurse aides' performance reviews and may address the special needs of residents as determined by the facility staff.

(3) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

(i) The facility must ensure that nurse aides and qualified medication aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the care plan.

(j) Medication shall be administered by licensed nursing personnel or qualified medication aides. If medication aides handle or administer drugs or perform treatments requiring medications, the facility shall ensure that the persons have been properly qualified in medication administration by a state-approved course. Injectable medications shall be given only by licensed personnel.

(k) There shall be an organized ongoing in-service education and training program planned in advance for all personnel. This training shall include, but not be limited to, the following:

(1) Resident rights.

(2) Prevention and control of infection.

(3) Fire prevention.

(4) Safety and accident prevention.

(5) Needs of specialized populations served.

(l) The frequency and content of in-service education and training programs shall be in accordance with the skills and knowledge of the facility personnel as follows. For nursing personnel, this shall include at least twelve (12) hours of in-services per calendar year and six (6) hours of in-service per calendar year for non-nursing personnel.

(m) In-service programs for items required under subsection (k) shall contain a means to assess learning by participants.

(n) The administrator may approve attendance at outside workshops and continuing education programs related to that individual's responsibilities in the facility. Documented attendance at these workshops and programs meets the requirements for in-service training.

(o) In-service records shall be maintained and shall indicate the following:

(1) The time, date, and location.

(2) Name of the instructor.

(3) The title of the instructor.

(4) The name of the participants.

(5) The program content of in-service.

The employee will acknowledge attendance by written signature.

(p) Initial orientation of all staff must be conducted and documented and shall include the following:

(1) Instructions on the needs of the specialized population(s) served in the facility, for example, aged, developmentally disabled, mentally ill, or children.

(2) A review of residents' rights and other pertinent portions of the facility's policy manual.

(3) Instruction in first aid, emergency procedures, and fire and disaster preparedness, including evacuation procedures and universal precautions.

(4) A detailed review of the appropriate job description, including a demonstration of equipment and procedures required of

the specific position to which the employee will be assigned.

(5) Review of ethical considerations and confidentiality in resident care and records.

(6) For direct care staff, instruction in the particular needs of each resident to whom the employee will be providing care.

(q) Each facility shall maintain current and accurate personnel records for all employees. The personnel records for all employees shall include the following:

(1) Name and address of employee.

(2) Social Security number.

(3) Date of beginning employment.

(4) Past employment, experience, and education if applicable.

(5) Professional licensure, certification, or registration number if applicable.

(6) Position in the facility and job description.

(7) Documentation of orientation to the facility and to the specific job skills.

(8) Signed acknowledgment of orientation to resident rights.

(9) Performance evaluations in accordance with the facility's policy.

(10) Date and reason for separation.

(r) The employee's personnel record shall be retained for at least three (3) years following termination or separation of the employee from employment.

(s) Professional staff must be licensed, certified, or registered in accordance with applicable state laws or rules.

(t) A physical examination shall be required for each employee of a facility within one (1) month prior to employment. The examination shall include a tuberculin skin test, using the Mantoux method (5 TU PPD), administered by persons having documentation of training from a department-approved course of instruction in intradermal tuberculin skin testing, reading, and recording unless a previously positive reaction can be documented. The result shall be recorded in millimeters of induration with the date given, date read, and by whom administered. The tuberculin skin test must be read prior to the employee starting work. The facility must assure the following:

(1) At the time of employment, or within one (1) month prior to employment, and at least annually thereafter, employees and nonpaid personnel of facilities shall be screened for tuberculosis. For health care workers who have not had a documented negative tuberculin skin test result during the preceding twelve (12) months, the baseline tuberculin skin testing should employ the two-step method. If the first step is negative, a second test should be performed one (1) to three (3) weeks after the first step. The frequency of repeat testing will depend on the risk of infection with tuberculosis.

(2) All employees who have a positive reaction to the skin test shall be required to have a chest x-ray and other physical and laboratory examinations in order to complete a diagnosis.

(3) The facility shall maintain a health record of each employee that includes:

(A) a report of the preemployment physical examination; and

(B) reports of all employment-related health examinations.

(4) An employee with symptoms or signs of active disease, (symptoms suggestive of active tuberculosis, including, but not limited to, cough, fever, night sweats, and weight loss) shall not be permitted to work until tuberculosis is ruled out.

(u) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (c), (e), (f), (g), (i), (j), or (s) is a deficiency;

(2) subsection (a), (b), (d), (h), (k), (l), (m), (n), (o), (p), or (t) is a noncompliance; and

(3) subsection (q) or (r) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-14; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1537, eff Apr 1, 1997; errata, 20 IR 1738; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; filed May 16, 2001, 2:09 p.m.: 24 IR 3024; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-15 Equal access to quality care

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 15. (a) A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the state plan for all individuals regardless of source of payment.

(b) The facility may charge any amount for services furnished to non-Medicaid residents consistent with the notice requirement

in section 4(f) of this rule describing the charges.

(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-3.1-15; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1540, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-16 Admissions policy

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 16. (a) The facility must not:

(1) require residents or potential residents to waive their rights to Medicare or Medicaid; or

(2) require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

(b) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

(c) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the state plan, any gift, money, or donation, or other consideration as a precondition of admission, expedited admission, or continued stay in the facility. However, a nursing facility may:

(1) charge a resident who is eligible for Medicaid for items and services the resident has requested and received and that are not specified in the state plan as included in the term "nursing facility services" so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; or

(2) solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid-eligible resident, or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid-eligible resident.

(d) A facility must not admit, on or after January 1, 1989, any new residents with:

(1) mental illness unless the state mental health authority or its designee has determined, based upon an independent physical and mental evaluation performed by a person or entity other than the state mental health authority or its designee, prior to admission that:

(A) because of the physical and mental condition of the individual, the individual requires the level of services provided by the facility; and

(B) if the individual requires such level of services, whether the individual requires specialized services for mental illnesses or services of a lesser intensity; or

(2) mental retardation unless the state mental retardation authority or its designee has determined prior to admission that:

(A) because of the physical and mental condition of the individual, the individual requires the level of services provided by the facility; and

(B) the individual requires such level of services, whether the individual requires specialized services or services of a lesser intensity for mental retardation.

(e) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (d) is a deficiency; and

(2) subsection (a), (b), or (c) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-16; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1540, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-17 Nursing services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 17. (a) The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and

individual plans of care.

(b) The facility must provide services by sufficient number of each of the following types of personnel on a twenty-four (24) hour basis to provide nursing care to all residents in accordance with resident care plans:

(1) Except when waived under subsection (f), the facility shall provide a licensed nurse hour-to-resident ratio of five-tenths (.5) licensed nurse hour per resident per day, averaged over a one (1) week period. The hours worked by the director of nursing shall not be counted in the staffing hours.

(2) Except when waived under subsection (f), the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

(3) Except when waived under subsection (f), the facility must use the services of a registered nurse for at least eight (8) consecutive hours a day, seven (7) days a week.

(4) Except as waived in subsection (f), the facility must designate a registered nurse who has completed a nursing management course with a clinical component or who has at least one (1) year of nursing supervision in the past five (5) years to serve as the director of nursing on a full-time basis.

(c) The director of nursing will also function in the following duties:

(1) Communication to the administrator and, where appropriate, the physician, the status of the residents, the occurrence of incidents, and accidents and unresolved administrative problems of the nursing department.

(2) Plan for and direct nursing care services in accordance with the physicians' orders and to meet the needs of the residents.

(3) Provide for the training of nursing staff.

(4) Supervise nursing personnel to assure that preventive and restorative nursing procedures for each resident are initiated and performed so as to attain and maintain the highest practicable physical, mental, and psychosocial well-being in accordance with the comprehensive assessment and care plan.

(5) Assure that the clinical records are maintained in accordance with the facility policies and procedures and in compliance with this rule.

(d) The director of nursing shall have, in writing, and shall exercise administrative authority, responsibility, and accountability for nursing services within the facility and shall serve only one (1) facility at a time in this capacity, and confer with the administrator on the evaluation of prospective residents to assure that only those residents whose physical, mental, and psychosocial needs can be met by the facility or through community resources are admitted to and retained by the facility.

(e) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of sixty (60) or fewer residents. These hours worked may be counted toward staffing requirements.

(f) A facility may request a waiver from either the requirement that a nursing facility provide a registered nurse for at least eight (8) consecutive hours a day, seven (7) days a week, or provide a registered nurse as the director of nursing, as specified in subsection (b), if the following conditions are met:

(1) The facility demonstrates to the satisfaction of the state that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel.

(2) The state determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility.

(3) The state finds that, for any periods in which registered nursing services are not available, a registered nurse or physician is obligated to respond immediately to telephone calls from the facility.

(4) A waiver granted under the conditions listed in this subsection is subject to annual state review.

(5) Effective October 1, 1990, in granting or renewing a waiver, a facility may be required by the state to use other qualified, licensed personnel.

(6) The state agency granting a waiver of such requirements provides notice of the waiver to the state long term care ombudsman and the protection and advocacy system in the state for the mentally ill and mentally retarded.

(7) The nursing facility that is granted such a waiver by the state notifies residents of the facility.

(g) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (c), or (d) is a deficiency; and

(2) subsection (b), (e), or (f) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-17; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1541, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-18 Infection control program

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 18. (a) The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of diseases and infection.

(b) The facility must establish an infection control program under which it does the following:

(1) Investigates, controls, and prevents infections in the facility, including, but not limited to, a surveillance system to:

(A) monitor, investigate, document, and analyze the occurrence of nosocomial infection;

(B) recommend corrective action; and

(C) review findings at least quarterly.

The system shall enable the facility to analyze clusters and/or significant increases in the rate of infection.

(2) Decides what procedures (such as isolation) should be applied to an individual resident, including, but not limited to, written, current infection control program policies and procedures for an isolation/precautions system to prevent the spread of infection that isolates the infectious agent and includes full implementation of universal precautions.

(3) Maintains a record of incidents and corrective actions related to infections.

(4) Provides orientation and in-service education on infection prevention and control, including universal precautions.

(5) Provides a resident health program, including, but not limited to, appropriate personal hygiene and immunization.

(6) Provides an employee health program, including appropriate handling of an infected employee as well as employee exposure.

(7) Reports communicable disease to public health authorities.

(c) A diagnostic chest x-ray completed no more than six (6) months prior to admission shall be required.

(d) Prior to admission, each resident shall be required to have a health assessment, including history of significant past or present infectious diseases and a statement that the resident shows no evidence of tuberculosis in an infectious stage as verified upon admission and yearly thereafter.

(e) In addition, a tuberculin skin test shall be completed within three (3) months prior to admission or upon admission and read at forty-eight (48) to seventy-two (72) hours. The result shall be recorded in millimeters of induration with the date given, date read, and by whom administered and read.

(f) The baseline tuberculin skin testing should employ the two-step method. For residents who have not had a documented negative tuberculin skin test result during the preceding twelve (12) months, the baseline tuberculin skin testing should employ the two-step method. If the first step is negative, a second test should be performed within one (1) to three (3) weeks after the first test. The frequency of repeat testing will depend on the risk of infection with tuberculosis.

(g) All residents who have a positive reaction to the tuberculin skin test shall be required to have a chest x-ray and other physical and laboratory examinations in order to complete a diagnosis.

(h) All skin testing for tuberculosis shall be done using the Mantoux method (5 TU PPD) administered by persons having documentation of training from a department-approved course of instruction in intradermal tuberculin skin testing, reading, and recording.

(i) Persons with a documented history of a positive tuberculin skin test, adequate treatment for disease, or preventive therapy for infection, shall be exempt from further skin testing. In lieu of a tuberculin skin test, these persons should have an annual risk assessment for the development of symptoms suggestive of tuberculosis, including, but not limited to, cough, fever, night sweats, and weight loss. If symptoms are present, the individual shall be evaluated immediately with a chest x-ray.

(j) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident only to the degree needed to isolate the infecting organism.

(k) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food if direct contact will transmit the disease. An employee with signs and symptoms of a communicable disease, including, but not limited to, an infected or draining skin lesion shall be handled according to a facility's policy regarding direct contact with residents, their food, or resident care items until the condition is resolved. Persons with suspected or proven active tuberculosis will not be permitted to work until determined to be noninfectious and documentation is provided for the employee record.

(l) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.

(m) For purposes of IC 16-28-5-1, a breach of:
(1) subsection (a) is an offense;
(2) subsection (b)(1), (b)(2), (j), (k), or (l) is a deficiency; and
(3) subsection (b)(3), (c), (d), (e), (f), (g), (h), or (i) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-18; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1542, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-19 Environment and physical standards

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 19. (a) The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel, and the public.

(b) The facility must meet the applicable provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association, which is incorporated by reference. This section applies to all facilities initially licensed on or after the effective date of this rule.

(c) Each facility shall comply with fire and safety standards, including the applicable rules of the state fire prevention and building safety commission (675 IAC) where applicable to health facilities.

(d) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits, equipment to maintain the fire detection, alarm, and extinguishing systems, and life support systems in the event the normal electrical supply is interrupted.

(e) When life support systems are used, the facility must provide emergency electrical power with an emergency generator that is located on the premises.

(f) The facility must provide a safe, functional, sanitary, and comfortable environment for residents, staff, and the public. The facility must do the following:
(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply.
(2) Have adequate outside ventilation by means of windows or mechanical ventilation, or a combination of the two (2).
(3) Equip corridors with firmly secured handrails.
(4) Maintain an effective pest control program so that the facility is free of pests and rodents.
(5) Provide a home-like environment for residents.

(g) Personnel shall handle, store, process, and transport linen in a manner that prevents the spread of infection as follows:
(1) Soiled linens shall be securely contained at the source where it is generated and handled in a manner that protects workers and precludes contamination of clean linen.
(2) Clean linen from a commercial laundry shall be delivered to a designated clean area in a manner that prevents contamination.
(3) When laundry chutes are used to transport soiled linens, the chutes shall be maintained in a clean and sanitary state.
(4) Linens shall be maintained in good repair.
(5) The supply of clean linens, washcloths, and towels shall be sufficient to meet the needs of each resident. The use of common towels, washcloths, or toilet articles is prohibited.

(h) The facility must provide comfortable and safe temperature levels.

(i) Each facility shall have an adequate heating and air conditioning system.

(j) The heating and air conditioning systems shall be maintained in normal operating condition and utilized as necessary to provide comfortable temperatures in all resident and public areas.

(k) Resident rooms must be designed and equipped for adequate nursing care, comfort, and full visual privacy of residents.

(l) Requirements for bedrooms must be as follows:
(1) Accommodate no more than four (4) residents.
(2) Measure at least eighty (80) square feet per resident in multiple resident bedrooms, and at least one hundred (100) square feet in single resident rooms.
(3) A facility initially licensed prior to January 1, 1964, must provide not less than sixty (60) square feet per bed in multiple occupancy rooms. A facility initially licensed after January 1, 1964, must have at least seventy (70) square feet of usable floor area for each bed. Any facility that provides an increase in bed capacity with plans approved after December 19, 1977, must

provide eighty (80) square feet of usable floor area per bed.

(4) Any room utilized for single occupancy must be at least eight (8) feet by ten (10) feet in size with a minimum ceiling height of eight (8) feet. A new facility, plans for which were approved after December 19, 1977, must contain a minimum of one hundred (100) square feet of usable floor space per room for single occupancy.

(5) Have direct access to an exit corridor.

(6) Be designed or equipped to assure full visual privacy for each resident in that they have the means of completely withdrawing from public view while occupying their beds.

(7) Except in private rooms, each bed must have ceiling suspended cubicle curtains or screens of flameproof or flame retardant material, which extend around the bed to provide total visual privacy, in combination with adjacent walls and curtains.

(8) Have at least one (1) window to the outside with an area equal to one-tenth ($^1/_{10}$) of the total floor area of such rooms, up to eighty (80) square feet per bed for rooms occupied by more than one (1) person and one hundred (100) square feet for single occupancy.

(9) Have a floor at or above grade level. A facility whose plans were approved before the effective date of this rule may use rooms below ground level for resident occupancy if the floors are not more than three (3) feet below ground level.

(m) The facility must provide each resident with the following:

(1) A separate bed of proper size and height for the convenience of the resident.

(2) A clean, comfortable mattress.

(3) Bedding appropriate to the weather, climate, and comfort of the resident.

(4) Functional furniture and individual closet space in the resident's room with clothes racks and shelves accessible to the resident and appropriate to the resident's needs, including the following:

(A) A bedside cabinet or table with hard surface, washable top.

(B) A clothing storage closet (which may be shared), including a closet rod and a shelf for clothing, toilet articles, and other personal belongings.

(C) A cushioned comfortable chair.

(D) A reading or bed lamp.

(E) If the resident is bedfast, an adjustable over-the-bed table or other suitable device.

(5) Each resident room shall have clothing storage, which includes a closet at least two (2) feet wide and two (2) feet deep, equipped with an easily opened door and a closet rod at least eighteen (18) inches long of adjustable height to provide access by residents in wheelchairs. The closet should be tall enough that clothing does not drag on the floor and to provide air circulation. A dresser, or its equivalent in shelf and drawer space equal to a dresser with an area of at least four hundred thirty-two (432) square inches, equipped with at least two (2) drawers six (6) inches deep to provide for clothing, toilet articles, and other personal belongings, shall also be provided.

(n) Each resident room must be equipped with or located near toilet or bathing facilities such that residents who are independent in toileting, including chair-bound residents, can routinely have access to a toilet on the unit. As used in this subsection, "toilet facilities" means a space that contains a lavatory with mirror and a toilet. Bathing and toilet facilities shall be partitioned or completely curtained for privacy and mechanically ventilated. Toilets, bath, and shower compartments shall be separated from rooms by solid walls or partitions that extend from the floor to the ceiling.

(o) Bathing facilities for residents not served by bathing facilities in their rooms shall be provided as follows:

Residents	Bathtubs or Showers
3 to 22	1
23 to 37	2
38 to 52	3
53 to 67	4
68 to 82	5
83 to 97	6

Portable bathing units may be substituted for one (1) or more of the permanent fixtures with prior approval of the division.

(p) Toilet facilities shall be provided as set out in the building code at the time the facility was constructed. This section applies to facilities and additions to facilities for which construction plans are submitted for approval after July 1, 1984. At least one (1) toilet and lavatory shall be provided for each eight (8) residents. At least one (1) toilet and one (1) lavatory of the appropriate height for

a resident seated in a wheelchair shall be available for each sex on each floor utilized by residents.

(q) Toilet rooms adjacent to resident bedrooms shall serve no more than two (2) resident rooms or more than eight (8) beds.

(r) Hot water temperature for all bathing and hand washing facilities shall be controlled by automatic control valves. Water temperature at point of use must be maintained between one hundred degrees Fahrenheit (100°F) and one hundred twenty degrees Fahrenheit (120°F).

(s) Individual towel bars shall be provided for each resident.

(t) All bathing and shower rooms shall have mechanical ventilation.

(u) The nurses' station must be equipped to receive resident calls through a communication system from the following:

(1) Resident rooms.

(2) Toilet and bathing facilities.

(3) Activity, dining, and therapy areas.

(v) The facility must provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by this rule and as identified in each resident's care plan.

(w) Each facility shall have living areas with sufficient space to accommodate the dining, activity, and lounge needs of the residents and to prevent the interference of one (1) function with another as follows:

(1) In a facility licensed prior to June 1970, the lounge area, which may also be used for dining, shall be a minimum of ten (10) square feet per bed.

(2) In a facility licensed since June 1970, total dining, activity, and lounge area shall be at least twenty (20) square feet per bed.

(3) Facilities for which construction plans are submitted for approval after 1984, the total area for resident dining, activity, and lounge purposes shall not be less than thirty (30) square feet per bed.

(4) Dining, lounge, and activity areas shall be:

(A) readily accessible to wheelchair and ambulatory residents; and

(B) sufficient in size to accommodate necessary equipment and to permit unobstructed movement of wheelchairs, residents, and personnel responsible for assisting, instructing, or supervising residents.

(5) Dining tables of the appropriate height shall be provided to assure access to meals and comfort for residents seated in wheelchairs, geriatric chairs, and regular dining chairs.

(x) Room-bound residents shall be provided suitable and sturdy tables or adjustable over-bed tables or other suitable devices and chairs of proper height to facilitate independent eating.

(y) Facilities having continuing deficiencies in the service of resident meals directly attributable to inadequacies in the size of the dining room or dining areas shall submit a special plan of correction detailing how meal service will be changed to meet the resident's needs.

(z) A comfortably furnished resident living and lounge area shall be provided on each resident occupied floor of a multi-story building. This lounge may be furnished and maintained to accommodate activity and dining functions.

(aa) The provision of an activity area shall be based on the level of care of the residents housed in the facility. The facility shall provide the following:

(1) Equipment and supplies for independent and group activities and for residents having special needs.

(2) Space to store recreational equipment and supplies for the activities program within or convenient to the area.

(3) Locked storage for potentially dangerous items such as scissors, knives, razor blades, or toxic materials.

(4) In a facility for which plans were approved after December 19, 1977, a rest room large enough to accommodate a wheelchair and equipped with grab bars located near the activity area.

(bb) Maintain all essential mechanical, electrical, and resident care equipment in safe operating condition. Each facility shall establish and maintain a written program for maintenance to ensure the continued upkeep of the facility.

(cc) The facility must provide one (1) or more rooms designated for resident dining and activities. These rooms must:

(1) be well lighted with artificial and natural lighting;

(2) be well ventilated, with nonsmoking areas identified;

(3) be adequately furnished with structurally sound furniture that accommodates residents' needs, including those in wheelchairs; and

(4) have sufficient space to accommodate all activities.

(dd) Each facility shall have natural lighting augmented by artificial illumination, when necessary, to provide light intensity and to avoid glare and reflective surfaces that produce discomfort and as indicated in the following table:

Minimum Average Area	Foot-Candles
Corridors and interior ramp	15
Stairways and landing	20
Recreation area	40
Dining area	20
Resident care room	20
Nurses' station	40
Nurses' desk for charts and records	60
Medicine cabinet	75
Utility room	15
Janitor's closet	15
Reading and bed lamps	20
Toilet and bathing facilities	20
Food preparation surfaces and utensil washing facilities	70

(ee) Each facility shall have a policy concerning pets. Pets may be permitted in a facility but shall not be allowed to create a nuisance or safety hazard. Any pet housed in a facility shall have periodic veterinary examinations and required immunizations in accordance with state and local health regulations.

(ff) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) is an offense;

(2) subsection (b), (c), (d), (e), (f), (g), (h), (i), (j), (r), (u), or (bb) is a deficiency; and

(3) subsection (k), (l), (m), (n), (o), (p), (q), (s), (t), (v), (w), (x), (z), (aa), (cc), (dd), or (ee) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-19; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1543, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-20 Dietary services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1; IC 25-14.5

Sec. 20. (a) The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

(b) The facility must employ a qualified dietitian either full time, part time, or on a consultant basis.

(c) If a qualified dietitian is not employed full time, the facility must designate a qualified person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian.

(d) A qualified dietitian is one who is certified under IC 25-14.5. However, a person employed by a health facility as of July 1, 1984, must:

(1) have a bachelor's degree with major studies in food management;

(2) have one (1) year of supervisory experience in the dietetic service of a health care institution; and

(3) participate annually in continuing dietetic education.

(e) The food service director must be one (1) of the following:

(1) A qualified dietitian.

(2) A graduate or student enrolled in and within one (1) year from completing a division approved, minimum ninety (90) hour classroom instruction course that provides classroom instruction in food service supervision who has a minimum of one (1) year experience in some aspect of institutional food service management.

(3) A graduate of a dietetic technician program approved by the American Dietetic Association.

(4) A graduate of an accredited college or university with a degree in foods and nutrition or food administration with a minimum of one (1) year experience in some aspect of food service management.

(5) An individual with training and experience in food service supervision and management in a military service equivalent in content to the program in subdivisions (2), (3), and (4).

(f) The number of consultant dietitian hours shall be commensurate with number of residents, complexity of resident services, and qualifications of food service director with at least the following number of hours being provided:

(1) Four (4) hours every two (2) weeks for a facility of sixty (60) residents or less.

(2) Five (5) hours every two (2) weeks for a facility of sixty-one (61) to ninety (90) residents.

(3) Six (6) hours every two (2) weeks for a facility of ninety-one (91) to one hundred twenty (120) residents.

(4) Seven (7) hours every two (2) weeks for a facility of one hundred twenty-one (121) to one hundred fifty (150) residents.

(5) Eight (8) hours every two (2) weeks for a facility of one hundred fifty-one (151) residents or more.

(g) Sufficient consultant hours shall be provided to allow the dietitian to correlate and integrate the nutritional aspects of resident care services by directing the following functions:

(1) Reviewing the resident's medical history, the comprehensive assessment, and assessing the resident's nutritional status.

(2) Interviewing and counseling the resident.

(3) Recording pertinent resident information on the record.

(4) Developing nutritional care goals.

(5) Conferring in interdisciplinary care planning.

(6) Sharing specialized knowledge with other members of the resident care team.

(7) Developing the regular diets to meet the specialized needs of residents.

(8) Developing therapeutic diets.

(9) Monitoring institutional food preparation and service.

(h) A facility must employ sufficient support personnel competent to carry out the functions of the dietary service.

(i) Menus must:

(1) meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

(2) be prepared in advance;

(3) be approved by a qualified dietitian; and

(4) be followed.

(j) A current diet manual shall be available.

(k) The regular menu for the facility must be posted or made available to the residents.

(l) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) is a deficiency; and

(2) subsection (b), (c), (d), (e), (f), (g), (h), (i), (j), or (k) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-20; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1546, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-21 Food

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 21. (a) Each resident receives and the facility provides the following:

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance.

(2) Food that is palatable, attractive, and at the proper temperature.

(3) Food prepared in a form designed to meet individual needs.

(4) Substitutes offered of similar nutritive value to residents who refuse food served.

(b) Therapeutic diets must be prescribed by the attending physician.

(c) Each resident receives and the facility provides at least three (3) meals daily, at regular times comparable to normal mealtimes in the community.

(d) There must be no more than fourteen (14) hours between a substantial evening meal and breakfast the following day, except as provided in subsection (f).

(e) The facility must offer snacks at bedtime daily.

(f) When a nourishing snack is provided at bedtime, up to sixteen (16) hours may elapse between a substantial evening meal

and breakfast the following day if a resident group agrees to this meal span and a nourishing snack is served. A nourishing snack is an offering of a minimum of a food item and a beverage.

(g) If a clear liquid diet is prescribed, the order shall be confirmed with the physician every forty-eight (48) hours, if it is the only source of nutrition unless a different time is specified in the physician's order.

(h) The facility must provide special eating equipment and utensils for residents who need them.

(i) The facility must do the following:

(1) Procure food from sources approved or considered satisfactory by federal, state, or local authorities.

(2) Comply with 410 IAC 7-20.

(3) Store, prepare, distribute, and serve food under sanitary conditions.

(4) Provide available storage space in a room adjacent to or convenient to the kitchen for at least a three (3) day supply of staple food both for normal and emergency needs in keeping dietary standards.

(5) Dispose of garbage and refuse properly.

(j) Any contracted food service to a facility must comply with all rules pertaining to dietary services.

(k) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (b), (g), (h), (i)(2), or (i)(3) is a deficiency; and

(2) subsection (a), (c), (d), (e), (f), (i)(1), (i)(4), (i)(5), or (j) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-21; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1547, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; errata filed Mar 28, 2002, 4:35 p.m.: 25 IR 2522)

410 IAC 16.2-3.1-22 Physician services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 22. (a) A physician must personally approve, in writing, a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

(b) The facility must ensure the following:

(1) The medical care of each resident is supervised by a physician.

(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

(3) Verbal/telephone orders shall contain the date and time, physician's order, signature of the licensed nurse accepting the order, and the name of the physician giving the order.

(c) The physician must do the following:

(1) Review the resident's total program of care as defined by the comprehensive assessment and care plan, including medications, and treatments, by signing and dating a recap of all current orders at each visit required by subsection (d).

(2) Write, or cause to be written, sign, and date progress notes at each visit. Dictated notes must be filed in the clinical record within seventy-two (72) hours of the visit and signed within seven (7) days of the time the transcription is completed, and notes shall become part of the permanent record within seventy-two (72) hours unless an emergency situation warrants immediate documentation.

(3) Sign and date all orders. Verbal orders shall be countersigned and dated on the clinical record at the physician's next visit. The use of facsimile to transmit physicians orders is permissible. All matters of privacy and confidentiality of records shall be maintained.

(d) Physician visits must conform to the following schedule:

(1) The resident must be seen by a physician at least once every thirty (30) days for the first ninety (90) days after admission, and at least every sixty (60) days thereafter, unless more frequent visits are indicated.

(2) A physician's routine visit is considered timely if it occurs not later than ten (10) days after the date the visit was required.

(3) Except as provided in subsection (f), all required physician visits must be made by the physician personally.

(4) At the option of the physician, required visits after the initial visit may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner, or clinical nurse specialist in accordance with subsection (f).

(e) The facility must provide or arrange for the provision of physician services twenty-four (24) hours a day, in case of emergency.

(f) A physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who:

(1) is acting within the scope of practice as defined by state law; and

(2) is under the supervision of the physician.

(g) If the physician employs other licensed or certified personnel, the administrator of the facility shall ensure that the means of supervision and duties delegated are filed in writing with the facility. The scope and content of their practice shall be within that specified by appropriate statutes governing each profession.

(h) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (e) is an offense;

(2) subsection (a), (b), or (f) is a deficiency; and

(3) subsection (c), (d), or (g) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-22; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1547, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-23 Specialized rehabilitative services

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 23. (a) If specialized rehabilitative services, such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive care plan, the facility must:

(1) provide the required services; or

(2) obtain the required services from an outside resource from a provider of specialized rehabilitative services.

(b) Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-23; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1548, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-24 Dental services

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 24. (a) The facility must assist residents in obtaining routine and twenty-four (24) hour emergency dental care. The facility must provide, or obtain from an outside resource, the following dental services to meet the needs of each resident:

(1) Routine dental services (to the extent covered under the state plan).

(2) Emergency dental services.

(3) Prompt referral of residents with lost or damaged dentures to a dentist.

(b) The facility must assist the resident, if needed, in making appointments and transportation arrangements to and from the source of the services.

(c) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) is a deficiency; and

(2) subsection (b) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-24; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1548, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-25 Pharmacy services

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1; IC 25-26-13

Sec. 25. (a) The facility must provide routine and emergency drugs and biologicals to its residents or obtain them under an agreement.

(b) The administration of drugs and treatments, including alcoholic beverages, nutrition concentrates, and therapeutic supplements, shall be as ordered by the attending physician and shall be supervised by a licensed nurse as follows:

(1) Medication shall be administered by licensed nursing personnel or qualified medication aides. When other than licensed

personnel administer drugs, the facility shall ensure that the person has been properly qualified in medication administration by a state approved course.

(2) The resident shall be observed for effects of medications. Documentation of any undesirable effects shall be contained in the clinical record. The physician shall be notified immediately if undesirable effects occur, and such notification shall be documented in the clinical record.

(3) The individual administering the medication shall document the administration indicating the time, name of drug or treatment, and dosage (if applicable), with name or initials.

(4) Medication shall be administered by the person who has set up the doses, except under a single unit dose package system.

(5) Setting up of doses for more than one (1) scheduled administration is not permitted.

(6) Injectable medications shall be given only by licensed personnel.

(7) No medication shall be used for any resident other than the resident for whom it was prescribed.

(8) Per required need (PRN) medications may be administered only upon authorization of a licensed nurse or physician. All contacts with a nurse or physician not on the premises for authorization to administer PRNs shall be documented in the nursing notes indicating the time and date of the contact.

(9) Any error in medication administration shall be noted in the resident's record. The physician shall be notified of any error in medication administration when there are any actual or potential detrimental effects to the resident. The facility must ensure that it is free of medication error rates of five percent (5%) or greater and that residents are free of any medication errors that jeopardize their health, safety, or welfare.

(c) The facility may permit qualified medication aides and student nurses to administer drugs under the general supervision of a licensed nurse following successful completion of the state qualifying test for medication aides.

(d) Student nurses may administer medications when under the direct supervision of the instructor and the activity is part of the student's educational programs.

(e) The facility must employ or obtain the services of a licensed pharmacist who is required to do the following:

(1) Provide consultation and written reports on all aspects of the provision of pharmacy services in the facility.

(2) Establish a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation.

(3) Determine that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(f) If a facility operates its own duly licensed pharmacy, it shall comply with IC 25-26-13.

(g) The facility shall only utilize a pharmacy that:

(1) complies with the facility policy regarding receiving, packaging, and labeling of pharmaceutical products unless contrary to state and federal laws and rules on pharmacy practices;

(2) provides prescribed drugs, including the availability of a twenty-four (24) hour prescription service on a prompt and timely basis; and

(3) refills prescription drugs, when needed, in order to prevent interruption of drug regimens.

(h) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(i) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(j) Over-the-counter medications, prescription drugs, and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(k) Labeling of prescription drugs shall include the following:

(1) Resident's full name.

(2) Physician's name.

(3) Prescription number.

(4) Name and strength of drug.

(5) Directions for use.

(6) Date of issue and expiration date (when applicable).

(7) Name and address of the pharmacy that filled the prescription.

If a facility is supplied medication in a unit dose packaging, reasonable variations that comply with the acceptable pharmaceutical procedures are permitted.

(l) Over-the-counter medications must be identified with the following:
(1) Resident name.
(2) Physician name.
(3) Expiration date.
(4) Name of drug.
(5) Strength.

(m) In accordance with state and federal law, the facility must store all drugs and biologicals in locked compartments under proper temperature controls and permit only authorized personnel to have access to the keys.

(n) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems, in which the quantity stored is minimal and a missing dose can be readily detected.

(o) Discontinued, outdated, or deteriorated medication shall not be maintained or used in the facility. Medications shall be disposed of in compliance with federal, state, and local laws.

(p) All unused portions of any properly labeled medications, including controlled substances, shall be released to the discharged resident, along with instructions for their use, upon written order of the physician.

(q) Unopened and unexposed medication may be returned to the issuing pharmacy for credit to the appropriate party.

(r) Unused portions of medications not released with the resident or returned for credit shall be destroyed on the premises within seven (7) days by the consultant pharmacist or licensed nurse with a witness.

(s) Disposition of any released, returned, or destroyed medication shall be written in the resident's clinical record and shall include the following information:
(1) The name of the resident.
(2) The name and strength of the drug.
(3) The prescription number.
(4) The reason for disposal.
(5) The amount disposed of.
(6) The method of disposition.
(7) The date of disposal.
(8) The signatures of the persons conducting the disposal of the drug.

(t) For purposes of IC 16-28-5-1, a breach of:
(1) subsection (a), (b), (c), (f), (g), (i), (j), (k), (l), (m), (n), or (o) is a deficiency;
(2) subsection (d), (e), (h), (p), (r), or (s) is a noncompliance; and
(3) subsection (q) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-25; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1548, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; filed May 16, 2001, 2:09 p.m.: 24 IR 3027; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-26 Resident behavior and facility practices

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 26. (a) Less restrictive measures must have been tried by the interdisciplinary team and shown to be ineffective before restraints are applied.

(b) Restraint or seclusion shall be employed only by order of a physician, and the type of restraint or seclusion shall be specified in the order.

(c) Per required need (PRN) restraint or seclusion shall only be employed upon the authorization of a licensed nurse. All contacts with a nurse or physician not on the premises for authorization to administer PRN restraints shall be documented in the nursing notes indicating the time and date of the contact.

(d) The facility policy manual shall designate who is authorized to apply restraints. The facility shall have written procedures in which the persons authorized to apply restraints have been properly trained.

(e) In emergencies when immediate physical restraint or seclusion is needed for the protection of the resident or others, restraint

or seclusion may be authorized by a licensed nurse for a period not to exceed twelve (12) hours. A physician's order to continue restraint or seclusion must be obtained in order to continue the restraint beyond the twelve (12) hour period.

(f) A record of physical restraint and seclusion of a resident shall be kept in accordance with this rule.

(g) Each resident under restraint and seclusion shall be visited by a member of the nursing staff at least once every hour and more frequently if the resident's condition requires.

(h) Each physically restrained or secluded individual shall be temporarily released from restraint or seclusion at least every two (2) hours or more often if necessary except when the resident is asleep. When the resident in restraint is temporarily released, the resident shall be assisted to ambulate, toileted, or changed in position as the resident's physical condition permits.

(i) A resident shall not be placed alone in a room with a full, solid locked door.

(j) Key lock restraints shall not be used or available in the facility. The acceptable forms of physical restraint include, but are not limited to, the following:

(1) Cloth vests.

(2) Soft cloth ties.

(3) Soft cloth mittens.

(4) Seat belts.

(5) Trays with spring release devices.

(k) Chemical restraint shall be authorized in writing by a physician.

(l) An order for chemical restraints shall specify the dosage and the interval of and reasons for the use of chemical restraint.

(m) Administration of chemical restraints shall be documented in accordance with this rule.

(n) Restraints and seclusion shall be used in such a way as not to cause physical injury to the resident.

(o) Restraints of any type or seclusion shall only be used for the protection and safety of residents or others as required by medical symptoms that warrant the restraint, or safety issues that warrant the seclusion, and shall not be used as a punishment. Restraints and seclusion shall be used in such a way as to minimize discomfort to the resident.

(p) Restraints or seclusion shall be applied in a manner that permits rapid removal in case of fire or other emergency.

(q) The resident's legal representative shall be notified of the need for restraint or seclusion at the time of the physician's initial order or within twenty-four (24) hours after emergency restraint or seclusion is applied. Such notification shall be documented in the nursing notes. After the physician's order for restraint or seclusion is initially written, the legal representative may request in writing not to be notified.

(r) The least restrictive restraint must be used. The continued use of the restraint or seclusion must be reviewed at each care plan conference. Least or lesser restrictive measures must be considered at each meeting.

(s) The use of restraints must be reviewed by the interdisciplinary team within one (1) month after the application of the restraint, and every thirty (30) days for the first ninety (90) days of the restraints, and at least quarterly thereafter.

(t) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (j) or (n) is an offense;

(2) subsection (a), (b), (c), (d), (e), (g), (h), (i), (k), (l), (o), (p), or (r) is a deficiency; and

(3) subsection (f), (m), (q), or (s) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-26; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1550, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-27 Abuse and neglect

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 27. (a) The resident has the right to be free from:

(1) sexual, physical, and mental abuse;

(2) corporal punishment;

(3) neglect; and

(4) involuntary seclusion.

(b) The resident has the right to be free from verbal abuse.

(c) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) is an offense; and

(2) subsection (b) is a deficiency.

(Indiana State Department of Health; 410 IAC 16.2-3.1-27; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1551, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-28 Staff treatment of residents

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 28. (a) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(b) The facility must:

(1) not employ individuals who have:

(A) been found guilty of abusing, neglecting, or mistreating residents or misappropriating residents' property by a court of law; or

(B) had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property; and

(2) report any knowledge the facility has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the state nurse aide registry or licensing authority.

(c) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property, are reported immediately to the administrator of the facility and other officials in accordance with state law through established procedures, including to the state survey and certification agency.

(d) The facility must have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress.

(e) The results of all investigations must be reported to the administrator or the administrator's designated representative and to other officials in accordance with state law (including to the department) within five (5) working days of the incident, and if the alleged violation is verified, appropriate corrective action must be taken.

(f) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (b), (c), (d), or (e) is a deficiency; and

(2) subsection (a) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-28; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1551, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-29 Preadmission evaluation

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 29. (a) The facility is responsible for the evaluation of prospective residents to ensure that only those residents whose medical and psychosocial needs can be met by the facility or through community resources are admitted to the facility.

(b) An evaluation of the prospective residents shall be made prior to admission. The evaluation shall include personal or telephone interviews with:

(1) the resident;

(2) the resident's physician; or

(3) the representative of the facility from which the resident is being transferred if applicable.

A brief record of the evaluation shall be retained by the facility for those residents who are admitted to the facility and shall be used, as applicable, in planning for the care of the resident.

(c) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) is an offense; and

(2) subsection (b) is a deficiency.

(Indiana State Department of Health; 410 IAC 16.2-3.1-29; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1551, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-30 Admission orders

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 30. (a) At the time each resident is admitted, the facility must have physician orders for the resident's immediate care that are based on a physical examination that shall be performed by the attending physician or the attending physician's designee on the day of admission or not earlier than thirty (30) days prior to admission. The physical information shall be updated to include new medical information if the resident's condition has changed since the physical examination was completed. Written admission orders and the physical examination, both signed by the physician, shall be on the resident's record on admission or within forty-eight (48) hours after the resident is admitted to the facility. The use of facsimile is acceptable.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-30; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1552, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-31 Comprehensive assessments

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 12-10-12; IC 16-28-5-1

Sec. 31. (a) The facility must make a comprehensive assessment of each resident's needs that describes the resident's capability to perform daily life functions and significant impairments in functional capacity.

(b) Comprehensive facilities must use an assessment instrument based on the uniform data set specified by the division. Facilities which are not certified by Medicare or Medicaid must comply with this subsection by April 1, 1999.

(c) The comprehensive assessment must include at least the following information:

(1) Medically defined conditions and prior medical history.
(2) Medical status measurement.
(3) Physical and mental functional status.
(4) Sensory and physical impairments.
(5) Nutritional status and requirements.
(6) Special treatments or procedures.
(7) Mental and psychosocial status.
(8) Discharge potential.
(9) Dental condition.
(10) Activities potential.
(11) Rehabilitation potential.
(12) Cognitive status.
(13) Drug therapy.

(d) The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity as follows:

(1) Assessments must be conducted no later than fourteen (14) days after the date of admission, and promptly after a significant change in the resident's physical or mental condition.
(2) Assessments shall be conducted at least once every twelve (12) months.
(3) The nursing facility must examine each resident no less than once every three (3) months, and, as appropriate, revise the resident's assessment to assure the continued accuracy of the assessment.

(e) The results of the assessment are used to develop, review, and revise the resident's comprehensive care plan.

(f) The facility must coordinate assessments with the state required preadmission screening program under IC 12-10-12 to the maximum extent practicable to avoid duplicative testing and effort.

(g) Each assessment must be conducted or coordinated with the appropriate participation of health professionals.

(h) Each assessment must be conducted or coordinated by a registered nurse who signs and certifies the completion of the assessment.

(i) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

(j) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (c), (d), or (e) is a deficiency; and

(2) subsection (b), (f), (g), (h), or (i) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-31; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1552, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-32 Quality of life

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 32. (a) A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-32; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1552, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-33 Activities

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 33. (a) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(b) The facility shall have a plan of activities appropriate to the needs of the residents of that facility that include, but is not limited to, the following:

(1) Group social activities.

(2) Indoor and outdoor activities, which may include daily walks.

(3) Activities away from the facility.

(4) Spiritual programs and attendance at houses of worship.

(5) Opportunity for resident involvement in planning and implementation of the activities program.

(6) Creative activities, such as the following:

(A) Arts.

(B) Crafts.

(C) Music.

(D) Drama.

(E) Educational programs.

(7) Exercise activities.

(8) One (1) to one (1) attention.

(9) Promotion of facility/community interaction.

(c) An activities program shall be provided on a daily basis, including evenings and weekends. At least thirty (30) minutes of staff time shall be provided per resident per week for activities duties. Participation shall be encouraged, although the final option remains with the resident.

(d) Responsibilities of the activities director shall include, but are not limited to, the following:

(1) Preparing a monthly calendar of activities written in large print and posted in a prominent location that is visible to residents and visitors.

(2) Assessing resident needs and developing resident activities goals for the written care plan.

(3) Reviewing goals and progress notes.

(4) Recruiting, training, and supervising volunteers when appropriate.

(5) Coordinating the activities program with other services in the facility.

(6) Requesting and maintaining equipment and supplies.

(7) Participation in developing a budget.

(e) The activities program must be directed by a qualified professional who:

(1) is a qualified therapeutic recreation specialist or an activities professional, who is eligible for certification as a therapeutic recreational specialist or an activities professional by a recognized accrediting body on or after October 1, 1990;

(2) has two (2) years of experience in a social or recreational program, approved by the department within the last five (5) years, one (1) of which was full time in a resident activities program in a health care setting;

(3) is a qualified occupational therapist or occupational therapy assistant; or

(4) has satisfactorily completed, or will complete within six (6) months, a ninety (90) hour training course approved by the division and has at least a high school diploma or its equivalent. Current employment as an activities director who completed an approved activities director course prior to the effective date of this rule shall be allowed to maintain a position as an activities director in health care facilities.

(f) After July 1, 1984, any person who has not completed an activities director course approved by the division and is assigned responsibility for the activities program shall receive consultation until the person has completed such a course. Consultation shall be provided by:

(1) a recreation therapist;

(2) an occupational therapist or occupational therapist assistant; or

(3) a person who has completed a division-approved course and has two (2) years' experience.

(g) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) or (b) is a deficiency; and

(2) subsection (c), (d), (e), or (f) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-33; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1553, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-34 Social services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1; IC 25-23.6-5-1

Sec. 34. (a) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, including the following where appropriate:

(1) Assessment of each resident’s psychosocial needs and development of a plan for providing care.

(2) Review of the resident’s needs and care plan with progress notes indicating implementation of methods to respond to identified needs.

(3) Assistance to residents and spouses to utilize community resources through referral when the services needed are not provided by the facility.

(4) Assistance to residents in adjusting to the facility, exercising rights as residents, and promoting the continuance of relationships with the family and community.

(5) Advice and appropriate referrals to minimize social and economic obstacles to discharge and coordination of discharge planning.

(6) Coordination of relocation planning, including advice and referral to community resources before and during relocation.

(7) Establishment of a positive and socially therapeutic environment through staff training and input on policies and procedures.

(8) Promotion of facility-community interaction.

(b) At least fifteen (15) minutes of time shall be provided per resident per week by the qualified social worker or social service designee for social service duties.

(c) In facilities of more than one hundred twenty (120) beds, the facility must employ, full time, a qualified social worker. A qualified social worker is one (1) of the following:

(1) Indiana board certification in social work under IC 25-23.6-5-1 with at least one (1) year’s experience in a health care setting working directly with individuals.

(2) An individual with a bachelor’s or advanced degree, or both, in social work or a bachelor’s or advanced degree, or both, in a human services field, including, but not limited to:

(A) sociology;

(B) special education;

(C) rehabilitation counseling; or

(D) psychology; or

(E) gerontology;

and one (1) year of supervised social service experience in a health care setting working directly with individuals.

(d) In facilities of one hundred twenty (120) beds or less, a person who provides social services is an individual with one (1) of the following qualifications:

(1) Indiana board certification in social work under IC 25-23.6-5-1 with at least one (1) year's experience in a health care setting working directly with individuals.

(2) A bachelor's or advanced degree, or both, in social work or a degree in the human services fields, including, but not limited to:

(A) sociology;

(B) special education;

(C) rehabilitation counseling;

(D) psychology; and

(E) gerontology;

and one (1) year of supervised social service experience under the supervision of a qualified social worker in a health care setting working directly with individuals.

(3) A high school diploma or its equivalent who has satisfactorily completed, or will complete within six (6) months, a forty-eight (48) hour social service course approved by the division. Consultation must be provided by a person who meets the qualifications under subdivision (1) or (2). Consultation by a person who meets the qualifications under subdivision (1) or (2) must occur no less than an average of four (4) hours per month.

(4) Ordained minister, priest, rabbi, or sister or brother of religious institutes who has satisfactorily completed a forty-eight (48) hour social service course approved by the division. A person who has not completed a course must have consultation of no less than an average of four (4) hours per month from a person who meets the qualifications of subdivision (1) or (2) until the person has satisfactorily completed the division approved course.

(e) Current employment as a social service designee who completed an approved social service course prior to the effective date of this rule shall be allowed to maintain a position as a social service designee in health care facilities. Consultation shall be provided in accordance with subsection (d).

(f) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) is a deficiency;

(2) subsection (b), (c), or (d) is a noncompliance; and

(3) subsection (e) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-34; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1553, eff Apr 1, 1997; errata filed Jan 10, 1997, 4:00 p.m.: 20 IR 1593; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; filed May 16, 2001, 2:09 p.m.: 24 IR 3028; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-35 Comprehensive care plan

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 35. (a) The facility must develop a written comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental, and psychosocial needs that are identified in the comprehensive assessment.

(b) The care plan must describe the following:

(1) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being.

(2) Any services that would otherwise be required, but are not provided due to the resident's exercise of rights, including the right to refuse treatment.

(c) A comprehensive care plan must be:

(1) developed within seven (7) days after the completion of the comprehensive assessment; and

(2) prepared by an interdisciplinary team that includes:

(A) the attending physician;

(B) a registered nurse with responsibility for the resident; and

(C) other appropriate staff in disciplines as determined by the resident's needs;

and to the extent practicable with the participation of the resident and the resident's family.

(d) The written care plan shall indicate the following:

(1) Resident care priorities.

(2) Plans of action to achieve identified goals as follows:

(A) For each goal, the disciplines responsible for assisting in achieving these goals.

(B) Periodically reviewed and revised at a care plan conference by a team of qualified persons, with the participation of the resident and the resident's family to the extent practicable, after each assessment or assessment review.

(e) Documentation of care plan reviews shall indicate the date of the review and the initials of each reviewer present and that the goals and approaches have been updated in accordance with the resident's condition.

(f) The resident's care plan shall be available for use by all personnel caring for the resident.

(g) The services provided or arranged by the facility must:

(1) meet professional standards of quality; and

(2) be provided by qualified persons in accordance with each resident's written care plan.

(h) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b), (f), or (g) is a deficiency; and

(2) subsection (c), (d), or (e) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-35; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1554, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-36 Discharge summary

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 36. (a) When the facility anticipates discharge, a resident must have a discharge summary that includes the following:

(1) A recapitulation of the resident's stay.

(2) A final summary of the resident's status to include the components of the comprehensive assessment, at the time of the discharge that is available for release to authorized persons and agencies with the consent of the resident or legal representative.

(3) A postdischarge care plan that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment. The postdischarge plan must be presented both orally and in writing and in a language that the resident and family understand.

(b) A postdischarge plan identifies specific resident needs after discharge, such as personal care, sterile dressings, and physical therapy, and describes resident/caregiver education needs and provides instructions where applicable, to prepare the resident for discharge.

(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-3.1-36; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1555, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-37 Quality of care

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 37. (a) Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with the comprehensive assessment and care plan.

(b) To ensure each resident receives proper care and treatment, the facility shall assist the resident in making appropriate appointments and in arranging for transportation to and from the office of the practitioner specializing in the needed treatment.

(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-37; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1555, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-38 Activities of daily living

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 38. (a) Based on the comprehensive assessment of a resident and the care plan, the facility must ensure the following:

(1) The resident's abilities in activities of daily living (ADL) do not diminish unless circumstances of the resident's clinical condition demonstrate that diminution was unavoidable. Conditions demonstrating unavoidable diminution in ADLs include the following:

(A) The natural progression of the resident's disease.

(B) Deterioration of the resident's physical condition associated with the onset of a physical or mental disability while receiving care to restore or maintain functional abilities.

(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities, including, but not limited to, the following:

(A) Bathing, dressing, and grooming.

(B) Transfer and ambulation.

(C) Toileting.

(D) Eating.

(E) Speech, language, or other functional communication systems.

(3) A resident who is unable to carry out ADL receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. Each resident shall show evidence of good personal hygiene, including, but not limited to, the following:

(A) Care of the skin.

(B) Shampoo and grooming of the hair.

(C) Oral hygiene and care of the lips to prevent dryness and cracking.

(D) Shaving and beard trimming.

(E) Cleaning and cutting of the fingernails and toenails.

(b) Consistent with the care plan and the resident's right to refuse care, the following services shall be provided:

(1) Each resident shall be given or assisted in oral care, at least daily, to promote clean and healthy gums and teeth. Dentures, when present, shall be properly cared for and cleaned at least daily.

(2) Each resident shall be bathed or assisted to bathe as frequently as is necessary, but at least twice weekly.

(3) Each resident shall have at least one (1) shampoo every week and more often if needed or requested as part of the resident's normal bathing schedule.

(4) Each resident shall be dressed in clean garments.

(5) Residents who are not bedfast shall be encouraged to be dressed each day.

(6) A resident who is bedfast or chair-fast shall have his or her body position changed in accordance with the resident's need as stated in the care plan. Proper body alignment shall be maintained in accordance with the capabilities of each resident.

(c) The resident shall be encouraged or assisted to be as independent as possible, including having self-help and ambulation devices readily available to meet the current needs of the resident with the devices in good repair.

(d) Each resident shall have personal care items such as combs and brushes, cleaned as appropriate.

(e) Each resident may retain personal care items if in the original container labeled by the manufacturer.

(f) The resident has the right to refuse care and treatment to restore or maintain functional abilities after efforts by the facility to counsel and/or offer alternatives to the resident. Refusal of such care and treatment should be documented in the clinical records.

(g) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b), (c), or (f) is a deficiency; and

(2) subsection (d) or (e) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-38; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1555, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-39 Vision and hearing

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 39. (a) To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident as follows:

(1) In making appointments.

(2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-39; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1556, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-40 Pressure sores

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 40. (a) Based on the comprehensive assessment of a resident and the care plan, the facility must ensure the following:

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrated that they were unavoidable. A determination that the development of a pressure sore was unavoidable may be made only if routine preventative and daily care was provided.

(2) A resident having pressure sores or other sign of skin breakdown receives prompt necessary treatment, pressure reducing devices and services to promote healing, prevent infection, and prevent new sores from developing.

(3) The resident's physician shall be notified at the earliest sign of a pressure sore or other skin breakdown. Such notification shall be documented in the clinical record.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-40; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1556, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-41 Urinary incontinence

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 41. (a) Based on the resident's comprehensive assessment and care plan, the facility must ensure the following:

(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary.

(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-41; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1556, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-42 Range of motion

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 42. (a) Based on the comprehensive assessment and care plan of a resident, the facility must ensure the following:

(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable.

(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-42; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1557, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-43 Mental and psychosocial functioning

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 43. (a) Based on the comprehensive assessment and care plan of the resident, the facility must ensure the following:

(1) A resident who displays mental or psychosocial adjustment difficulty receives appropriate treatment and services to correct the assessed problem.

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors unless the resident's clinical condition demonstrates that such a pattern was unavoidable.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-43; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1557, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-44 Naso-gastric tubes

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 44. (a) Based on the comprehensive assessment and comprehensive care plan of a resident, but subject to the resident's right to refuse, the facility must ensure the following:

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable.

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-44; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1557, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-45 Accidents

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 45. (a) The facility must ensure the following:

(1) The resident's environment remains as free of accident hazards as is reasonably possible.

(2) Each resident receives adequate supervision and assistive devices to prevent accidents.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-45; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1557, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-46 Nutrition and hydration

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 46. (a) Based on a resident's comprehensive assessment and care plan, but subject to the resident's right to refuse, the facility must ensure the following:

(1) That a resident maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible.

(2) Receives a therapeutic diet when there is a nutritional problem.

(b) Based on the resident's comprehensive assessment and care plan, the facility must provide each resident with sufficient fluid intake to maintain proper hydration and health. Fresh drinking water shall be provided to each resident and be available to each resident at all times, and a clean drinking glass and covered water pitcher shall be provided at least daily to each resident unless contraindicated by the resident's care plan. Ice shall be available to the residents at all times.

(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-46; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1557, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-47 Special needs

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 47. (a) The facility must ensure that the residents receive proper treatment and care by qualified personnel for the following special services if offered:

(1) Injections.
(2) Parenteral and enteral fluids.
(3) Colostomy, ureterostomy, or ileostomy care.
(4) Tracheostomy care.
(5) Tracheal suctioning.
(6) Respiratory care.
(7) Foot care.
(8) Prostheses.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-47; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1558, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-48 Drug therapy

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 48. (a) Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(1) in excessive dose (including duplicate drug therapy);
(2) for excessive duration;
(3) without adequate monitoring;
(4) without adequate indications for its use;
(5) in the presence of adverse consequences that indicate the dose should be reduced or discontinued; or
(6) any combination of the reasons in this subsection.

(b) Based on a comprehensive assessment and care plan of a resident, the facility must ensure the following:

(1) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record.
(2) Residents who use antipsychotic drugs receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

(c) The facility must ensure the following:

(1) It is free of medication error rates of five percent (5%) or greater.
(2) Residents are free of any medication errors that jeopardize their health, safety, or welfare.

(d) For purposes of IC 16-28-5-1, a breach of subsection (a), (b), or (c) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-3.1-48; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1558, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-3.1-49 Laboratory, radiology, and other diagnostic services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 49. (a) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(b) If the facility provides its own laboratory services, the services must meet the applicable requirements for coverage of the services furnished by independent laboratories specified in 42 CFR 493.

(c) If the facility provides blood bank and transfusion services, it must meet the requirements for laboratories specified in 42 CFR 493.

(d) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be approved or licensed to test specimens in the appropriate specialties and/or subspecialties of service in accordance with the requirements of 42

CFR 493.

(e) If the facility does not provide laboratory services on-site, it must have an agreement to obtain these services only from a laboratory that meets the requirements of 42 CFR 493.

(f) The facility must:

(1) provide or obtain laboratory services only when ordered by the attending physician;

(2) assure that the attending physician is promptly notified of the findings;

(3) assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(4) file in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

(g) The nursing facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(h) If the facility provides its own diagnostic services, the services must meet the applicable rules for licensure of these services.

(i) If the facility does not provide its own diagnostic services, it must have a written agreement to obtain these services from a provider or supplier that is licensed under applicable state rules.

(j) The facility must do the following:

(1) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician.

(2) Promptly notify the attending physician of the findings.

(3) Assist the resident in making transportation arrangements to and from the source of the service if the resident needs assistance.

(4) File in the resident's clinical record signed and dated report of x-ray and other diagnostic services.

(k) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b), (c), (d), (e), (f)(1), (f)(2), (g), (h), (j)(1), or (j)(2) is a deficiency; and

(2) subsection (f)(3), (f)(4), (i), (j)(3), or (j)(4) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-49; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1558, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-50 Clinical records

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 50. (a) The facility must maintain clinical records on each resident. These records must be maintained under the supervision of an employee of the facility designated with that responsibility. Any consultation must be provided by a medical records practitioner in accordance with accepted professional standards and practices. The records must be as follows:

(1) Complete.

(2) Accurately documented.

(3) Readily accessible.

(4) Systematically organized.

(b) Clinical records must be retained after discharge for:

(1) a minimum period of one (1) year in the facility and five (5) years total; or

(2) for a minor, until twenty-one (21) years of age.

(c) If a facility ceases operation, the director shall be informed within three (3) business days by the licensee of the arrangements made for the preservation of the residents' clinical records.

(d) The facility must safeguard clinical record information against loss, destruction, or unauthorized use.

(e) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is required by one (1) or more of the following:

(1) Transfer to another health care institution.

(2) Law.

(3) Third party payment contract.

(4) The resident or legal representative.

(f) The clinical record must contain the following:
(1) Sufficient information to identify the resident.
(2) A record of the resident's assessments.
(3) The care plan and services provided.
(4) The results of any preadmission screening conducted by the state.
(5) Progress notes.
(g) Each facility shall have a well-defined policy that ensures the staff has sufficient progress information to meet the residents' needs.
(h) A transfer form shall include:
(1) Identification data.
(2) Name of the transferring institution.
(3) Name of the receiving institution and date of transfer.
(4) Resident's personal property.
(5) Nurses' notes relating to the resident's:
(A) functional abilities and physical limitations;
(B) nursing care;
(C) medications;
(D) treatment;
(E) current diet; and
(F) condition on transfer.
(6) Diagnosis.
(7) Presence or absence of decubitus ulcer.
(8) Date of chest x-ray and skin test for tuberculosis.
(i) Current clinical records shall be completed promptly and those of discharged residents shall be completed within seventy (70) days of the discharge date.
(j) If a death occurs, information concerning the resident's death shall include the following:
(1) Notification of the physician, family, responsible person, and legal representative.
(2) The disposition of the body, personal possessions, and medications.
(3) A complete and accurate notation of the resident's condition and most recent vital signs and symptoms preceding death.
(k) For purposes of IC 16-28-5-1, a breach of:
(1) subsection (a), (d), (e), (f), (g), (h), or (j) is a noncompliance; and
(2) subsection (b), (c), or (i) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-50; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1559, eff Apr 1, 1997; errata, 20 IR 1738; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-51 Disaster and emergency preparedness

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 51. (a) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters.
(b) The facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures.
(c) Fire exit drills in facilities shall include the transmission of a fire alarm signal and simulation of emergency fire conditions except that the movement of infirm or bedridden residents to safe areas or to the exterior of the building is not required. Drills shall be conducted at least four (4) times a year at regular intervals throughout the year, on each shift to familiarize all facility personnel with signals and emergency action required under varied conditions. At least twelve (12) drills shall be held every year. When drills are conducted between 9 p.m. and 6 a.m., a coded announcement may be used instead of audible alarms.
(d) At least annually, a facility shall attempt to hold a fire and disaster drill in conjunction with the local fire department. A record of all training and drills shall be documented with the names and signatures of the personnel present.
(e) For purposes of IC 16-28-5-1, a breach of:
(1) subsection (a) is an offense;

(2) subsection (b) or (c) is a deficiency; and
(3) subsection (d) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-51; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1559, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-3.1-52 Quality assessment and assurance

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 52. (a) A facility must maintain a quality assessment and assurance committee consisting of the following:
(1) The director of nursing services.
(2) A physician designated by the facility.
(3) At least three (3) other members of the facility's staff.
(b) The quality assessment and assurance committee shall do the following:
(1) Meet at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary.
(2) Develop and implement appropriate plans of action to correct identified issues.
(c) For purposes of IC 16-28-5-1, a breach of:
(1) subsection (a) is a deficiency; and
(2) subsection (b) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-3.1-52; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1560, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2414; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 4. Intermediate Care Facilities for the Mentally Retarded

(NOTE: Rule 4 of LSA Document #83-154(F) was disapproved by the Attorney General–see Attorney General's action letter dated April 27, 1984 in the June 1, 1984 issue of the Indiana Register at 7 IR 1606. See printed version of Rule 4, LSA Document #83-154(F) at 7 IR 1488.)

Rule 5. Residential Care Facilities

410 IAC 16.2-5-1 Applicability

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-2

Sec. 1. This rule applies to all residential care facilities licensed under IC 16-28-2. *(Indiana State Department of Health; 410 IAC 16.2-5-1; filed May 2, 1984, 2:50 p.m.: 7 IR 1497; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1560, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-5-1.1 Licenses

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-18-2-167; IC 16-28-1-10; IC 16-28-2-2; IC 16-28-2-4; IC 16-28-5-7

Sec. 1.1. (a) Any person, in order to lawfully operate a health facility as defined in IC 16-18-2-167, shall first obtain an authorization to occupy the facility or a license from the director. The applicant shall notify the director, in writing, before it begins to operate a facility that is being purchased or leased from another licensee. Failure to notify the director precludes the issuance of a full license.

(b) An application shall be submitted on the prescribed form in accordance with IC 16-28-2-2. The application shall include identification of direct or indirect ownership interest of five percent (5%) or more and of corporate officers or partners.

(c) Any change in direct or indirect corporate ownership of five percent (5%) or more that occurs during the licensure period shall be reported to the director, in writing, at the time the change occurs. The facility must also provide written notice at the time the change occurs in the officers, directors, agents, or managing employees, or the corporation, association, or other company responsible for the management of the facility.

(d) A license for a new facility, an existing facility that proposes a change in the number of beds, or a facility that has changed ownership, is obtained as follows:

(1) Prior to the start of construction, detailed architectural and operational plans shall be submitted through the office of the state building commissioner to the division for consideration and approval. The plans shall state the licensure classification sought. Plans for projects involving less than thirty thousand (30,000) cubic feet require suitable detailed plans and sketches. Plans for projects involving more than thirty thousand (30,000) cubic feet require certification by an architect or an engineer registered in Indiana. A plan of operation, in sufficient detail to facilitate the review of functional areas, that is, nursing unit, laundry, and kitchen, shall accompany the submitted plan.

(2) Upon receipt of a design release from the state building commissioner and the state fire marshal, an application shall be submitted to the director on the form provided and approved by the division, with the documents required by the application form.

(3) Information and supporting documents that the facility will be operated in reasonable compliance with this article and applicable statutes shall be furnished.

(4) A report by the state fire marshal that the facility is in reasonable compliance with the fire safety rules of the fire prevention and building safety commission (675 IAC) shall be furnished.

(5) If new construction or remodeling is involved, information verified by the appropriate building official that the building is in reasonable compliance with the building rules of the department of fire and building services (675 IAC) shall be furnished.

(6) A plan of operation shall be submitted to the director. The plan shall include, but is not limited to:

(A) corporate or partnership structure;

(B) policies and procedures, including personnel, operations, and resident care;

(C) a disaster plan; and

(D) a copy of agreements and contracts.

(7) The appropriate licensure fee shall be submitted.

(e) The director may approve occupancy and use of the structure pending a final licensure decision.

(f) The director may issue a provisional license to a new facility or to a facility under new ownership in accordance with IC 16-28-2-4(2).

(g) For the renewal of a license, the director may issue a full license for any period up to one (1) year or a probationary license, or the director may refuse to issue a license as follows:

(1) The facility shall submit a renewal application to the director at least forty-five (45) days prior to the expiration of the license. The renewal application shall be on a form provided and approved by the division, that includes identification of direct or indirect ownership interest of five percent (5%) or more and of corporate officers or partners.

(2) The licensure fee shall be included with the renewal application.

(3) The director shall verify that the facility is operated in reasonable compliance with IC 16-28-2 and this article.

(4) The state fire marshal shall verify that the facility is in reasonable compliance with the applicable fire safety statutes and rules (675 IAC).

(h) If the director issues a probationary license, the license may be granted for a period of three (3) months. However, no more than three (3) probationary licenses may be issued in a twelve (12) month period. Although the license fee for a full twelve (12) month period has been paid, a new fee shall be required prior to the issuance of a probationary license.

(i) If the director denies renewal or reduces, revokes, or issues a probationary license, then a hearing officer will be appointed to hold a hearing. However, a facility may waive its right to a hearing and accept the director recommendation.

(j) For a good cause shown, waiver of nonstatutory provisions of this rule may be granted by the executive board for a specified period in accordance with IC 16-28-1-10.

(k) A licensure survey finding or complaint allegation does not constitute a breach for the purposes of IC 16-28-2 until or unless the commissioner makes a specific determination that a breach has occurred. Moreover, the director shall issue a citation only upon a determination by the commissioner that a breach has occurred. Regardless of whether the commissioner makes a determination that a breach has occurred, a licensure survey finding or complaint allegation may be used as evidence as to whether a violation actually occurred for the purposes of licensure hearings or any other proceedings initiated under IC 16-28-2 or this article.

(l) The classification of rules into the categories that are stated at the end of each section of 410 IAC 16.2-3.1, this rule, and 410 IAC 16.2-6 through 410 IAC 16.2-7 shall be used to determine the corrective actions and penalties, if appropriate, to be imposed by the commissioner upon a determination that a breach has occurred as follows:

(1) An offense presents a substantial probability that death or a life-threatening condition will result. For an offense, the

commissioner shall issue an order for immediate correction of the offense. In addition, the commissioner may:

(A) impose a fine not to exceed ten thousand dollars ($10,000); or

(B) order the suspension of new admissions to the health facility for a period not to exceed forty-five (45) days;

or both. If the offense is immediately corrected, the commissioner may waive up to fifty percent (50%) of any fine imposed and reduce the number of days for suspension of new admissions by one-half (½). The director may revoke the facility's license or issue a probationary license.

(2) A deficiency presents an immediate or direct, serious adverse effect on the health, safety, security, rights, or welfare of a resident. For a deficiency, the commissioner shall issue an order for immediate correction of the deficiency. In addition, the commissioner may:

(A) order the suspension of new admissions to the health facility for a period not to exceed thirty (30) days; or

(B) impose a fine not to exceed five thousand dollars ($5,000) if the facility holds a probationary license or if the breach is a repeat of the same deficiency within a twelve (12) month period;

or both. However, the commissioner shall impose a fine upon the occurrence of the first deficiency, regardless of the licensure status of the facility, if the first deficiency is intentional or is the result of gross negligence.

(3) A noncompliance presents an indirect threat on the health, safety, security, rights, or welfare of a resident. For a noncompliance, the commissioner shall require the health facility to submit a plan of correction under IC 16-28-5-7. If the facility is found to have a pattern of noncompliance, the commissioner may suspend new admissions to the health facility for a period not to exceed ten (10) days. Additionally, if the health facility is found to have a repeat of the same noncompliance in any eighteen (18) month period, the commissioner may impose a fine not to exceed one thousand dollars ($1,000).

(4) A nonconformance is any other classified rule that does not fall in the three (3) categories established in subdivisions (1) through (3). For a nonconformance, the commissioner may request the health facility to submit a plan of correction in accordance with IC 16-28-5-7.

(Indiana State Department of Health; 410 IAC 16.2-5-1.1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1560, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-1.2 Residents' rights

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 4-21.5; IC 16-28-5-1

Sec. 1.2. (a) Residents have the right to have their rights recognized by the licensee. The licensee shall establish written policies regarding residents' rights and responsibilities in accordance with this article and shall be responsible, through the administrator, for their implementation. These policies and any adopted additions or changes thereto shall be made available to the resident, staff, legal representative, and general public. Each resident shall be advised of these rights prior to admission and shall signify, in writing, upon admission and thereafter if the residents' rights are updated or changed, receipt of the described rights and responsibilities.

(b) Residents have the right to exercise any or all of the enumerated rights without restraint, interference, coercion, discrimination, or threat of reprisal by the facility. These rights shall not be abrogated or changed in any instance, except that, when the resident has been adjudicated incompetent, the rights devolve to the resident's legal representative. When a resident is found by his or her physician to be medically incapable of understanding or exercising his or her rights, the rights may be exercised by the resident's legal representative.

(c) Residents have the right to be treated with consideration, respect, and recognition of their dignity and individuality.

(d) Residents have the right to be provided, at the time of admission to the facility, a written notice of the facility's basic daily or monthly rates, a written statement of all facility services (including those offered on a need basis), information on related charges and admission, readmission, and discharge policies.

(e) Residents have the right to be informed by the facility, in writing, at least thirty (30) days in advance of the effective date, of any changes in the rates or services that these rates cover.

(f) Residents have the right to:

(1) participate in the treatment plan development;

(2) choose the attending physician and other providers of services;

(3) be fully informed of their medical condition by the physician;

(4) refuse treatment, including medication;

(5) be informed of the medical consequences of such refusal and have such data recorded in his or her clinical record; and

(6) be afforded confidentiality of treatment.

The resident may participate or refuse to participate in experimental research, and there must be written acknowledgment of informed consent prior to participation in research activities.

(g) Residents have the right to form and participate in a resident council to discuss alleged grievances, facility operation, resident rights, or other problems, and to participate in the resolution of these matters as follows:

(1) Participation is voluntary.

(2) During resident council meetings, privacy shall be afforded unless a member of the staff is invited by the resident council to be present.

(3) The licensee shall provide space for meetings and assistance to residents who desire to attend meetings.

(h) Residents have the right to appropriate housing assignments as follows:

(1) When both husband and wife are residents in the facility, they have the right to live as a family in a suitable room or quarters, if practical, and may occupy a double bed unless contraindicated for medical reasons by the attending physician.

(2) Written facility policy and procedures shall address the circumstances in which persons of the opposite sex, other than husband and wife, will be allowed to occupy a bedroom, if such an arrangement is agreeable to the residents or the residents' legal representatives.

(i) The transfer and discharge rights of residents of a facility are as follows:

(1) As used in this section, "interfacility transfer and discharge" means the movement of a resident to a bed outside of the licensed facility.

(2) As used in this section, "intrafacility transfer" means the movement of a resident to a bed within the same licensed facility.

(3) When a transfer or discharge of a resident is proposed, whether intrafacility or interfacility, provision for continuity of care shall be provided by the facility.

(4) Health facilities must permit each resident to remain in the facility and not transfer or discharge the resident from the facility unless:

(A) the transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(B) the transfer or discharge is appropriate because the resident's health has improved sufficiently so that the resident no longer needs the services provided by the facility;

(C) the safety of individuals in the facility is endangered;

(D) the health of individuals in the facility would otherwise be endangered;

(E) the resident has failed, after reasonable and appropriate notice, to pay for a stay at the facility; or

(F) the facility ceases to operate.

(5) When the facility proposes to transfer or discharge a resident under any of the circumstances specified in subdivision (4)(A), (4)(B), (4)(C), (4)(D), or (4)(E), the resident's clinical records must be documented. The documentation must be made by the following:

(A) The resident's physician when transfer or discharge is necessary under subdivision (4)(A) or (4)(B).

(B) Any physician when transfer or discharge is necessary under subdivision (4)(D).

(6) Before an interfacility transfer or discharge occurs, the facility must, on a form prescribed by the department, do the following:

(A) Notify the resident of the transfer or discharge and the reasons for the move, in writing, and in a language and manner that the resident understands. The health facility must place a copy of the notice in the resident's clinical record and transmit a copy to the following:

(i) The resident.

(ii) A family member of the resident if known.

(iii) The resident's legal representative if known.

(iv) The local long term care ombudsman program (for involuntary relocations or discharges only).

(v) The person or agency responsible for the resident's placement, maintenance, and care in the facility.

(vi) In situations where the resident is developmentally disabled, the regional office of the division of disability, aging, and rehabilitative services, who may assist with placement decisions.

(vii) The resident's physician when the transfer or discharge is necessary under subdivision (4)(C), (4)(D), (4)(E), or (4)(F).

(B) Record the reasons in the resident's clinical record.

(C) Include in the notice the items described in subdivision (9).

(7) Except when specified in subdivision (8), the notice of transfer or discharge required under subdivision (6) must be made by the facility at least thirty (30) days before the resident is transferred or discharged.
(8) Notice may be made as soon as practicable before transfer or discharge when:
(A) the safety of individuals in the facility would be endangered;
(B) the health of individuals in the facility would be endangered;
(C) the resident's health improves sufficiently to allow a more immediate transfer or discharge;
(D) an immediate transfer or discharge is required by the resident's urgent medical needs; or
(E) a resident has not resided in the facility for thirty (30) days.
(9) For health facilities, the written notice specified in subdivision (7) must include the following:
(A) The reason for transfer or discharge.
(B) The effective date of transfer or discharge.
(C) The location to which the resident is transferred or discharged.
(D) A statement in not smaller than 12-point bold type that reads, “You have the right to appeal the health facility's decision to transfer you. If you think you should not have to leave this facility, you may file a written request for a hearing with the Indiana state department of health postmarked within ten (10) days after you receive this notice. If you request a hearing, it will be held within twenty-three (23) days after you receive this notice, and you will not be transferred from the facility earlier than thirty-four (34) days after you receive this notice of transfer or discharge unless the facility is authorized to transfer you under subdivision (8). If you wish to appeal this transfer or discharge, a form to appeal the health facility's decision and to request a hearing is attached. If you have any questions, call the Indiana state department of health at the number listed below.”.
(E) The name of the director and the address, telephone number, and hours of operation of the division.
(F) A hearing request form prescribed by the department.
(G) The name, address, and telephone number of the state and local long term care ombudsman.
(H) For health facility residents with developmental disabilities or who are mentally ill, the mailing address and telephone number of the protection and advocacy services commission.
(10) If the resident appeals the transfer or discharge, the health facility may not transfer or discharge the resident within thirty-four (34) days after the resident receives the initial transfer or discharge notice, unless an emergency exists as provided under subdivision (8).
(11) If nonpayment is the basis of a transfer or discharge, the resident shall have the right to pay the balance owed to the facility up to the date of the transfer or discharge and then is entitled to remain in the facility.
(12) The department shall provide a resident who wishes to appeal the transfer or discharge from a facility the opportunity to file a request for a hearing postmarked within ten (10) days following the resident's receipt of the written notice of the transfer or discharge from the facility.
(13) If a health facility resident requests a hearing, the department shall hold an informal hearing at the health facility within twenty-three (23) days from the date the resident receives the notice of transfer or discharge. The department shall attempt to give at least five (5) days' written notice to all parties prior to the informal hearing. The department shall issue a decision within thirty (30) days from the date the resident receives the notice. The health facility must convince the department by a preponderance of the evidence that the transfer or discharge is authorized under subdivision (4). If the department determines that the transfer is appropriate, the resident must not be required to leave the health facility within the thirty-four (34) days after the resident's receipt of the initial transfer or discharge notice unless an emergency exists under subdivision (8). Both the resident and the health facility have the right to administrative or judicial review under IC 4-21.5 of any decision or action by the department arising under this section. All hearings held de novo shall be held in the facility where the resident resides.
(14) An intrafacility transfer can be made only if:
(A) the transfer is necessary for medical reasons as judged by the attending physician; or
(B) the transfer is necessary for the welfare of the resident or other persons.
(15) If an intrafacility transfer is required, the resident must be given notice at least two (2) days before relocation, except when:
(A) the safety of individuals in the facility would be endangered;
(B) the health of individuals in the facility would be endangered;
(C) the resident's health improves sufficiently to allow a more immediate transfer; or
(D) an immediate transfer is required by the resident's urgent medical needs.

(16) The written notice of an intrafacility transfer must include the following:

(A) Reasons for transfer.

(B) Effective date of transfer.

(C) Location to which the resident is to be transferred.

(D) Name, address, and telephone number of the local and state long term care ombudsman.

(E) For health facility residents with developmental disabilities or who are mentally ill, the mailing address and telephone number of the protection and advocacy services commission.

(17) The resident has the right to relocate prior to the expiration of the two (2) day notice.

(18) Prior to any interfacility or involuntary intrafacility relocation, the facility shall prepare a relocation plan to prepare the resident for relocation and to provide continuity of care. In nonemergency relocations, the planning process shall include a relocation planning conference to which the resident, his or her legal representative, family members, and physician shall be invited. The planning conference may be waived by the resident.

(19) At the planning conference the resident's medical, psychosocial, and social needs with respect to the relocation shall be considered and a plan devised to meet these needs.

(20) The facility shall provide reasonable assistance to the resident to carry out the relocation plan.

(21) The facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

(22) If the relocation plan is disputed, a meeting shall be held prior to the relocation with the administrator or his or her designee, the resident, and the resident's legal representative. An interested family member, if known, shall be invited. The purpose of the meeting shall be to discuss possible alternatives to the proposed relocation plan.

(23) A written report of the content of the discussion at the meeting and the results of the meeting shall be reviewed by the administrator or his or her designee, the resident, the resident's legal representative, and an interested family member, if known, each of whom may make written comments on the report.

(24) The written report of the meeting shall be included in the resident's permanent record.

(j) Residents have the right to exercise their rights as residents and citizens. Residents may, throughout the period of their stay, voice grievances to the facility staff or to an outside representative of their choice, recommend changes in policy and procedure, and receive reasonable responses to their requests without fear of reprisal or interference. The address and telephone number of:

(1) the department;

(2) the office of the secretary of family and social services;

(3) the ombudsman designated by the division of disability, aging, and rehabilitative services;

(4) the area agency on aging;

(5) the local mental health center; and

(6) the protection and advocacy services commission;

shall be displayed in a prominent place in the facility. A telephone accessible to the residents shall be provided for emergency and reasonable personal use.

(k) Residents have the right to manage their personal affairs and funds or may, by written request, allow the facility to execute all or part of their financial affairs. If the facility agrees to handle the resident's funds, the resident must be provided with:

(1) a quarterly accounting of all financial affairs handled by the facility;

(2) reasonable access, during normal business hours, to the written records of all financial transactions involving the individual resident's funds upon request;

(3) separation of resident and facility funds; and

(4) return to the resident no later than fifteen (15) calendar days, upon written request, all or any part of the resident's funds given the facility for safekeeping.

(l) Residents have the right to be free from physical and mental abuse (including sexual abuse), neglect, and restraint.

(m) Residents have the right to confidentiality of all personal records. Information from these sources shall not be released without the resident's consent, except upon transfer to another health facility, when required by law, or under a third party payment contract. The resident's records shall be made immediately available to the resident for inspection, and the resident may receive a copy within a reasonable time, at the resident's expense.

(n) Residents have the right to be treated as individuals with consideration and respect for their privacy. Privacy shall be afforded for at least the following:

(1) Bathing.

(2) Personal care.

(3) Physical examinations and treatments.

(4) Visitations.

(o) Residents have the right not to be required to perform services for the facility unless such work is medically indicated and included in the therapeutic treatment plan as prescribed by the physician, or unless the resident so requests and the attending physician approves, in writing.

(p) Residents have the right to choose with whom they associate. The facility shall provide reasonable visiting hours, which should include at least nine (9) hours a day, and the hours shall be posted in a prominent place in the facility and made available to each resident. Policies shall also provide for emergency visitation at other than posted hours. The facility shall not restrict visits from the resident's legal representative, sponsor, surrogate advocate, or spiritual advisor except at the request of the resident or sponsor. The resident's mail, either incoming or outgoing, shall remain intact and unopened unless the administrator has been instructed otherwise in writing by the resident.

(q) Residents have the right to participate in social, religious, community services, and other activities of their choice that do not interfere with the rights of other residents at the facility.

(r) Residents have the right to individual expression through retention of personal clothing and belongings as space permits unless to do so would infringe upon the rights of others or would create a health or safety hazard. The facility shall exercise reasonable care for the protection of residents' property from loss and theft. The administrator or his or her designee is responsible for investigating reports of lost or stolen resident property.

(s) For purposes of IC 16-28-5-1, a breach of subsection (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), or (r) is a deficiency. *(Indiana State Department of Health; 410 IAC 16.2-5-1.2; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1562, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-5-1.3 Administration and management

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1; IC 25-19-1

Sec. 1.3. (a) The licensee is responsible for compliance with all applicable laws. The licensee has full authority and responsibility for the organization, management, operation, and control of the licensed facility. The delegation of any authority by the licensee does not diminish the responsibilities of the licensee.

(b) The licensee shall employ the number of staff as required to carry out all the functions of the facility, including the following:

(1) Initial orientation of all employees.

(2) A continuing in-service education and training program for all employees.

(3) Provision of supervision for all employees.

(c) The licensee shall appoint and delegate to an administrator licensed pursuant to IC 25-19-1 the authority to organize and implement the day-to-day operations of the facility. The licensee, if a licensed administrator, may act as the administrator of the facility.

(d) If a facility offers services in addition to those provided to its long term care residents, the administrator is responsible for assuring that such additional services do not adversely affect the care provided to its residents.

(e) The licensee shall notify the director within three (3) working days of a vacancy in the administrator's position. The licensee shall also notify the director of the name and license number of the replacement administrator.

(f) An administrator shall be employed to work in each licensed health facility. For purposes of this subsection, an individual can only be employed as an administrator in one (1) health facility or one (1) hospital based long term care unit at a time.

(g) In the administrator's absence, an individual shall be authorized, in writing, to act on the administrator's behalf.

(h) The administrator is responsible for the overall management of the facility, but shall not function as a departmental supervisor, for example, director of nursing or food service supervisor, during the same hours. The responsibilities of the administrator shall include, but are not limited to, the following:

(1) Immediately informing the division by telephone, followed by written notice within twenty-four (24) hours, of unusual occurrences that directly threaten the welfare, safety, or health of the residents, including, but not limited to, any epidemic outbreaks, poisonings, fires, or major accidents. If the division cannot be reached, such as on holidays or weekends, a call shall be made to the emergency telephone number ((317) 383-6144) of the division.

(2) Promptly arranging for medical, dental, podiatry, or nursing care or other health care services as prescribed by the attending physician.

(3) Obtaining director approval prior to the admission of an individual under eighteen (18) years of age to an adult facility.

(4) Ensuring that the facility maintains, on the premises, time schedules and an accurate record of actual time worked that indicates the employees' full name and the dates and hours worked during the past twelve (12) months. This information shall be furnished to the division staff upon request.

(5) Once furnished a copy by the division, maintaining a copy of this article, and making it available to all personnel, the residents, sponsors, or surrogates.

(6) Once furnished a copy by the division, informing affected staff of any amendments to this article no later than the effective date of the amendments.

(7) Maintaining reports of surveys conducted by the division in each facility for a period of two (2) years and making the reports available for inspection to any member of the public upon request.

(i) Each facility, except a facility that cares for children or an intermediate care facility for the mentally retarded, shall encourage all employees serving residents or the public to wear name and title identification.

(j) Each facility shall establish and implement a written policy manual to ensure that resident care and facility objectives are attained, to include the range of services offered, resident rights, personnel administration, and facility operations.

(k) The licensee shall approve the policy manual, and subsequent revisions, in writing. The policy manual shall be reviewed and dated at least annually.

(l) The policies shall be maintained in a manual accessible to employees and made available upon request to residents, the division, the legal representative of a resident, and the public. Management/ownership confidential directives are not required to be included in the policy manual; however, the policy manual must include all of the facility's operational policies.

(m) The policy manual shall contain a written fire and disaster preparedness plan to assure continuity of care of residents in cases of emergency as follows:

(1) Facilities caring for children shall have a written plan outlining the staff procedures, including isolation and evacuation, in case of an outbreak of childhood diseases.

(2) Fire exit drills in facilities shall include the transmission of a fire alarm signal and simulation of emergency fire conditions, except that the movement of infirm or bedridden patients to safe areas or to the exterior of the building is not required. Drills shall be conducted quarterly on each shift to familiarize all facility personnel with signals and emergency action required under varied conditions. At least twelve (12) drills shall be held every year. When drills are conducted between 9 p.m. and 6 a.m., a coded announcement may be used instead of audible alarms.

(3) At least every six (6) months, a facility shall attempt to hold the fire and disaster drill in conjunction with the local fire department. A record of all training and drills shall be documented with the names and signatures of the personnel present.

(n) If professional or diagnostic services are to be provided to the facility by an outside resource, either individual or institutional, an arrangement shall be developed between the licensee and the outside resource for the provision of the services. If a written agreement is used, it shall specify the responsibilities of both the facility and the outside resource, the qualifications of the outside resource staff, a description of the type of services to be provided, including action taken and reports of findings, and the duration of the agreement.

(o) Each facility shall conspicuously post the license or a true copy thereof within the facility in a location accessible to public view.

(p) Each facility shall submit an annual statistical report to the department.

(q) The facility shall have a written and signed transfer agreement with one (1) or more hospitals within reasonable proximity of the facility to make feasible the transfer of residents and applicable records as follows:

(1) A facility that has been unable to establish a transfer agreement with the hospitals in the community or service area, after documented attempts to do so, is considered to have an agreement in effect.

(2) The written transfer agreement shall be as follows:

(A) Be in writing and shall be signed by persons authorized to execute the agreement on behalf of the institutions. Each institution shall maintain a copy of the agreement.

(B) Ensure the change of medical and other information necessary or useful in the care and treatment of residents transferred between the institutions or in determining whether such residents can be adequately cared for.

(C) Specify the responsibilities assumed by both the discharging and receiving institutions for:

(i) prompt notification of the impending transfer of the resident;

(ii) agreement by the receiving institution to admit the resident;

(iii) arranging appropriate transportation and care of the resident during transfer; and

(iv) the transfer of personal effects, particularly money and valuables and of information related to such items.

(D) Specify restrictions with respect to the types of services available and/or the types of residents or health conditions that will not be accepted by the hospital or the facility, including any other criteria relating to the transfer of residents.

(r) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (d), or (h) is a deficiency;

(2) subsection (b), (c), (f), (g), (j), (m), or (q) is a noncompliance; and

(3) subsection (e), (i), (k), (l), (n), (o), or (p) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-5-1.3; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1565, eff Apr 1, 1997; errata filed Jan 10, 1997, 4:00 p.m.: 20 IR 1593; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-1.4 Personnel

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1; IC 16-28-13-3

Sec. 1.4. (a) Each facility shall have specific procedures written and implemented for the screening of prospective employees. Specific inquiries shall be made for prospective employees. The facility shall have a personnel policy that considers references and any convictions in accordance with IC 16-28-13-3.

(b) Each facility shall maintain a staffing pattern for all departments that shall be made available to the division as follows:

(1) The minimum staffing ratios required by this article shall be maintained at all times, including relief periods, vacation periods, and holidays.

(2) Each employee on duty shall be dressed in accordance with facility policy, awake, and mentally and physically capable of giving care as required and responding appropriately in an emergency.

(3) Each residential care facility shall have at least one (1) employee on duty at all times. Residential facilities with over one hundred (100) residents shall have one (1) additional employee on duty at all times for every additional fifty (50) residents or major fraction thereof. In a facility having both comprehensive and residential distinct parts, the employee or employees assigned to the residential distinct part may be stationed and may work in the comprehensive distinct part during the second and third shifts. Residential employees assigned to the comprehensive distinct part must be readily available to the residents of the residential distinct part. However, such employees' time does not count toward the staffing requirements of the comprehensive distinct part.

(4) Personnel shall be assigned only those duties for which they are trained to perform. Employee duties shall conform with written job descriptions.

(c) Prior to working independently, each employee shall be given an orientation to the facility by the supervisor (or his designee) of the department in which the employee will work. Orientation of nursing staff shall be supervised by the director of nursing or a licensed designee. Orientation of all employees shall include the following:

(1) Instructions on the needs of the specialized populations served in the facility (aged, developmentally disabled, mentally ill, or children).

(2) A review of the facility's policy manual and applicable procedures including organization chart, personnel policies, appearance and grooming, and residents rights.

(3) Instruction in first aid, emergency procedures, and fire and disaster preparedness, including evacuation procedures.

(4) A detailed review of the appropriate job description, including a demonstration of equipment and procedures required of the specific position to which the employee will be assigned.

(5) Review of ethical considerations and confidentiality in resident care and records.

(6) For direct care staff, personal introduction to, and instruction in, the particular needs of each resident to whom the employee will be providing care.

(7) Documentation of the orientation in the employee's personnel record by the person supervising the orientation and that the employee has demonstrated sufficient knowledge to properly carry out the job.

(d) Each nurse aide without one (1) year of experience in a health care setting who is hired after January 1, 1985, to work in a facility shall have successfully completed a nurse aide training program approved by the division or shall enroll in the first available

approved training program scheduled to commence within sixty (60) days of the date of the nurse aide's employment. The program may be established by the facility or by an organization or institution. The training program shall consist of at least the following:

(1) Thirty (30) hours of classroom instruction within one hundred eighty (180) days of employment. At least fifteen (15) of these hours shall be given before the nurse aide is assigned direct resident care duties. The instruction shall include orientation to the:

(A) facility;
(B) facility policies;
(C) employee's duties;
(D) basic nursing skills;
(E) clinical practice;
(F) resident safety and rights; and
(G) social and psychological problems of residents.

The thirty (30) hours may not be counted toward a facility's required staffing.

(2) Seventy-five (75) hours of supervised training. These hours shall consist of normal employment as a nurse aide under the supervision of a licensed nurse. The seventy-five (75) hours shall be counted toward the facility's required staffing.

(e) There shall be an organized ongoing in-service education and training program planned in advance for all personnel in all departments. This training shall include, but is not limited to, prevention and control of infection, fire prevention, safety and accident prevention, and the needs of specialized populations served, that is, the aged, developmentally disabled, mentally ill, or children, as follows:

(1) In-service training programs shall contain means to assess learning by participants. These may include testing such as self-graded, before-and-after tests, clinical practice sessions under close supervision, or instructor assessment.

(2) In-service programs shall be designed to enable the staff to meet the needs of residents.

(3) The frequency and content of in-service education and training programs shall be in accordance with the skills and knowledge of the facility personnel.

(4) Monthly in-service training shall be conducted for the nursing staff. In addition, for personnel administering medications, no less than eight (8) programs on medication administration shall be offered per year.

(5) Annual in-service training shall be conducted for all nursing personnel on supportive therapy measures, that is:

(A) range of motion;
(B) transfers;
(C) positioning;
(D) supportive use of hearing aids; or
(E) self-help feeding devices.

(6) Programs shall be offered at least quarterly for all departments.

(7) The administrator may approve attendance at outside workshops and continuing education programs that are related to that individual's responsibilities in the facility. Documented attendance at these workshops and programs meets the requirements for in-service training.

(8) In-service records shall be maintained and shall indicate the following:

(A) Time, date, and location.
(B) Name of instructor.
(C) Title of instructor.
(D) Name of participants.
(E) Program content of in-service.

The employee will acknowledge attendance by written signature.

(f) A physical examination shall be required for each employee of a facility at the time of employment. The examination shall include a tuberculin skin test, using the Mantoux method (5 TU PPD), unless a previously positive reaction can be documented. The result shall be recorded in millimeters of induration with the date given, date read, and by whom administered. The facility must assure the following:

(1) At the time of employment, and at least annually thereafter, employees and nonpaid personnel of facilities shall be screened for tuberculosis. For health care workers who have not had a documented negative tuberculin skin test result during the preceding twelve (12) months, the baseline tuberculin skin testing should employ the two-step method. If the first step is negative, a second test should be performed one (1) to three (3) weeks after the first step. The frequency of repeat testing will

depend on the risk of infection with tuberculosis.

(2) All employees who have a positive reaction to the skin test shall be required to have a chest x-ray and other physical and laboratory examinations in order to complete a diagnosis.

(3) The facility shall maintain a health record of each employee that includes:

(A) a report of the preemployment physical examination; and

(B) reports of all employment-related health examinations.

(4) An employee with symptoms or signs of active disease, (symptoms suggestive of active tuberculosis, including, but not limited to, cough, fever, night sweats, and weight loss) shall not be permitted to work until tuberculosis is ruled out.

(g) Each facility shall maintain current and accurate personnel records for all employees. The personnel records for all employees shall include the following:

(1) Name and address of employee.

(2) Social Security number.

(3) Date of beginning employment.

(4) Past employment, experience, and education if applicable.

(5) Professional licensure or registration number if applicable.

(6) Position in the facility and job description.

(7) Documentation of orientation to the facility and to the specific job skills.

(8) Signed acknowledgment of orientation to resident rights.

(9) Performance evaluations in accordance with facility policy.

(10) Date and reason for separation.

(h) The employee personnel record shall be retained for at least three (3) years following termination or separation of the employee from employment.

(i) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b), (c), (d), (e), or (f) is a noncompliance; and

(2) subsection (g) or (h) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-5-1.4; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1567, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-1.5 Sanitation and safety standards

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 1.5. (a) Each facility shall be clean, orderly, and in a state of good repair, both inside and out, and shall provide reasonable comfort for all residents.

(b) Each facility shall maintain equipment and supplies in a safe and operational condition and in sufficient quantity to meet the needs of the residents.

(c) Each facility shall not have more residents or beds set up for use than the number for which it is licensed, except in the case of emergency when temporary permission may be granted by the director.

(d) Each facility shall store inactive clinical records in a safe and accessible manner. The storage facilities shall provide protection from vermin and unauthorized use.

(e) Each facility shall comply with fire and safety standards, including the applicable rules of the state fire prevention and building safety commission (675 IAC) where applicable to health facilities.

(f) Each facility shall maintain buildings, grounds, and equipment in a clean condition, in good repair, and free of hazards that may adversely affect the health and welfare of the residents or the public as follows:

(1) Each facility shall establish a written program for maintenance to ensure the continued upkeep of the facility.

(2) The electrical system, including appliances, cords, switches, alternate power sources, fire alarm and detection systems, and emergency communication and signaling systems, shall be maintained to guarantee safe functioning and compliance with state electrical codes.

(3) All plumbing shall function properly and comply with state plumbing codes.

(4) At least yearly, heating and ventilating systems shall be inspected.

(g) Each facility shall routinely clean articles and surfaces as follows:

(1) Cleaning schedules and procedures shall be accessible to and followed by employees and shall indicate the areas of the facility that shall be cleaned daily, weekly, and monthly.

(2) Housekeeping personnel shall utilize accepted practices and procedures to keep the facility free from offensive odors and the accumulation of dust, rubbish, dirt, and hazards, including the following:

(A) Floors in resident areas shall be maintained in a clean condition.

(B) Toilet and bathing areas shall be thoroughly cleaned at least daily and sanitized as needed.

(C) All furniture, bedding, and equipment shall be cleaned as often as necessary to maintain a sanitary environment, but at least monthly and before use by another resident.

(D) Deodorizers shall not be used to cover up odors caused by unsanitary conditions.

(E) Janitor's closets, service sinks, and storage areas shall be cleaned and maintained to meet the needs of the facility.

(F) Storage areas, attics, or cellars shall be kept safe and free from accumulation of unserviceable articles.

(G) Cleaning supplies and equipment shall be stored in a safe and secure manner. Residents shall not have access to any cleaning agents, bleaches, or other poisonous or flammable materials.

(H) Mop heads shall be removable and changed as often as necessary to assure that the mop head in use is clean and free of odors.

(I) Polishes used for floors shall provide a nonslip finish.

(3) Employees engaged in housekeeping or laundry functions shall not be simultaneously involved in the preparation of food.

(4) A person qualified by experience and training shall be in charge of the housekeeping department.

(5) If the facility has a contract with an outside resource for housekeeping services, the outside resource shall meet the requirements of this subsection.

(h) Each facility shall have a pest control program in operation in compliance with 410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*.

(i) Each facility shall have a policy concerning pets. Pets may be permitted in a facility but shall not be allowed to create a nuisance or safety hazard.

(j) Any pet housed in a facility shall have periodic veterinary examinations and required immunizations.

(k) Each facility shall handle, store, process, and transport clean linen in a safe and sanitary manner as follows:

(1) Clean linen shall be stored, handled, and transported in a way that prevents contamination. Personnel handling clean or soiled linen shall hold it in such a manner to prevent contamination of the linen or the employee.

(2) Clean linen from a commercial laundry shall be delivered to a designated clean area in a manner that prevents contamination.

(3) Linens shall be maintained in good repair.

(4) The supply of clean linens, washcloths, and towels shall be sufficient to meet the needs of each resident. The use of common towels, washcloths, or toilet articles is prohibited.

(l) Each facility shall handle, store, process, and transport soiled linen in a manner that will prevent the spread of infection as follows:

(1) Soiled linen shall be sorted by methods affording protection from contamination.

(2) Soiled linens shall be stored and transported in a closed container that does not permit contamination of corridors and precludes contamination of clean linen.

(3) When laundry chutes are used to transport soiled linens, the chutes shall be maintained in a clean and sanitary state.

(m) Each facility shall handle, store, process, and transport resident clothing in a clean and orderly manner. If the resident's clothing is laundered by the facility, the facility shall identify the clothing in a suitable manner. The facility is only responsible for marking that clothing that is recorded on the resident's inventory sheet.

(n) Each facility shall observe safety precautions when oxygen is stored or administered as follows:

(1) Oxygen containers shall be suitably anchored to the bed, floor, wall, or carrier to prevent the containers from tipping over.

(2) Oxygen containers when not in use shall be stored in an unheated room vented to the outside or in an outside secured area. Building code standards shall apply.

(3) “Oxygen–No Smoking” signs shall be posted on the outside of the door and the inside of the door of a resident room in which oxygen is being administered.

(o) Each facility shall keep all kitchens, kitchen areas, equipment, and utensils clean, free from litter and rubbish, and maintained in good repair in accordance with 410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*.

(p) Each facility shall have an effective garbage and waste disposal program in accordance with 410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]*. Provision shall be made for the safe and sanitary disposal of solid waste, including dressings, needles, syringes, and similar items.

(q) Each facility's food supplies shall meet the standards of 410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]* as follows:

(1) At least a twenty-four (24) hour supply of perishable food and a three (3) day supply of staple food shall be maintained on the premises to meet the planned menu.

(2) The three (3) day supply of staple foods shall include a variety of canned or processed foods from each of the four (4) basic food groups for serving meals to the residents for a minimum of three (3) days in the event of an emergency or disaster.

(3) Invoices for the preceding three (3) months, showing the amount and kind of food purchased, shall be made available to division staff upon request.

(r) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (e) or (n) is a deficiency;

(2) subsection (a), (b), (c), (f), (g), (h), (j), (k), (l), (m), (o), (p), or (q) is a noncompliance; and

(3) subsection (d) or (i) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-5-1.5; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1569, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-1.6 Physical plant standards

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-2; IC 16-28-5-1

Sec. 1.6. (a) This section applies to residential facilities licensed under IC 16-28-2.

(b) Each facility shall make provisions for the handicapped as required by state or federal codes.

(c) Each facility shall have adequate plumbing, heating, and ventilating systems as governed by applicable rules of the fire prevention and building safety commission (675 IAC). Plumbing, heating, and ventilating systems shall be maintained in normal operating condition and utilized as necessary to provide comfortable temperatures in all areas.

(d) After July 1, 1987, each facility shall have an adequate air conditioning system, as governed by applicable rules of the fire prevention and building safety commission (675 IAC). The air conditioning system shall be maintained in normal operating condition and utilized as necessary to provide comfortable temperatures in all resident and public areas.

(e) Each facility shall use an approved public water supply if available. Water service shall be adequate, brought into the building and installed in compliance with state and local requirements, and free of cross connections. If a private water supply is used, the facility shall comply with appropriate laws and rules.

(f) Sewage shall be discharged into an approved public sewerage system where a system is available. Otherwise, sewage shall be collected, treated, and disposed of in an independent system that complies with appropriate laws and rules.

(g) Each facility shall have, for each room used for dining, living, or sleeping purposes, light and ventilation by means of outside windows with an area equal to one-tenth ($^1/_{10}$) of the total floor area of such rooms, up to eighty (80) square feet per bed for rooms occupied by more than one (1) person and one hundred (100) square feet for single occupancy.

(h) Each facility shall have natural lighting augmented by artificial illumination, when necessary, to provide light intensity and to avoid glare and reflective surfaces that produce discomfort and as indicated in the following table:

Minimum Average Area	Foot-Candles
Corridors and interior ramp	15
Stairways and landing	20
Recreation area	40
Dining area	20
Resident care room	20
Nurses' station	40
Nurses' desk for charts and records	60
Medicine cabinet	75

Utility room	15
Janitor's closet	15
Reading and bed lamps	20
Toilet and bathing facilities	20
Food preparation surfaces and utensil washing facilities	70

(i) Each facility shall house residents only in areas approved by the director for resident housing and given a fire clearance by the state fire marshal. Each facility must comply with the following:

(1) Five (5) resident beds per room shall be the maximum bedroom capacity.

(2) A facility initially licensed prior to January 1, 1964, must provide not less than sixty (60) square feet per bed in multiple occupancy rooms. A facility initially licensed after January 1, 1964, must have at least seventy (70) square feet of usable floor area for each bed. Any facility that provides an increase in bed capacity, with plans approved after December 19, 1977, must provide eighty (80) square feet of usable floor area per bed.

(3) Any room utilized for single occupancy must be at least eight (8) feet by ten (10) feet in size with a minimum ceiling height of eight (8) feet. A new facility, plans for which were approved after December 19, 1977, must contain a minimum of one hundred (100) square feet of usable floor space per room for single occupancy.

(4) Each bed shall have an access aisle not less than three (3) feet wide leading to it. Bed arrangement in a multi-occupancy room shall provide at least three (3) feet between beds. If an access aisle is used as a means of egress, it shall not be less than four (4) feet wide.

(5) Basement rooms shall not be used to house residents. For new construction, plans for which were approved after December 19, 1977, rooms below grade level may be used for resident occupancy if the floor of such a room is not more than three (3) feet below ground level.

(6) The resident shall have the following:

(A) A bed:

(i) of proper size and height for the convenience of the resident;

(ii) with a clean and comfortable mattress; and

(iii) with bedding appropriate to the weather, climate, and the comfort of the resident.

A resident may choose his or her own furniture in compliance with the facility's policy manual.

(B) The bed linen, consisting of at least two (2) sheets, a pillowcase for each pillow, and a mattress pad, if required, shall be changed as necessary but not less than once a week.

(C) A blanket and/or bedspread shall be provided and shall be changed as necessary, although a bedspread is not required for a bedfast resident.

(D) Additional clean pillows shall be available for the positioning and comfort of residents.

(7) Each individual resident shall be provided with a complete bedside unit; however, the resident may choose not to use this bedside unit. This unit shall include, but is not limited to, the following:

(A) Bedside cabinet or table with hard surface and washable top.

(B) Private closet space.

(C) Cushioned comfortable chair.

(D) Reading or bed lamp.

(E) If the resident is bedfast, an adjustable over-the-bed table or other suitable device.

(8) Cubicle curtains or screens are not required in a licensed residential facility or in the residential distinct part of a facility, but cubicle curtains or screens must be provided if requested by a resident.

(9) Each facility shall provide an adequate method by which each resident may summon a staff person at any time.

(10) Each resident bedroom shall have a door that swings into the room and opens directly into the corridor or common living area.

(11) Each resident room shall be labeled with a raised or indented number (if approved prior to 1974) or letter, or combination of both.

(12) A resident shall not be housed in such a manner as to require passage through the room of another resident. Bedrooms shall not be used as a thoroughfare.

(13) Hallways and corridors shall not be used as sleeping rooms; use for other purposes may not violate fire codes.

(j) Each facility shall have adequate toilet and bathing facilities as follows:

(1) Bathing facilities for residents not served by bathing facilities in their rooms shall be provided as follows:

Residents	Bathtubs or Showers
3 to 22	1
23 to 37	2
38 to 52	3
53 to 67	4
68 to 82	5
83 to 97	6

Portable bathing units may be substituted for one (1) or more of the permanent fixtures with prior approval of the director.

(2) Central bathing and toilet facilities shall be partitioned or curtained for privacy.

(3) Toilets, bath, and shower compartments shall be separated from rooms by solid walls or partitions that extend from the floor to the ceiling.

(4) Toilet facilities shall be provided as follows:

Residents of the Same Sex	Toilets	Open-Front Lavatories
3 to 18	1	1
19 to 30	2	2
31 to 42	3	3
43 to 54	4	4
55 to 66	5	5
67 to 78	6	6

(5) Rubber mats or other suitable safety measures shall be used in bathing facilities. Grab bars shall be installed within easy reach of the bather. Additional adaptive equipment for the multi-handicapped shall be provided as needed.

(6) Hot water temperature for all bathing and hand washing facilities shall be controlled by an automatic control valve. Water temperature at point of use must be maintained between one hundred degrees Fahrenheit (100°F) and one hundred twenty degrees Fahrenheit (120°F).

(7) The use of common towels, washcloths, or toilet articles is prohibited. Each facility shall maintain towels and washcloths in a satisfactory condition for each resident. Individual towel bars shall be provided in the resident's room.

(k) Each facility shall have a nurses' station in a convenient location in the nursing area. The nurses' station shall be equipped with the following:

(1) A desk.

(2) A chair.

(3) Records storage.

(4) A bookshelf for references.

(5) A bulletin board.

(6) A telephone for staff use.

(l) Each facility shall have a nourishment pantry or station for supplemental food service.

(m) Ice shall be available at all times in the facility.

(n) Each facility that administers medication to residents shall provide a medicine station for convenient and prompt twenty-four (24) hour distribution of medicine to residents as follows:

(1) The medicine preparation room shall be under the visual control of the nursing staff, be located adjacent to the nurses' station, and contain a well-lighted work counter, refrigerator, and locked storage for biochemicals and drugs.

(2) The medication preparation room shall have provision of water for hand washing and for medication administration.

(3) If medicine dispensing carts are used, a specific space shall be provided in the nurses' station, medication room, or an alcove or other space under direct control of the nursing staff. The nurses' station shall have provision for hand washing and water for medication purposes.

(4) The medicine room shall be clean, orderly, and used for the storage of drugs, nursing supplies, and first aid supplies.

(o) Each facility shall have equipment storage rooms for storage of equipment such as wheelchairs, walkers, or bed rails, so as not to interfere with the operation of any department or be inconvenient for residents or personnel. A hallway shall not be used for the storage of equipment.

(p) Each facility shall have living areas with sufficient space to accommodate the dining, activity, and lounge needs of the residents and to prevent the interference of one (1) function with another as follows:

(1) In a facility licensed prior to June 1970, the lounge area, which may also be used for dining, shall be a minimum of ten (10) square feet per bed.

(2) In a facility licensed since June 1970, total dining, activity, and lounge area shall be at least twenty (20) square feet per bed.

(3) Dining, lounge, and activity areas shall be:

(A) readily accessible to wheelchair and ambulatory residents; and

(B) sufficient in size to accommodate necessary equipment and to permit unobstructed movement of wheelchairs, residents, and personnel responsible for assisting, instructing, or supervising residents.

(4) Dining tables of the appropriate height shall be provided to assure access to meals and comfort for residents seated in wheelchairs, geriatric chairs, and regular dining chairs. Facilities having continuing deficiencies in the service of resident meals directly attributable to inadequacies in the size of the dining room or dining areas shall submit a special plan of correction detailing how meal service will be changed to meet the residents' needs.

(5) A comfortably furnished resident living and lounge area shall be provided on each resident occupied floor of a multi-story building. This lounge may be furnished and maintained to accommodate activity and dining functions.

(6) The provision of an activity area shall be based on the level of care of the residents housed in the facility. The facility shall provide the following:

(A) Equipment and supplies for independent and group activities and for residents having special needs.

(B) Space to store recreational equipment and supplies for the activities program within or convenient to the area.

(C) Locked storage for potentially dangerous items such as scissors, knives, razor blades, or toxic materials.

(D) In a facility for which plans were approved after December 19, 1977, a restroom large enough to accommodate a wheelchair and equipped with grab bars located near the activity area.

(q) Each facility shall have an adequate kitchen that complies with 410 IAC 7-15.1 *[410 IAC 7-15.1 was repealed filed Mar 30, 2000, 3:51 p.m.: 23 IR 1984.]* as follows:

(1) The kitchen shall be properly located for efficient food service and be large enough to accommodate the equipment and personnel needed to prepare and serve the number of meals required.

(2) Available storage space in a room adjacent to or convenient to the kitchen shall be provided for at least a three (3) day supply of staple food both for normal and emergency needs.

(3) A supervisory work area, not necessarily in the kitchen, but including space for at least one (1) desk, chair, bookshelf, and filing cabinet, shall be provided.

(4) Facilities having continuing food service deficiencies that are directly attributable to inadequacies in the size of the kitchen, food storage area, food preparation or dish washing area or to inadequacies in furnishings, equipment or arrangement will require a special plan of correction. The plan of correction shall be prepared by a person having knowledge in the design of food service operations, such as a registered dietitian, food facilities consultant, or licensed architect or registered engineer.

(5) This rule does not preclude the development of alternate food preparation and service systems. If a facility wishes to implement an alternate system, a written proposal and plan of operation shall be submitted to the director for review and approval.

(r) Each facility shall have a janitor's closet conveniently located on each resident-occupied floor of the facility. The janitor's closet shall contain a sink or floor receptacle and storage for cleaning supplies. The door to the janitor's closet shall be equipped with a lock and shall be locked when hazardous materials are stored in the closet.

(s) Each facility shall have laundry services either in-house or by contract as follows:

(1) If a facility operates its own laundry, the laundry shall be:

(A) designed and operated to promote a flow of laundry from the soiled utility area toward the clean utility area to prevent contamination;

(B) adequate in size, well lighted, and ventilated to meet the needs of the facility;

(C) equipped with suitable capacity machines that shall be kept in good repair and maintained in a sanitary condition; and

(D) maintained in a clean and sanitary condition.

(2) If a facility does not maintain a laundry on the premises, a commercial laundry shall be utilized.

(3) Laundry areas shall have, at a minimum, the following:

(A) Separate areas for the storage of clean linen and soiled linen.

(B) Hand washing and toilet facilities maintained at locations convenient for laundry personnel.

(C) Separate linen carts appropriately labeled for soiled or clean linen and constructed of washable materials that shall be laundered or suitably cleaned as needed to maintain sanitation.

(4) Written procedures for handling, storage, transportation, and processing of linens shall be posted in the laundry and shall be implemented.

(t) Each facility that has a beauty or barber shop shall locate it in a separate room in accordance with the facility's policy for hair care. Provisions shall be made for the disinfection of equipment used, such as brushes, combs, or hair rollers. The room shall be equipped with a shampoo sink that is installed and maintained in accordance with applicable plumbing codes.

(u) Each facility that provides living quarters for owners, managers, employees, and their families shall provide them in a manner that will not interfere with the privacy, well-being, comfort, and safety of the residents.

(v) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (d) is a deficiency;

(2) subsection (c), (e), (f), (h), (i), (j), (k), (l), (m), or (o) is a noncompliance; and

(3) subsection (a), (b), (g), (n), (p), (q), (r), (s), (t), (u), or (v) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-5-1.6; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1571, eff Apr 1, 1997; errata filed Jan 10, 1997, 4:00 p.m.: 20 IR 1593; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-1.7 Physical plant standards after July 1, 1984

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 1.7. (a) This section applies to facilities and additions to facilities for which construction plans are submitted for approval after July 1, 1984.

(b) If, after July 1, 1984, a facility engages in a building addition that directly affects resident services, then the existing physical plant shall be evaluated by a licensed architect, registered engineer, or other appropriate professional and if necessary upgraded to meet the needs of the facility. The recommendations from the evaluation shall be incorporated into the building expansion plan filed with the board.

(c) Any new facility for which plans are submitted for approval after July 1, 1984, shall be as follows:

(1) Be located on a well-maintained, all-weather road and near a community that can provide the necessary supportive services for the facility, such as fire protection, medical services, and public utilities.

(2) Be in a district that has been designated by ordinance as suitable for a health facility. If there is no applicable ordinance, then in a clean, quiet, and safe area and not in a flood plain, and avoiding proximity to health hazards or nuisance conditions.

(3) Be located on a lot large enough to accommodate outdoor activities and to permit emergency vehicles, such as fire protection apparatus, access to the building as required by local and state building codes.

(4) Be planned and constructed to provide off-street parking in accordance with local ordinances or the state building commissioner for the maximum number of employees on duty at any one (1) time and visitors.

(5) Provide parking space for the physically handicapped.

(d) A room made available for isolation or for a seriously ill resident shall be equipped with a private toilet and hand washing facilities.

(e) At least one (1) toilet and lavatory shall be provided for each eight (8) residents. At least one (1) toilet and one (1) lavatory of the appropriate height for a resident seated in a wheelchair shall be available for each sex on each floor utilized by residents as follows:

(1) Toilet rooms adjacent to resident bedrooms shall serve no more than two (2) resident rooms or more than eight (8) beds.

(2) The toilet room shall contain a toilet, lavatory, liquid soap, and disposable towel dispenser.

(3) Each resident shall have access to a toilet and lavatory without entering a common corridor area.

(f) All bathing and shower rooms shall have mechanical ventilation.

(g) The nourishment pantry shall contain:

(1) a refrigerator for resident food;

(2) storage cabinets;

(3) hot plate, burner top, or equivalent means to heat water or food;

(4) hand washing lavatory with soap and disposable towels; and

(5) soiled dish holding equipment.

(h) The total area for resident dining, activities, and lounge purposes shall not be less than thirty (30) square feet per bed.

(i) The food preparation and serving areas of the kitchen shall be a minimum area of at least two hundred (200) square feet with additional space according to the needs of the facility.

(j) Resident rooms shall not contain more than four (4) residents' beds per room.

(k) Each resident room shall have clothing storage that includes a closet at least two (2) feet wide and two (2) feet deep, equipped with an easily opened door and a closet rod at least eighteen (18) inches long of adjustable height to provide access by residents in wheelchairs. The closet should be tall enough that clothing does not drag on the floor and to provide air circulation. A dresser, or its equivalent in shelf and drawer space equal to a dresser with an area of at least four hundred thirty-two (432) square inches, equipped with at least two (2) drawers six (6) inches deep to provide for clothing, toilet articles, and other personal belongings, shall also be provided.

(l) If the facility provides therapy, the facility shall have a therapy area.

(m) For purposes of IC 16-28-5-1, a breach of any subsection (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), or (l) is a nonconformance. *(Indiana State Department of Health; 410 IAC 16.2-5-1.7; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1574, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-5-2 Assessment

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 2. (a) An assessment of the individual needs of each resident shall be initiated prior to admission and shall be updated at least semiannually.

(b) The preadmission evaluation (interview) shall provide the baseline information for the initial assessment. Subsequent assessments shall compare the resident's current status to his status on admission and shall be used to assure that the care the resident requires is within the range of personal care and supervision provided by a residential care facility.

(c) The scope and content of the assessment shall be delineated in the facility policy manual, but at a minimum the needs assessment shall include an evaluation of the following:

(1) Each resident's physical and mental ability to manage his own affairs.

(2) Each resident's independence in the activities of daily living.

(3) Each resident's weight taken on admission and semiannually thereafter.

(4) Each resident's height measured on admission.

(d) The assessment shall be documented in writing, kept in the facility, and used by the facility personnel in meeting the medical and psychosocial needs of the resident.

(e) For purposes of IC 16-28-5-1, a breach of any subsection (a) through (d) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-5-2; filed May 2, 1984, 2:50 p.m.: 7 IR 1497; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1575, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-5-3 Medical and dental services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 3. (a) Each resident shall have a designated physician and dentist selected by the resident.

(b) Within forty-eight (48) hours of admission, the administrator shall obtain from the attending physician a signed medical examination record, including prescribed medicines and diet restrictions, if applicable. Such orders shall be updated at least semiannually. Each facility shall choose whether or not they administer medication to residents. This policy shall be delineated in the facility policy manual.

(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-5-3; filed May 2, 1984, 2:50 p.m.: 7 IR 1497; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1575, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-5-4 Health services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 4. (a) Personal care and supervision shall be provided based upon individual needs as follows:

(1) Each resident shall be assisted in or occasionally given personal care, as needed.

(2) Each resident shall show evidence of good personal hygiene and clean clothing.

(b) Personnel shall supervise the nutritional status of the residents.

(c) Bedside medications and treatments for self-administration shall be permitted with the approval of the resident's attending physician, unless self-administration of medications is contraindicated by the facility's policy.

(d) The administration of drugs and treatments, including alcoholic beverages, nutrition concentrates, and therapeutic supplements, shall be as ordered by the attending physician and shall be supervised by a licensed nurse on the premises or on call as follows:

(1) Medication shall be administered by licensed nursing personnel or qualified medication aides. If medication aides handle or administer drugs or perform treatments requiring medications, the facility shall ensure that the person or persons have been properly qualified in medication administration by a state-approved course except as limited in subdivision (6).

(2) The resident shall be observed for effects of medications. Documentation of any undesirable effects shall be contained in the clinical record. The physician shall be notified immediately if undesirable effects occur, and such notification shall be documented in the clinical record.

(3) The individual administering the medication shall document the administration in medication and treatment records, including records of oxygen administration, that indicate the time, name of medication or treatment, dosage (if applicable), and name or initials of the person administering the drug or treatment as follows:

(A) Notations shall describe nursing care provided and the reason for and results of all per required need (PRN) treatments and medications administered.

(B) The facility may use a separate medication or treatment sheet to record the information and the medication or treatment sheet may be kept separately from the nurses' notes until completed.

(C) Completed medication or treatment sheets shall be added to each individual resident's record.

(4) Medication shall be administered by the person who has prepared the doses, except under a single unit dose package system.

(5) Preparation of doses for more than one (1) scheduled administration is not permitted.

(6) Injectable medications shall be given only by licensed personnel.

(7) No medication shall be used for any resident other than the resident for whom it was prescribed.

(8) PRN medications may be administered by qualified medication aides (QMAs) only upon authorization by a licensed nurse or physician. All contacts with a nurse or physician not on the premises for authorization to administer PRNs shall be documented in the nursing notes indicating the time and date of the contact.

(9) Any error in medication administration shall be noted in the resident's record. The physician shall be notified of any error in medication administration, when there are any actual or potential detrimental effects to the resident.

(e) If treatment(s) not involving medication are given by facility personnel, the treatment(s) shall be prescribed by the physician and shall be instituted using proper and safe techniques as follows:

(1) Treatments not involving medications may be given by nurse aides who have been instructed in the administration of the treatment by licensed nursing personnel. All PRN treatments, not involving medications, may be given only upon authorization by a licensed nurse.

(2) The resident shall be observed for effects of the treatment. Documentation of any undesirable effect shall be contained in the clinical record and the physician shall be notified. Such notification shall be documented in the clinical record.

(3) The person who has administered the treatment shall document such in accordance with subsection (d)(3).

(f) The facility shall have available on the premises or on call the services of a licensed nurse at all times. The licensed nurse may, at the request of a resident, provide consultation and advice to residents, review clinical records, and assess the health condition of the residents. If medications are administered by the facility, then the facility shall provide at least ten (10) minutes of licensed nursing care per resident receiving medication during each two (2) week period.

(g) The facility shall develop, adopt, and implement a manual of written policies and procedures on cleaning, disinfecting, and sterilization. All procedures shall be carried out in accordance with the manual, which shall be available for the use of the facility

personnel. The manual shall include procedures in the care of utensils, instruments, solutions, dressings, articles, and surfaces, including, but not limited to, the following:

(1) Bedside equipment such as commode pails, wash basins, emesis basins, bedpans, and urinals shall be maintained in a clean condition and disinfected as appropriate. Bedside equipment shall be washed and rinsed and then disinfected daily, if used by the same resident or after each use between residents by one (1) of the following techniques:

(A) Immersion for at least two (2) minutes in clean, hot water at a temperature of at least one hundred seventy degrees Fahrenheit (170°F).

(B) Immersion in a clean solution containing an appropriate disinfecting agent that will provide the equivalent bactericidal effect of a solution containing at least one hundred (100) parts per million of available chlorine as hypochlorite at a temperature between seventy-five degrees Fahrenheit (75°F) and one hundred ten degrees Fahrenheit (110°F) for at least one (1) minute.

(C) Mechanical utensil washing by a machine capable of rendering the bedside equipment clean and disinfecting by means of hot water or chemicals.

(D) Steam operated sterilizer.

(2) Bathing tubs shall be disinfected after each use.

(3) Bedside equipment and eating or drinking utensils shall not be commingled during the disinfection process.

(4) Individualized resident care supply items designed and identified by the manufacturer to be disposable shall not be reused and shall be destroyed.

(h) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (d) or (e) is a deficiency; and

(2) subsection (a), (b), (c), (f), or (g) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-5-4; filed May 2, 1984, 2:50 p.m.: 7 IR 1497; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1576, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-5 Food and nutrition services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 5. (a) Each facility shall meet the following requirements related to food and nutrition services:

(1) Food served to residents each day shall be sufficient in quantity and quality to meet nutritional needs. The current Recommended Dietary Allowances of the Food and Nutrition Board of the National Research Council with consideration given to medical condition, age, sex, activity, food habits, and cultural background shall be the standard used for the evaluation of regular and modified diets. Unless a specific nutrient restriction is prescribed by the physician, at a minimum, the daily food allowance planned and served shall include the following:

(A) Two (2) or more cups of milk (fluid whole, two percent (2%), skim, or buttermilk) or equivalent shall be served as a beverage or used in cooking daily for mature adults. Four (4) or more cups of milk or equivalent shall be served to children over ten (10) years of age and teenagers. Three (3) or more cups of milk or equivalent shall be served to children under ten (10) years of age.

(B) Five (5) ounces of meat, poultry, fish, or protein equivalent shall be provided daily to adults and teenagers. Three (3) ounces of meat, poultry, fish, or protein equivalent shall be provided daily to children under ten (10) years of age.

(C) Two (2) cups of fruits and vegetables or equivalent shall be served daily. One (1) serving (one-half (½) cup) of a good source of vitamin C daily and one (1) serving (one-half (½) cup) of vitamin A at least four (4) times weekly shall be served.

(D) Four (4) or more servings of breads and cereal, whole grain or enriched, shall be served daily.

(E) Three (3) or more teaspoons of butter or fortified margarine shall be served daily (as spread or used in cooking).

(F) Other foods shall be served as necessary to satisfy individual appetites, improve the flavor and variety of the meals, and meet individual needs for calories and other nutrients.

(2) At least three (3) well-planned meals shall be served at regularly scheduled hours daily to provide a balanced distribution of the daily nutrition requirements as follows:

(A) Not less than a two (2) ounce portion of meat or another protein rich food shall be planned and served at each midday and evening meal to contribute to the minimum of five (5) ounces of protein rich food per day.

(B) Not less than the equivalent of a one-half (½) cup serving of a fruit or vegetable shall be planned and served in each meal to contribute to the minimum of two (2) cups of fruit and vegetables per day.
(C) The evening meal and the succeeding breakfast shall be served no more than fourteen (14) hours apart.
(D) Between meal feedings shall be provided according to the needs of the resident.
(E) Bedtime nourishment consisting of a serving of food and a beverage in accordance with the planned menu shall be offered to each resident unless contraindicated by the physician in writing.
(F) The menus for all diets, regular or modified, shall be as follows:
(i) Approved by the dietitian.
(ii) Prepared in writing and available at the facility at least one (1) week in advance of service. The menu shall be clean and legible.
(iii) Developed to include a variety of foods prepared by diverse methods and adjusted to include seasonal commodities.
(iv) Dated for the current week on the face of the menu.
(v) Posted to be visually accessible in the cooking area and the service area.
(vi) Specific as to each kind of food, the method of preparation, and the amount to be served on each individually planned diet.
(vii) Followed in the preparation of resident's meals as follows:
(AA) If any food served varies from the planned menu the food substituted shall be of similar nutritive value to the food on the planned menu.
(BB) Menu substitutions or changes shall be noted on or affixed to the face of the posted copy of the menu used to serve meals, and a permanent record of such changes and the reason for the menu change shall be maintained.
(viii) Kept on file for at least six (6) months.
(ix) Updated, reviewed, and revised annually.
(3) Tested recipes appropriate for at least the number of individuals to be served shall be kept on file and shall be used to prepare attractive and palatable meals. Methods described in the recipes and used in the preparation of foods shall be such that the nutritive value, texture, flavor, and appearance of the food are conserved. If commercially prepared items are served, a nutrient analysis of the products shall be available upon request.
(4) All regular and modified diets shall be prescribed by the attending physician. Verbal orders for diet changes may be received and recorded by the registered dietitian or licensed nursing personnel and shall be countersigned and dated on the clinical record by the physician at the physician's next visit to the facility. The food service staff shall have on file a current written diet order for each resident. The diet order shall include the following information:
(A) Name of resident.
(B) Room number.
(C) Type of diet.
(D) Date the diet order was sent to dietary.
(E) Name of physician.
(5) If a clear liquid diet is prescribed, the order shall be confirmed with the physician every forty-eight (48) hours.
(6) Modified diets shall be accurately written in accordance with the facility's diet manual and correctly served as prescribed by the physician.
(7) Nutrient concentrates, that is, pharmaceutically prepared powdered or liquid feedings, shall be given only on the written order of the physician. The physician shall specify if other than commercially processed products shall be used.
(8) All food shall be neatly and attractively served at a palatable and safe temperature.
(9) Durable tableware appropriate to the needs of the resident shall be provided. Tableware shall include, but is not limited to:
(A) flatware (knife, fork, or spoon);
(B) napkin;
(C) dishes; and
(D) glassware;
needed to properly eat the meal, unless a physician's order, or the dietary supervisor with concurrence of the director of nursing, indicates otherwise in accordance with the care plan. Simple self-help devices such as plate guards or scoop plates

shall be provided as designated in the resident's care plan.

(10) Measuring scoops, ladles, and portion scales shall be provided and used when foods are prepared and served.

(11) Attention shall be given to the resident's reasonable food preferences. Records shall be maintained and followed for each resident indicating likes, dislikes, and food allergies. The resident shall be observed to determine acceptance of diet.

(12) Foods served shall be in a form (whole, chopped, or ground) in accordance with the physician's order and consistent with the needs of the resident.

(13) There shall be an organized food service department directed by a supervisor who is competent in food service management and knowledgeable in sanitation standards, food handling, food preparation, and meal service. The supervisor must be one (1) of the following:

(A) A dietitian.

(B) A graduate of a state-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision who has a minimum of one (1) year of experience in some aspect of institutional food service management.

(C) A graduate of a dietetic technician program approved by the American Dietetic Association.

(D) A graduate of an American Dietetic Association approved dietetic assistant course that includes the fundamentals of food service management and nutrition.

(E) A graduate of an accredited college or university with a degree in foods and nutrition or food administration with a minimum of one (1) year of experience in some aspect of food service management.

(F) An individual with training and experience in food service supervision and management in a military service equivalent in content to the program in subdivision (B), (C), (D), or (E).

(14) If the supervisor is not a dietitian, a dietitian shall provide consultant services on the premises at peak periods of operation on a regularly scheduled basis. A written contract delineating the duties of the consultant dietitian and the frequency of visits shall be available.

(15) Food service staff shall be on duty to ensure proper food preparation, serving, and sanitation.

(16) In facilities with sixty (60) residents or fewer, the supervisor may assume cooking or other dietary duties provided these duties do not interfere with the responsibilities of management and supervision, and the time schedule clearly indicates the hours assigned to cooking.

(17) Standard references in food service management, diet therapy, and nutrition shall be available to personnel in the food service department.

(b) Diet orders shall be reviewed and revised by the physician as the resident's condition requires, but at a minimum the diet order shall be reviewed and updated at least annually.

(c) Meals may be served family or cafeteria style if the policy manual allows. However, each modified diet shall be individually served, checked for accuracy, and identified with the resident's name, location, and type of diet.

(d) A current diet manual, no more than five (5) years old and approved by the dietitian and physician, shall be provided.

(e) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a) is a deficiency; and

(2) subsection (b), (c), or (d) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-5-5; filed May 2, 1984, 2:50 p.m.: 7 IR 1498; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1577, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-6 Pharmaceutical services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1; IC 25-26-13

Sec. 6. (a) If the residents retain and self-administer medications, the facility shall make arrangements to ensure that pharmaceutical services are available to provide residents with prescribed medications in accordance with applicable laws of Indiana if requested by the residents.

(b) If the facility controls, handles, and administers medications, the facility shall do the following:

(1) Make arrangements to ensure that pharmaceutical services are available to provide residents with prescribed medications in accordance with applicable laws of Indiana.

(2) A consultant pharmacist shall be employed, or under contract, and shall be responsible for the duties as specified in 856

IAC 1-7-7 as follows:

(A) Review the drug handling and storage practices in the facility.

(B) Provide consultation on methods and procedures of ordering, storing, administering, and disposing of drugs as well as medication record keeping.

(C) Report, in writing, to the administrator and director of nursing any irregularities in dispensing or administration of drugs.

(3) Pharmacy consultation shall be provided to licensed personnel.

(4) The consultant pharmacist shall provide written reports to the administrator of the frequency, nature, and duration of the visits to the facility.

(5) The medication review and recommendations shall be documented as well as the notification of the physician, if necessary, in accordance with the facility's policy.

(6) A facility shall not purchase or store anywhere on the premises any drug for a resident except those prescribed or ordered for the individual resident by the physician and those drugs authorized for the emergency kit.

(c) If a facility operates its own duly licensed pharmacy, it shall comply with IC 25-26-13.

(d) The facility shall only utilize a pharmacy that:

(1) complies with the facility policy regarding receiving, packaging, and labeling of pharmaceutical products unless contrary to state and federal laws and rules on pharmacy practices;

(2) provides prescribed drugs, including the availability of a twenty-four (24) hour prescription service on a prompt and timely basis; and

(3) refills prescription drugs, when needed, in order to prevent interruption of drug regimens.

(e) All drugs shall be labeled in compliance with state and federal laws governing prescription dispensing. If the facility receives incorrectly labeled medications, the pharmacy shall be notified immediately. Labeling shall be done as follows:

(1) Labeling shall include the following:

(A) The resident's full name.

(B) The physician's name.

(C) The prescription number.

(D) The name and strength of the drug.

(E) Directions for use.

(F) Date of issue.

(G) An expiration date (when applicable).

(H) The name and address of the pharmacy that filled the prescription.

If a facility is supplied medication in a unit dose packaging, reasonable variations which comply with the acceptable pharmaceutical procedures are permitted.

(2) Nursing supplies, such as hydrogen peroxide, sterile water, rubbing alcohol, nonmedicated skin preparations, and emollients, need not comply with subdivision (1), although such supplies must be in the original manufacturer's container with the manufacturer's label intact.

(3) Therapeutic concentrates, nutritional supplements, and alcoholic beverages shall be labeled in conformance with state and federal food and drug laws. Such items shall be in containers with the original manufacturer's label still intact and legible. Containers of therapeutic concentrates, that is, vitamins or minerals, shall be identified with the resident's name and room number.

(4) No person other than the dispenser of the drug shall alter any prescription label.

(5) The labels on all medications shall be clean and legible. If, in the opinion of the consultant pharmacist or licensed nurse, the labels on the medication are illegible, the medication shall either be relabeled by the issuing pharmacy or destroyed. Containers that are cracked, soiled, or without secure closure shall not be used.

(f) Medicine or treatment cabinets or rooms shall be locked at all times except when authorized personnel are present. These cabinets shall also be used as follows:

(1) The key for the lock of the room or cabinet shall be carried or be accessible to only those persons authorized to handle and administer drugs.

(2) Drugs shall be stored in a clean and orderly manner in cabinets, drawers, or carts of sufficient size to prevent crowding.

(3) All Schedule II drugs individually prescribed shall be kept in individual containers under double lock and stored in a substantially constructed box, cabinet, or mobile drug storage unit.

(4) Bedside medications for self-administration shall be allowed only upon order of the resident's attending physician.

(5) Only authorized personnel shall handle or administer drugs or other therapy as specified in section 4(d) of this rule.

(6) Emergency medication shall be stored in a suitable box or cubicle equipped with a seal.

(g) Discontinued, outdated, or deteriorated medication shall not be maintained or used in the facility. Medications shall be disposed of in compliance with federal, state, and local laws as follows:

(1) All unused portions of any properly labeled medications, including controlled substances, shall be released to the discharged resident upon written order of the physician.

(2) Unopened and unexposed medication may be returned to the issuing pharmacy for credit to the appropriate party.

(3) Unused portions of medications not released with the resident or returned for credit shall be destroyed on the premises within seven (7) days by the consultant pharmacist or licensed nurse with a witness.

(4) Disposition of any released, returned, or destroyed medication shall be written in the resident's clinical record and shall include the following information:

(A) The name of the resident.

(B) The name and strength of the drug.

(C) The prescription number.

(D) The reason for disposal.

(E) The amount disposed of.

(F) The method of disposition.

(G) The date of the disposal.

(H) The signatures of the persons conducting the disposal of the drug.

(h) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b)(1), or (f) is a deficiency; and

(2) subsection (b)(2), (b)(3), (b)(4), (b)(5), (b)(6), (c), (d), (e), or (g) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-5-6; filed May 2, 1984, 2:50 p.m.: 7 IR 1498; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1579, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-7 Activities programs

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 7. (a) An activities program shall be provided by qualified staff with equipment to meet the individual needs and interests of the residents on a daily basis as follows, including evenings and weekends:

(1) An activities program shall have a planned schedule of purposeful individual and group activities.

(2) The schedule shall be designed to:

(A) make the resident's life more meaningful;

(B) stimulate physical and mental capabilities; and

(C) attain the optimal social, physical, and emotional state.

(3) The facility shall have a plan of activities that may include, but is not limited to, the following:

(A) Group social activities.

(B) Indoor and outdoor activities, which may include daily walks.

(C) Activities away from the facility.

(D) Religious programs and attendance at local churches.

(E) Opportunity for resident involvement in planning and implementation of the activities program.

(F) Creative activities, such as arts, crafts, music, drama, and educational programs.

(G) Exercise activities.

(H) One-to-one attention.

(I) Promotion of facility/community interaction.

(4) Participation shall be encouraged, although the final option remains with the resident.

(b) Activities program personnel with appropriate training and experience shall be available to meet the needs and interests of the residents.

(c) An activities director shall be designated and must be one (1) of the following:

(1) A recreation therapist.
(2) An occupational therapist or a certified occupational therapy assistant.
(3) An individual who has satisfactorily completed or will complete within six (6) months an activities director's course approved by the division.
(d) Responsibilities of the activities director shall include, but are not limited to, the following:
(1) Preparing a monthly calendar of activities that is written in large print and posted in a prominent location visible to residents and visitors.
(2) Recruiting, training, and supervising volunteers when appropriate.
(3) Coordinating the activities program with other services in the facility.
(4) Requesting and maintaining equipment and supplies.
(e) After July 1, 1984, any person who has not completed an activities director course approved by the division and is assigned responsibility for the activities program shall receive consultation until the person has completed such a course. Consultation shall be provided by:
(1) a recreation therapist;
(2) an occupational therapist or occupational therapist assistant; or
(3) a person who has completed a division approved course and has two (2) years of experience.
(f) For purposes of IC 16-28-5-1, a breach of subsection (a), (b), (c), (d), or (e) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-5-7; filed May 2, 1984, 2:50 p.m.: 7 IR 1498; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1580, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-5-8 Clinical records

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 8. (a) Each facility shall maintain clinical records as follows:
(1) An accurate and complete written record shall be maintained for each resident. A computerized record is equivalent to a written record. All entries in the clinical records shall be authenticated with date, signature, and title or computer key of the person making the entry. Accurate census data shall be maintained daily for each facility and for each distinct part of a facility, with the census day running from midnight to midnight.
(2) The scope and detail of the record shall be consistent with the facility's policy manual and shall include, at a minimum, the following:
(A) Identification data as follows:
(i) Resident's name.
(ii) Date of birth.
(iii) County of last residence.
(iv) Date of admission.
(v) Name, address, and telephone number of the legal representative.
(vi) Physician's name and telephone number.
(vii) Dentist's name and telephone number.
(viii) Pharmacist's name and telephone number.
(ix) Date of discharge or death.
(B) Inventory, upon admission and discharge, of personal effects, money, and valuables declared by the resident or sponsor at the time of admission.
(C) Progress notes entered in the resident's record by the physician, dentist, or other professionals at the time of each visit to the resident.
(D) Nursing notes, signed and dated at the time of each entry, which shall include the following:
(i) Admitting notes shall include resident's location prior to admission, allergies or sensitivities, if known, time and mode of transportation, room assignment, symptoms and complaints, general condition, skin condition, vital signs, weight, and height of the resident.
(ii) Notations may indicate the following:
(AA) General condition of the resident.

(BB) Any unusual symptoms.
(CC) Failure to take medication.
(DD) Behavior.
(EE) Appetite.

(iii) Notations shall describe nursing care provided and the reason for and results of all per required need (PRN) treatments and medications administered.

(iv) Notations shall indicate visits made by the resident to clinics or hospitals, if known.

(v) The resident's weight shall be documented in the nursing notes or vital records sheet upon admission and semiannually thereafter.

(vi) Notations shall indicate each unusual incident or accident and the action taken.

(vii) All attempts to notify the physician regarding the resident's condition shall be documented in the resident's record, including the time and method of communication, the name and title of the person making the contact, and the name of the person acknowledging the contact, if any.

(viii) The nursing personnel in charge shall be responsible for notifying the resident's physician when in their professional judgment there has been an incident of sufficient magnitude to notify the physician.

(ix) Condition of the resident at the time of discharge or final disposition shall be documented in the nursing notes as follows:

(AA) Discharge or transfer notes shall include the time and mode of transportation, general condition, instructions given to the resident or sponsor, list of medications and disposition, and transfer form, if applicable.

(BB) A transfer form shall include identification data, name of the transferring institution, name of the receiving institution, and date of transfer, resident's personal property, nurses' notes relating to the resident's functional abilities and physical limitations, nursing care, medications, treatment, current diet and condition on transfer, diagnosis, presence or absence of decubitus ulcer, and date of chest x-ray and skin test for tuberculosis.

(CC) A resident who is discharged shall be furnished information for continuity of care in lay terms.

(DD) If a death occurs, information concerning the resident's death shall include notification of the physician and sponsor or surrogate, the disposition of the body, personal possessions and medications, and a complete and accurate notation of the resident's condition and most recent vital signs and symptoms, if any, preceding death.

(E) Medication and treatment records, including records of oxygen administration, that indicate the time, name of medication, or treatment, dosage (if applicable), and name or initials of the person administering the drug or treatment as follows:

(i) Notations shall describe nursing care provided and the reason for and results of all PRN treatments and medications administered.

(ii) The facility may use a separate medication or treatment sheet to record the information and the medication or treatment sheet may be kept separately from the nurses' notes until completed.

(iii) Completed medication or treatment sheets shall be added to each individual resident's record.

(F) Reports of x-rays, laboratory, and other diagnostic examinations as prescribed and completed.

(G) When a medication, treatment, or modified diet is discontinued, the order in writing signed by the physician and dated.

(b) A diagnostic chest x-ray completed no more than six (6) months prior to admission shall be required.

(c) Prior to admission, each resident shall be required to have a health assessment to include history of significant past or present infectious diseases and a statement that the resident shows no evidence of tuberculosis in an infectious stage as verified upon admission and yearly thereafter.

(d) In addition, a tuberculin skin test shall be completed within three (3) months prior to admission or upon admission and read at seventy-two (72) hours. The result shall be recorded in millimeters of induration with the date given, date read, and by whom administered and read.

(e) The baseline tuberculin skin testing should employ the two-step method. If the first step is negative, a second test should be performed within one (1) to three (3) weeks after the first test. The frequency of repeat testing will depend on the risk of infection with tuberculosis.

(f) All residents who have a positive reaction to the tuberculin skin test shall be required to have a chest x-ray and other physical and laboratory examinations in order to complete a diagnosis.

(g) All skin testing for tuberculosis shall be done using the Mantoux method (5 TU PPD) administered by persons having documentation of training from a department approved course of instruction in intradermal tuberculin skin testing, reading, and recording.

(h) Persons with a documented history of a positive tuberculin skin test, adequate treatment for disease, or preventive therapy for infection, shall be exempt from further skin testing. In lieu of a tuberculin skin test, these persons should have an annual risk assessment for the development of symptoms suggestive of tuberculosis, including, but not limited to, cough, fever, night sweats, and weight loss. If symptoms are present, the individual shall be evaluated immediately with a chest x-ray.

(i) A short record form may be used for a resident admitted to the facility for respite care. The facility shall maintain a record of treatments and medications given to the resident and other data necessary to indicate the care provided to the resident. The components of a respite care record shall be defined in the facility's policy manual and shall include, at a minimum, the following:

(1) Identification data.

(2) A description of the resident's condition.

(3) Physician's orders.

(4) A statement that the resident is free of communicable disease, including tuberculosis.

(j) Information contained in the clinical record is confidential and shall be disclosed only to authorized persons.

(k) Current clinical records shall be completed promptly, and those of discharged residents shall be completed within seventy (70) days of the discharge date. The record of each transferred or discharged resident must include a physician's discharge summary, including the following:

(1) Admission diagnosis.

(2) Pertinent findings.

(3) Summary of treatment rendered.

(4) Condition of patient on discharge.

(5) Final diagnosis.

(l) Resident clinical records shall be protected from loss, destruction, or unauthorized use as follows:

(1) Clinical records shall be available to division staff upon request.

(2) Current clinical records shall be kept in the nursing unit during the resident's stay at the facility.

(3) Individual records shall be preserved in the facility for a minimum of one (1) year after discharge of the resident or in accordance with applicable federal and state laws.

(4) Storage of records shall provide for prompt retrieval.

(5) If a facility ceases operation, the division shall be informed within three (3) business days by the licensee of the arrangements made for the safe preservation of the residents' clinical records.

(6) The division shall be informed, in writing, within three (3) business days whenever resident clinical records are defaced or destroyed before termination of the required one (1) year retention period.

(m) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), or (l) is a noncompliance; and

(2) subsection (k) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-5-8; filed May 2, 1984, 2:50 p.m.: 7 IR 1498; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1581, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-5-9 Facility equipment

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28

Sec. 9. (a) Residents may use facility equipment, such as washing machines, if permitted by facility policy.

(b) For purposes of IC 16-10-4-15 *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, a breach of subsection (a) is a nonconformance. *(Indiana State Department of Health; 410 IAC 16.2-5-9; filed May 2, 1984, 2:50 pm: 7 IR 1498; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-5-10 Staffing

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 10. (a) Each residential care facility shall have at least one (1) employee on duty at all times. Residential facilities with over one hundred (100) residents shall have one (1) additional employee on duty at all times for every additional fifty (50) residents or major fraction thereof. In a facility having both comprehensive and residential distinct parts, the employees assigned to the residential distinct part may be stationed and may work in the comprehensive distinct part during the second and third shift. Residential employees assigned to the comprehensive distinct part must be readily available to the residents of the residential distinct part. However, such employees' time does not count toward the staffing requirements of the comprehensive distinct part. In addition, each residential facility shall have a sufficient staff of qualified persons present at all times to assure adequate care of the residents, to maintain the facility in a clean and orderly manner, to do necessary laundry, and to prepare and serve food.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-5-10; filed May 2, 1984, 2:50 p.m.: 7 IR 1498; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1583, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-5-11 Mental illness screening

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 11. (a) As used in this section, "community mental health center" means the community mental health center local to the residential care facility.

(b) The individual needs assessment provided in section 2(a) of this rule shall include, but not be limited to, the following:

(1) Evaluation of the individual for major mental illness.

(2) Obtaining a history of treatment received by the individual for psychiatric conditions.

(3) Obtaining a history of individual behavior that is dangerous to facility residents, the staff, or the individual.

(c) Except as noted in subsection (d), if a person has a mental illness as defined by the residential care facility screening, the person will be referred to the local mental health center for a consultation on needed treatment services. All residents admitted after the effective date of this rule shall have a completed residential care facility screening in their clinical record. All persons admitted after the effective date of this rule shall have the screening completed prior to the admission, and, if a mental health center consultation is needed, the consultation shall be completed prior to the admission and a copy maintained in the clinical record.

(d) When a state hospital refers a person with a mental illness, the residential care facility shall request that a copy of the psychosocial and treatment recommendations collaboratively developed between the state hospital and the mental health center be forwarded to the residential care facility so that the residential care facility can determine the degree to which it can provide or arrange for the provision of such service.

(e) An individual who has been determined to be disabled because of mental illness may be admitted to a home or residential care facility that provides residential care to the extent that funds are available for the provision of such care as provided and/or arranged by the residential care facility for residents with a mental illness.

(f) The residential care facility shall not admit residents with a mental illness if:

(1) the community mental health center determines that the patient's needs cannot be met;

(2) the residential care facility does not have a means to access needed community services to carry out the comprehensive care plan;

(3) the community does not have the needed services to meet the psychosocial rehabilitative needs of the resident; or

(4) the residential care facility or resident does not have the funds, or chooses to not utilize available financial resources, or is otherwise unwilling to pay for the consultation services needed to develop the comprehensive care plan in cooperation with the community mental health center or to pay for the needed services.

(g) Each resident with a mental illness must have a comprehensive care plan that is developed within thirty (30) days after admission to the residential care facility.

(h) The residential care facility, in cooperation with the community mental health center serving the area in which the residential care facility is located, shall develop the comprehensive care plan for the resident that includes the following:

(1) Psychosocial rehabilitation services that are to be provided within the community.

(2) A comprehensive range of activities to meet multiple levels of need, including the following:

(A) Recreational and socialization activities.

(B) Social skills.

(C) Training, occupational, and work programs.

(D) Opportunities for progression into less restrictive and more independent living arrangements.

(3) The residential care facility shall assure that the community mental health center has approved all comprehensive care plans developed pursuant to this section.

(i) The residential care facility shall provide or arrange for services to carry out the resident's comprehensive care plan.

(j) The residential care facility shall seek appropriate alternate placement in accordance with 410 IAC 16.2-2-3 *[410 IAC 16.2-2 was repealed filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588.]* if the resident's needs or comprehensive care plan, or both, cannot be met by the residential care facility.

(k) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (h) or (i) is a deficiency; and

(2) subsection (b), (c), (d), (e), (f), (g), or (j) is a noncompliance.

(Indiana State Department of Health; 410 IAC 16.2-5-11; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1583, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 6. Health Care Facilities for Children

410 IAC 16.2-6-1 Applicability of rule

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-2; IC 16-28-5-1

Sec. 1. This rule applies to facilities that care for children licensed under IC 16-28-2. *(Indiana State Department of Health; 410 IAC 16.2-6-1; filed May 2, 1984, 2:50 p.m.: 7 IR 1498; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1584, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-6-2 Medical and dental services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 2. (a) A complete physical, including an acceptable skin test for tuberculosis, a dental examination, and an evaluation of the child's medical and physical capabilities, shall be completed on the day of admission or not earlier than thirty (30) days prior to admission.

(b) Upon admission, written evidence shall indicate completion of an immunization series for diphtheria, tetanus, rubella, whooping cough, measles, and polio. The age of the child or the written order by the attending physician, contraindicating a new immunization, may alter the series. A planned program for booster immunization shall be maintained for each resident.

(c) For purposes of IC 16-28-5-1, a breach of subsection (a) or (b) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-6-2; filed May 2, 1984, 2:50 p.m.: 7 IR 1499; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1585, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-6-3 Nursing services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 3. (a) Each child shall be given nursing care and supervision based on individual needs.

(b) Nursing care shall include, but is not limited to, providing the following:

(1) Each child shall be bathed or assisted to bathe as frequently as is necessary but at least daily, unless contraindicated by the physician.

(2) Each child shall be dressed in clean clothing at least daily or more often as needed to keep the child clean.

(3) Each child shall be given or assisted in oral care daily.

(4) Each child shall be checked at least every two (2) hours and shall be given a diaper change and clothing change if soiled. Skin care shall be given with each diaper change to prevent pressure sores, heat rashes, or other skin breakdown.

(5) A minimum of two (2) supervised play periods shall be provided daily. Each child shall be taken out of the bed for the play periods unless in the judgment of the charge nurse or physician it is contraindicated due to conditions or medical treatment.

(6) Helpless children shall be protected from active children.

(7) Each child shall be held or placed in a chair for feeding unless otherwise ordered by the attending physician.

(c) The growth and development of each child shall be monitored and encouraged by the following:

(1) Adopting food habits as near as possible to those of normal children.

(2) Obtaining specific diet orders for each child that include the kind, consistency, and quantity of food required. Children shall receive solid foods whenever possible.

(3) Evaluation of the diet order by the physician or dietitian at least every six (6) months.

(4) Obtaining and recording the weight and height on admission.

(5) Subsequent to admission, weights shall be taken and recorded monthly and height measured and recorded as ordered by the physician.

(d) No child shall be restrained except to prevent injury to himself or others, and then, only upon the written order of the physician.

(e) According to his needs, each child shall be taught the activities of daily living, including:

(1) toilet training;

(2) hand washing;

(3) self-feeding; and

(4) social skills.

(f) A program shall be provided for children to participate in daily living activity, that is, household tasks, which is not dangerous or injurious to the health or general welfare of the child.

(g) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (d) is a deficiency;

(2) subsection (b), (c), (e), or (f) is a noncompliance; and

(3) subsection (a) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-6-3; filed May 2, 1984, 2:50 p.m.: 7 IR 1499; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1585, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-6-4 Counseling and educational services

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 4. (a) Group and parent counseling and education shall be provided as indicated in the facility's policy manual to aid in promoting the education of and consultation with the parents. The facility shall notify the educational authority of the admission of a child to the facility and shall comply with applicable state department of public instruction statutes and rules.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a nonconformance. *(Indiana State Department of Health; 410 IAC 16.2-6-4; filed May 2, 1984, 2:50 p.m.: 7 IR 1499; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1585, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-6-5 Personnel

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 5. (a) Each person employed to care for, train, and supervise children shall be capable of exercising good judgment in the handling of children and have knowledge and understanding of the care required for children with special mental, emotional, and physical problems.

(b) All staff shall participate in staff development training programs designed to address the specific problems of the children housed in the facility.

(c) Each employee's health record shall contain evidence of current immunization against polio, diphtheria, rubella, and tetanus

unless contraindicated by a physician who must state that the employee is free of such conditions and qualifies for employment.

(d) If the facility has more than one (1) unit, one (1) nurse or attendant shall be on duty at all times on each unit or section of the building in which children are housed.

(e) Adequate numbers of additional nursing staff shall be on duty at all times to provide proper care, such as frequent change of position, frequent diapering, bathing, careful observation to prevent injury, and for other nursing care responsibilities.

(f) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (d) or (e) is a deficiency;

(2) subsection (b) or (c) is a noncompliance; and

(3) subsection (a) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-6-5; filed May 2, 1984, 2:50 p.m.: 7 IR 1500; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1586, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 16.2-6-6 Physical plant standards

Authority: IC 16-28-1-7; IC 16-28-1-12

Affected: IC 16-28-5-1

Sec. 6. (a) Housing space shall be provided as follows:

(1) At least eighty (80) square feet of floor space shall be provided for each adult-size bed or adult-size crib in sleeping rooms.

(2) At least fifty (50) square feet of floor space shall be provided for each child-size crib in sleeping rooms.

(3) There shall be a minimum of three (3) feet between heads, sides, or feet of beds or cribs.

(4) No more than eight (8) children shall sleep in one (1) bedroom. In facilities or additions to facilities for which plans are submitted for approval after July 1, 1984, no more than four (4) children shall sleep in one (1) bedroom.

(5) Separate bedrooms shall be provided for children of each sex over the age of six (6) years (except where the physician indicates otherwise).

(6) Size and type of beds, bedside cabinets, tables, and chairs shall be appropriate to the age, size, and needs of the children. Double-deck beds, trundle beds, rollaway beds, or cots shall not be used.

(7) There shall be a minimum of one (1) lavatory and one (1) toilet for each eight (8) children, or fraction thereof, and one (1) bathtub, shower, or bathing sink for each twelve (12) children. The fixtures shall be of proper design and installed so as to satisfactorily serve the types of children who will be using them.

(8) There shall be a minimum of one (1) complete bathroom on each floor occupied by children.

(9) Separate toilet rooms shall be provided for boys and girls over six (6) years of age. Partitions between toilet stools shall be provided. Nursery seats and steps shall be provided for use by small children if junior toilets are not available.

(10) Toilet facilities shall be provided for the staff and shall be separate from those provided for the children.

(b) Play or exercise area shall be provided as follows:

(1) An indoor play and exercise area shall be provided for all children over the age of one (1) year. This area shall be separate from the bedrooms and shall provide floor space sufficient to allow a minimum of thirty-five (35) square feet per licensed bed.

(2) An adequate outdoor play or exercise area shall be provided. The area shall be fenced, adequately equipped, and supervised at all times when children are present.

(3) Washable toys and other developmental and training equipment meeting sanitary and safe design standards shall be provided for both indoor and outdoor play or exercise areas.

(4) All play equipment shall be maintained in a constant state of good repair.

(5) Playpens shall be provided for children as required.

(6) A storage area shall be provided for all movable play equipment.

(c) Appropriate and safe padding of cribs, beds, playpens, and other equipment shall be provided as needed to prevent injury.

(d) At least one (1) room shall be available for isolation of a child suspected or diagnosed as having a communicable disease.

(e) A visitors' room shall be provided for visitors and group and parent counseling. Visiting shall be encouraged at any reasonable time.

(f) For purposes of IC 16-28-5-1, a breach of:

(1) subsection (c) is a deficiency;

(2) subsection (b) is a noncompliance; and

(3) subsection (a), (d), or (e) is a nonconformance.

(Indiana State Department of Health; 410 IAC 16.2-6-6; filed May 2, 1984, 2:50 p.m.: 7 IR 1500; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1586, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 7. Health Facilities for Developmentally Disabled Persons

410 IAC 16.2-7-1 Applicability

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-2; IC 16-28-5-1

Sec. 1. This rule applies to facilities licensed under IC 16-28-2 that serve three (3) or more developmentally disabled individuals. *(Indiana State Department of Health; 410 IAC 16.2-7-1; filed May 2, 1984, 2:50 p.m.: 7 IR 1501; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1587, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-7-2 Admission policies and program statements

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 2. (a) Each facility shall have a written program statement and policies to assure that the facility admits only those individuals whose needs can be met. The policies shall be available to staff, residents, sponsors, and members of the public. The policies and program statement include, but are not limited to, the following:

(1) Classification of services offered.

(2) Arrangements to assure that the facility, in cooperation with community resources, can meet the needs of the individuals.

(3) The conditions of the people to be served.

(4) Admission, retention, and discharge policy.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-7-2; filed May 2, 1984, 2:50 p.m.: 7 IR 1501; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1587, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-7-3 Staff training and development programs

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 3. (a) Each facility shall provide in service training and shall require all staff working with developmentally disabled residents to attend staff development programs concerning developmental disabilities. Written records of such training shall be kept in the facility.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-7-3; filed May 2, 1984, 2:50 p.m.: 7 IR 1501; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1587, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-7-4 Resident programs

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 4. (a) The facility shall provide a program for developmentally disabled individuals, which assures the following:

(1) There is a designated staff member qualified by a minimum of two (2) years experience with developmentally disabled individuals, or through completion of the council approved training program on developmental disabilities, responsible for the program. If the designated staff member does not qualify as a qualified mental retardation professional, as defined in 410 IAC 16.2-1-32, the designee must be supervised by a qualified mental retardation professional or the facility must have a consultant qualified mental retardation professional.

(2) The designated staff member is responsible for the development and implementation of the habilitation program which shall include an assessment of need for community services and a care habilitation plan based upon a diagnostic screening.

(3) The habilitation plan which comprises the developmental component of the care plan, or in residential care the individual needs assessment, shall be reviewed and updated in accordance with the scheduled review of the overall care plan or as changes in the resident's condition indicate.

(4) Sheltered workshop programs, adult day activity programs, work activity programs, and work adjustment programs designed to meet the developmental program needs of developmentally disabled persons shall be provided outside the facility and in other community settings. These programs shall be provided by community resources whose programs are approved by the Indiana state department of public welfare in consultation with the Indiana department of mental health. A facility is in compliance with this rule, even if it is unable to obtain developmental programs from approved community resources, if:

(A) the facility has documented that it will arrange for the provision of the services from a community resource, and the community resource is willing to provide the programs and has developed a plan for implementation within a mutually agreed upon time frame; or

(B) the facility has documented that a community resource is unavailable or is unwilling to provide the services.

(b) For purposes of IC 16-28-5-1, a breach of subsection (a) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-7-4; filed May 2, 1984, 2:50 p.m.: 7 IR 1501; errata, 7 IR 1941; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1587, eff Apr 1, 1997; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 16.2-7-5 Diagnostic screening

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28-5-1

Sec. 5. (a) A diagnostic screening shall be performed within the twelve (12) month period prior to admission by a physician, or diagnostic and evaluation teams designated by the department of mental health, unless medically contraindicated by the attending physician.

(b) Permission for the diagnostic screening must be received from the resident (or sponsor where appropriate).

(c) The diagnostic screening performed after admission shall include the following:

(1) An annual medical evaluation to determine the general medical status of an applicant, and to identify any medical factors which limit client activity or ability in such areas as vocational training and residential placement in less restrictive settings.

(2) A psychological evaluation to measure the applicant's potential across a wide range of skills, for example, intellectual and adaptive functioning level, aptitude, and interests. After the initial psychological evaluation, a reevaluation shall be completed at least every three (3) years for children and every five (5) years for adults or more frequently as identified by the QMRP.

(3) An annual developmental assessment which measures what the applicant is doing in a wide range of skill areas, for example, ability to dress self, tell time, and move freely in the community without assistance.

(4) A social history and an annual social services update which provides information on services and programs the applicant has received in the past, as well as what services the applicant was receiving at the time of the diagnostic screening.

(d) If the attending physician after consultation with, and the concurrence of, the QMRP has stated in writing that there is no known effective treatment or training program likely to produce significant improvement or be necessary to maintain existing skills, the facility may exclude the resident from the developmental training program. The facility shall document the reasons for exclusion and make such documentation available to survey staff. However, the facility shall continue to meet the care planning requirements of 410 IAC 16.2-3.1-35.

(e) For purposes of IC 16-28-5-1, a breach of subsection (a), (b), (c), or (d) is a noncompliance. *(Indiana State Department of Health; 410 IAC 16.2-7-5; filed May 2, 1984, 2:50 p.m.: 7 IR 1502; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 8. Incorporation by Reference

410 IAC 16.2-8-1 Incorporation by reference

Authority: IC 16-28-1-7; IC 16-28-1-12
Affected: IC 16-28

Sec. 1. (a) When used in this article, references to the publications in this subsection shall mean the version of that publication listed below. The following publications are hereby incorporated by reference:

(1) National Fire Protection Association (NFPA) 101, Life Safety Code Handbook (1985 Edition). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 99101, Quincy, Massachusetts 02269-9904.
(2) 42 CFR 493 (October 1, 1995 Edition).
(3) 42 CFR 483.75(e)(1) (October 1, 1995 Edition).

(b) Federal rules that have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. All incorporated material is available for public review at the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 16.2-8-1; filed Jan 10, 1997, 4:00 p.m.: 20 IR 1588, eff Apr 1, 1997; errata filed Apr 10, 1997, 12:15 p.m.: 20 IR 2415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 17. HOME HEALTH AGENCIES

Rule 1. Home Health Agencies' Licensure; General Regulations (Repealed)
(Repealed by Indiana State Department of Health; filed Dec 5, 1991, 2:30 p.m.: 15 IR 487)

Rule 1.1. Definitions (Repealed)
(Repealed by Indiana State Department of Health; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2490)

Rule 2. Home Health Licensure (Repealed)
(Repealed by Indiana State Department of Health; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2490)

Rule 3. State Administrative Actions (Repealed)
(Repealed by Indiana State Department of Health; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2490)

Rule 4. Home Health Administration and Management (Repealed)
(Repealed by Indiana State Department of Health; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2490)

Rule 5. Home Health Patient Care (Repealed)
(Repealed by Indiana State Department of Health; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2490)

Rule 6. Home Health Care Services (Repealed)
(Repealed by Indiana State Department of Health; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2490)

Rule 7. Home Health Clinical Records (Repealed)
(Repealed by Indiana State Department of Health; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2490)

Rule 8. Incorporation by Reference (Repealed)
(Repealed by Indiana State Department of Health; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2490)

Rule 9. Definitions

410 IAC 17-9-1 Applicability
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 17-9-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2477)*

410 IAC 17-9-2 "Administrator" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. "Administrator" means any health care professional who has at least one (1) year of supervisory or administrative experience in health service, or any other individual who has at least one (1) year of experience in health service administration or health service finance. *(Indiana State Department of Health; 410 IAC 17-9-2; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2477)*

410 IAC 17-9-3 "Advance directive" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. "Advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under state law and relating to the provision of such care when the individual is incapacitated. *(Indiana State Department of Health; 410 IAC 17-9-3; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-4 "Attendant care services" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 4. "Attendant care services" means those services that could be performed by an impaired individual for whom the services are provided if the individual were not impaired, that enable the impaired individual to live in the individual's home and community, rather than in an institution, and to carry out functions of daily living, self care, and mobility. The term includes the following:

(1) Assistance in getting in and out of beds, wheelchairs, and motor vehicles.
(2) Assistance with routine bodily functions, including the following:
    (A) Bathing and personal hygiene.
    (B) Using the toilet.
    (C) Dressing and grooming.
    (D) Feeding, including preparation and cleanup.
(3) The provision of assistance as follows:
    (A) Through providing reminders or cues to take medication, the opening of pre-set medication containers, and providing assistance in the handling or ingesting of noncontrolled substance medications, including eye drops, herbs, supplements, and over-the-counter medications.
    (B) To an individual who is unable to accomplish the task due to an impairment and who is:
        (i) competent and has directed the services; or
        (ii) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.

(Indiana State Department of Health; 410 IAC 17-9-4; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)

410 IAC 17-9-5 "Branch office" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 5. "Branch office" means a location or site from which a home health agency provides services for a portion of the total geographic area served by the parent home health agency. To be a branch office, the office must be part of the parent agency and share administration, supervision, and services with the parent agency. The parent agency and the branch office must be capable of sharing emergency functions, including services, on a daily basis. A branch office must be located within one hundred and *[sic.]* twenty (120) minutes driving time of the parent agency. *(Indiana State Department of Health; 410 IAC 17-9-5; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-6 "Bylaws" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 6. "Bylaws" means a written set of rules adopted by a home health agency for governing the agency's operation. *(Indiana State Department of Health; 410 IAC 17-9-6; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-7 "Clinical note" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 7. "Clinical note" means a notation written and dated by a member of the health team regarding his or her contact with a patient who is being treated under a medical plan of care. *(Indiana State Department of Health; 410 IAC 17-9-7; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-8 "Closed files" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 8. "Closed files" means those files which concern services provided prior to a patient's discharge. *(Indiana State Department of Health; 410 IAC 17-9-8; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-9 "Continuing education program" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 9. "Continuing education program means one (1) or more in-service training classes offered to home health aides for the purpose of satisfying the continuing education requirement. *(Indiana State Department of Health; 410 IAC 17-9-9; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-10 "Current service files" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 10. "Current service files" means those files concerning a patient who is currently receiving services from the home health agency. *(Indiana State Department of Health; 410 IAC 17-9-10; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-11 "Department" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 11. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 17-9-11; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-12 "Encounter" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 12. "Encounter" means a direct personal contact between a patient and the person authorized by the home health agency to furnish services to the patient. *(Indiana State Department of Health; 410 IAC 17-9-12; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)*

410 IAC 17-9-13 "Frequency of visits" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 13. "Frequency of visits" means the number of encounters in a given period between a patient and the person authorized by the home health agency to furnish services to the patient. "Frequency of visits" may be expressed as a number or a range. The number of encounters must be at least one (1). *(Indiana State Department of Health; 410 IAC 17-9-13; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)*

410 IAC 17-9-14 "Governing body" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 14. "Governing body" means person or group of persons who have the legal and financial responsibility for the home health agency's overall operation. *(Indiana State Department of Health; 410 IAC 17-9-14; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)*

410 IAC 17-9-15 "Health care professional" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-10-1; IC 25-14; IC 25-22.5; IC 25-23-1; IC 25-23.5; IC 25-23.6-6-2; IC 25-24; IC 25-26-13; IC 25-27; IC 25-29; IC 25-35.6-1-2; IC 25-35.6-3

Sec. 15. "Health care professional" means any of the following:
(1) A licensed physician.
(2) A licensed dentist.
(3) A licensed chiropractor.
(4) A licensed podiatrist.
(5) A licensed optometrist.
(6) A nurse licensed under IC 25-23-1.
(7) A physical therapist licensed under IC 25-27 or a physical therapy assistant certified under IC 25-27.
(8) A speech-language pathologist or an audiologist licensed under IC 25-35.6-3.
(9) A speech-language pathology aide or an audiology aide (as defined in IC 25-35.6-1-2).
(10) An occupational therapist or an occupational therapist assistant certified under IC 25-23.5.
(11) A social worker licensed under IC 25-23.6 or a social work assistant.
(12) A pharmacist licensed under IC 25-26-13.

(Indiana State Department of Health; 410 IAC 17-9-15; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479; errata filed Mar 28, 2002, 4:28 p.m.: 25 IR 2522)

410 IAC 17-9-16 "Home health aide" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 16. "Home health aide" means an individual who provides home health aide services. The term does not include the following:
(1) A health care professional.
(2) A volunteer who provides home health aide services without compensation.
(3) An immediate member of the patient's family.

(Indiana State Department of Health; 410 IAC 17-9-16; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)

410 IAC 17-9-17 "Home health aide services" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 17. "Home health aide services" means only those home health services that may be performed by a home health aide. *(Indiana State Department of Health; 410 IAC 17-9-17; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)*

410 IAC 17-9-18 "Home health services" defined

Authority: IC 16-27-1-7
Affected: IC 12-10-17; IC 16-27-1-10; IC 25-22.5

Sec. 18. (a) "Home health services" means services that are:
(1) provided to a patient by:
(A) a home health agency; or
(B) another person under an arrangement with a home health agency;
in the temporary or permanent residence of the patient; and
(2) ordered by a licensed physician, a licensed dentist, a licensed chiropractor, a licensed podiatrist, or a licensed optometrist.
(b) The term includes the following:
(1) Nursing treatment and procedures.
(2) Physical therapy.
(3) Occupational therapy.
(4) Speech therapy.
(5) Medical social services.
(6) Home health aide services.
(7) Other therapeutic services.
(c) The term does not apply to the following:
(1) Services provided by a physician licensed under IC 25-22.5.
(2) Incidental services provided by a licensed health facility to patients of the licensed health facility.
(3) Services provided by employers or membership organizations using health care professionals for their employees, members, and families of the employees or members if the health or home care services are not the predominant purpose of the employer or a membership organization's business.
(4) Nonmedical nursing care given in accordance with the tenets and practice of a recognized church or religious denomination to a patient who depends upon healing by prayer and spiritual means alone in accordance with the tenets and practices of the patient's church or religious denomination.
(5) Services that are allowed to be performed by an attendant under IC 16-27-1-10.
(6) Authorized services provided by a personal services attendant under IC 12-10-17.
(Indiana State Department of Health; 410 IAC 17-9-18; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)

410 IAC 17-9-19 "Medical plan of care" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 19. "Medical plan of care" means written instructions signed by the physician, dentist, chiropractor, podiatrist, or optometrist for the provision of care or treatment to be given by a registered or practical nurse, physical or occupational therapist, speech-language pathologist, social worker, or a home health aide to a patient in the patient's place of residence. *(Indiana State Department of Health; 410 IAC 17-9-19; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-20 "Medication assistance" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 20. "Medication assistance" means the provision of assistance:

(1) through providing reminders or cues to take medication, the opening of pre-set medication containers, and providing assistance in the handling or ingesting of noncontrolled substance medications, including eye drops, herbs, supplements, and over-the-counter medications; and

(2) to an individual who is unable to accomplish the task due to an impairment and who is:

(A) competent and has directed the services; or

(B) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.

(Indiana State Department of Health; 410 IAC 17-9-20; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)

410 IAC 17-9-21 "Member of the health team" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 21. "Member of the health team" means a health care professional or a home health aide. *(Indiana State Department of Health; 410 IAC 17-9-21; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-22 "Parent home health agency" and "parent agency" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 22. "Parent home health agency" or "parent agency" means the home health agency that develops and maintains administrative and fiscal control over branch offices. *(Indiana State Department of Health; 410 IAC 17-9-22; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-23 "Licensed practical nurse" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23

Sec. 23. "Licensed practical nurse" means a person who is licensed as a practical nurse pursuant to IC 25-23. *(Indiana State Department of Health; 410 IAC 17-9-23; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-24 "Registered nurse" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23

Sec. 24. "Registered nurse" means a nurse who is licensed as a registered nurse pursuant to IC 25-23. *(Indiana State Department of Health; 410 IAC 17-9-24; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-25 "Social worker" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23

Sec. 25. "Social worker" means a person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and who has one (1) year of social work experience in a health care setting. *(Indiana State Department of Health; 410 IAC 17-9-25; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-26 "Social work assistant" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 26. "Social work assistant" means an individual who has a baccalaureate degree in psychology, sociology, or other field related to social work, and has had at least one (1) year of social work experience in a health care setting and is supervised by a social worker. *(Indiana State Department of Health; 410 IAC 17-9-26; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-27 "Speech language pathologist" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-35.6

Sec. 27. "Speech language pathologist" means an individual who is licensed to practice speech language pathology pursuant to IC 25-35.6. *(Indiana State Department of Health; 410 IAC 17-9-27; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-28 "Summary report" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 28. "Summary report" means a clinical synopsis of the pertinent factors from the clinical notes regarding a patient requiring a medical plan of care, which is submitted as a report to the physician. *(Indiana State Department of Health; 410 IAC 17-9-28; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2481)*

410 IAC 17-9-29 "Supervision" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 29. "Supervision" means guidance to a subordinate by a qualified health care professional for the accomplishment of a function or activity. Supervision shall be evidenced by documentation that demonstrates consistent, meaningful interaction and guidance between the qualified health care professional and his or her subordinate. *(Indiana State Department of Health; 410 IAC 17-9-29; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2481)*

Rule 10. Home Health Licensure

410 IAC 17-10-1 Licensure

Authority: IC 16-27-1-7
Affected: IC 5-2-5; IC 12-17-15-3; IC 16-20; IC 16-22-8; IC 16-27-1; IC 25-22.5

Sec. 1. (a) No home health agency shall be opened, operated, managed, maintained, or otherwise conduct business without a license issued by the department.

(b) A license is required for any home health agency providing care in Indiana where the parent agency is located in a state other than Indiana. The home health agency must be authorized by the secretary of state to conduct business in Indiana and have a branch office located in Indiana.

(c) Application for a license to operate a home health agency shall be made on a form provided by the department and shall be accompanied by a nonrefundable fee of one hundred dollars ($100).

(d) Disclosure of ownership and management information must be made to the department at the time of the home health agency's initial request for licensure, for each survey, and at the time of any change in ownership or management. The disclosure must include the following:

(1) The name and address of all persons having at least five percent (5%) ownership or controlling interest in the home health agency.

(2) The name and address of each person who is an officer, a director, a managing agent, or a managing employee of the home health agency.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the home health agency, and the name and address of the chief executive officer and the chairman or equivalent position of the governing body of that corporation, association, or other legal entity responsible for the management of the home health

agency.

(e) After receiving a completed application, the nonrefundable fee required by subsection (c) of this rule, and disclosure of ownership and management information, the department may issue a letter of approval for operating a home health agency for a period of up to ninety (90) days pending an on-site inspection. In determining whether to issue the letter of approval, the department shall consider the following factors:

(1) Whether the department has filed an action against an agency owned or operated by the applicant that resulted in:

(A) the revocation of a license;

(B) the denial or renewal of a license;

(C) the issuance or renewal of a probationary license; or

(D) the payment of a civil penalty.

(2) Whether the department has issued an order against an agency owned or operated by the applicant.

(3) Whether an agency owned or operated by the applicant has surrendered its license to the department.

(4) Whether any injunction has been issued against an agency owned or operated by the applicant; and

(5) Whether an agency owned or operated by the applicant has operated in substantial violation of this rule or any other law governing home health agencies at any time within two (2) years immediately preceding the date that the applicant applied for a license.

(f) The department may extend this ninety (90) day period for a total of one hundred twenty (120) days in fifteen (15) day increments. Such decision to grant an extension shall take into consideration the health, safety, and welfare of the citizens the home health agency serves and the individual circumstances warranting the need for the extension. The home health agency must provide the service(s) that have been specified on the application prior to the inspection and must have a minimum of three (3) patients for record review. Record review may consist of both open and closed patient files.

(g) In determining whether to issue the initial license to operate a home health agency, the department may consider the factors described under subsection (e) of this rule and the results of the initial survey.

(h) The license shall relate back to and reflect the date of the first day of the ninety (90) day letter issued by the department.

(i) In determining whether to renew a license to operate a home health agency, the department may consider the factors described under subsection (e) of this rule and any actions pending against the home health agency.

(j) In conducting a survey, a surveyor shall receive copies of any and all documents necessary to make a determination of compliance. The surveyor may make copies with permission of the home health agency, or supervise any copying process to ensure that photocopies are true and accurate. At the sole discretion of the department and for good cause shown, the home health agency may be granted up to twenty-four (24) hours to produce documents requested by the surveyor.

(k) A home health agency may apply to provide a service that was not listed in its application or renewal application by notifying the department in writing of the new service, the date the service is intended to be offered and all supporting documentation that shows the home health agency is qualified to provide the additional service. Such documentation includes, but is not limited to, the following:

(1) Personnel qualifications and licensing.

(2) Limited criminal history from the Indiana central repository established by IC 5-2-5.

(3) Procedures for the supervision of personnel.

(4) Contracts between the home health agency and any person offering the new service.

(5) Records of physical exams showing that personnel are free of communicable disease. In the event the initial information submitted is not sufficient for the department to determine the home health agency's compliance regarding the new service, the department will inform the home health agency of the additional documents required. A home health agency may not offer additional services until it has received approval from the department to do so.

(l) The following are not required to be licensed as a home health agency:

(1) A physician licensed under IC 25-22.5.

(2) An individual whose permanent residence is in the patient's residence or who is a member of the patient's immediate family.

(3) Incidental services provided by licensed health facilities to their patients.

(4) An employee of a person holding a license under IC 16-27-1 who provides home health services only as an employee of the licensed person.

(5) A local health department established under IC 16-20.

(6) A health care professional who provides one health service through a contract with a person licensed under IC 16-27-1.

(7) A durable medical equipment supply company that furnishes equipment but provides no home health services to persons in their homes.

(8) A drugstore or wholesale medical supply company that furnishes no home health services to persons in their home.

(9) A volunteer who provides home health aide services without compensation.

(10) An individual health care professional who provides professional services to a patient in the temporary or permanent residence of the patient.

(11) An entity does not need a home health license to provide early intervention services (as defined in IC 12-17-15-3) to a child pursuant to a state program funded by the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(m) Except as provided in 410 IAC 17-11-5, each license shall be for a term of one (1) year and shall expire one (1) year from the date of issuance. The licensee shall notify the department in writing thirty (30) days in advance of closing or selling the home health agency.

(n) Each license shall be issued only for the home health agency named in the application and shall not be transferred or assigned. Upon sale, assignment, lease, or other transfer, voluntary or involuntary, including those transfers that qualify as changes of ownership, a new owner or person in interest shall obtain a license from the department prior to maintaining, operating, or conducting a home health agency.

(o) The licensee shall submit an annual activity report to the department on a form provided by the department.

(p) Surveys may be, but are not limited to, the following:

(1) Unannounced surveys conducted annually for compliance.

(2) Post survey revisits conducted based on a home health agency's plan of correction and for the purpose of determining compliance.

(3) Patient care complaints.

(Indiana State Department of Health; 410 IAC 17-10-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2481)

Rule 11. State Administrative Actions

410 IAC 17-11-1 Actions by the commissioner

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. The commissioner of the department may take one (1) or more of the following actions on any ground listed in section 2 of this rule:

(1) Issue a letter of correction.

(2) Issue a probationary license.

(3) Conduct a resurvey.

(4) Deny a license or renewal of a license.

(5) Revoke a license.

(6) Impose a civil penalty in an amount not to exceed ten thousand dollars ($10,000).

(Indiana State Department of Health; 410 IAC 17-11-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2482)

410 IAC 17-11-2 Grounds for actions by the commissioner

Authority: IC 16-27-1-7
Affected: IC 4-21.5; IC 16-27-1

Sec. 2. The commissioner may take action under section 1 of this rule on any of the following grounds:

(1) Violation of any of the provisions of IC 16-27 or these rules *[this article]*.

(2) Permitting, aiding, or abetting the commission of an illegal act in a home health agency.

(3) Conduct or practice found by the department to be detrimental to the welfare of the patients of the home health agency.

(Indiana State Department of Health; 410 IAC 17-11-2; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)

410 IAC 17-11-3 Renewal of home health licensure

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. An application for renewal of license shall be filed with the department at least sixty (60) days prior, but not sooner than ninety (90) days before, the expiration date of the current license. *(Indiana State Department of Health; 410 IAC 17-11-3; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)*

410 IAC 17-11-4 Civil penalties

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 4. (a) The commissioner may commence an action under IC 16-27-1 to levy civil penalties against a person who:

(1) fails to comply with IC 16-27 or this article; or

(2) interferes with or obstructs the department or its designated agent in the performance of duties pursuant to IC 16-27-1.

(b) A monetary civil penalty may be sought for each documented violation of IC 16-27-1 or this article. Monetary civil penalties issued may not exceed ten thousand dollars ($10,000) per violation.

(c) In determining the seriousness of the violation and the specific amount of the civil penalty to be sought for each violation, the commissioner may consider, but is not limited to, the following:

(1) The potential for harm or imminent threat to the patient's health.

(2) The extent of deviation from statutory or regulatory requirements.

(3) The degree of willfulness or negligence.

(4) The history of noncompliance.

(d) The absence of direct harm will not necessarily result in assessment of a lower penalty for a violation. *(Indiana State Department of Health; 410 IAC 17-11-4; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)*

410 IAC 17-11-5 Probationary license

Authority: IC 16-27-1-7
Affected: IC 16-27-1-12

Sec. 5. A probationary license may be issued pursuant to IC 16-27-1-12 for three (3) months. The probationary license may be reissued but not more than three (3) probationary licenses may be issued during a twelve (12) month period. The issuance of a probationary license results in the automatic expiration of any other license held under this article. *(Indiana State Department of Health; 410 IAC 17-11-5; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)*

Rule 12. Home Health Administration and Management

410 IAC 17-12-1 Home health agency administration and management

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 16-27-2

Sec. 1. (a) Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level shall be clearly set forth in writing and be readily identifiable. Administrative and supervisory responsibilities shall not be delegated to another agency or organization, and all services not furnished directly, including services provided through a branch office, shall be monitored and controlled by the parent agency.

(b) A governing body, or designated person(s) so functioning, shall assume full legal authority and responsibility for the operation of the home health agency. The governing body shall appoint a qualified administrator, adopt and periodically review written bylaws or an acceptable equivalent, and oversee the management and fiscal affairs of the home health agency.

(c) An individual need not be a home health agency employee or be present full time at the home health agency in order to qualify as its administrator. The administrator, who may also be the supervising physician or registered nurse required by subsection (d) of this rule, shall do the following:

(1) Organize and direct the home health agency's ongoing functions.
(2) Maintain ongoing liaison among the governing body and the staff.
(3) Employ qualified personnel and ensure adequate staff education and evaluations.
(4) Ensure the accuracy of public information materials and activities.
(5) Implement a budgeting and accounting system.
(6) Ensure that the home health agency meets all rules and regulations for licensure.
(7) Upon request, make available to the commissioner or his designated agent all:
(A) reports;
(B) records;
(C) minutes;
(D) documentation;
(E) information; and
(F) files;
required to determine compliance within seventy-two (72) hours of such request or, in the event such a request is made in conjunction with a survey, by the time the surveyor exits the home health agency, whichever is sooner.
(8) Ensure that a qualified person is authorized in writing to act in the administrator's absence.

(d) A physician or a registered nurse who has two (2) years of nursing experience, with at least one (1) year of supervisory or administrative experience, shall supervise and direct nursing and other therapeutic services. Such person or similarly qualified alternate shall be on the premises or capable of being reached immediately by phone, pager, or other means. In addition, the person must be able to respond to an emergency, provide guidance to staff, answer questions, and resolve issues within a reasonable amount of time, given the emergency or issue that has been raised.

(e) The administrator shall be responsible for an ongoing quality assurance program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, resolve identified problems, and improve patient care.

(f) Personnel practices for employees shall be supported by written policies. All employees caring for patients in Indiana shall be subject to Indiana licensure, certification, or registration required to perform the respective service. Personnel records of employees who deliver home health services shall be kept current and shall include documentation of orientation to the job, including:
(1) Receipt of job description.
(2) Qualifications.
(3) A copy of limited criminal history pursuant to IC 16-27-2.
(4) A copy of current license, certification, or registration.
(5) Annual performance evaluations.

(g) Personnel records of the supervising nurse, appointed pursuant to subsection (d) of this rule, shall be kept current and shall include a copy of the following:
(1) Limited criminal history pursuant to IC 16-27-2.
(2) Nursing license.
(3) Annual performance evaluations.
(4) Documentation of orientation to the job.
Performance evaluations required by this subsection must be performed every nine (9) to fifteen (15) months of active employment.

(h) Each employee who will have direct patient contact shall have a physical examination by a physician or nurse practitioner no more than one hundred eighty (180) days before the date that the employee has direct patient contact. The physical examination shall be of sufficient scope to ensure that the employee will not spread infectious or communicable diseases to patients.

(i) The home health agency shall require all employees who will have direct patient contact to complete a PPD (mantoux) skin test for tuberculosis no more than thirty (30) days before the date that the employee has direct patient contact and annually thereafter for negative findings. Positive findings shall require appropriate clinical follow-up before the employee has direct patient contact, but no repeat skin test. A physician shall advise and approve policies regarding positive outcomes. The home health agency shall follow the Centers for Disease Control and Prevention guidelines for administering the tuberculin skin test. These guidelines are the "Core Curriculum on Tuberculosis", Chapter IV(B), Fourth Edition (2000).

(j) The information obtained from the physical examinations required by subsection (h) of this rule and PPD (mantoux) skin tests and clinical follow-ups required by subsection (i) of this rule must be maintained in separate medical files and treated as confidential medical records, except as provided in subsection (k) of this rule.

(k) The following records shall be made available, on request, to the department for review:

(1) Personnel records and policies that document the home health agency's compliance with subsection (f) of this rule.

(2) Records of physical examinations that document the agency's compliance with subsection (h) of this rule.

(3) Records of PPD (mantoux) skin tests, the results of the skin tests, appropriate clinical follow-up for positive findings, and any other records that document the home health agency's compliance with subsection (i) of this rule.

(l) The department shall treat the information described in subsection (k) of this rule as confidential medical records and use it only for the purposes for which it was obtained.

(m) Policies and procedures shall be written and implemented for the control of communicable disease in compliance with applicable federal and state laws. *(Indiana State Department of Health; 410 IAC 17-12-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)*

410 IAC 17-12-2 Quality assessment and performance improvement

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. (a) The home health agency must develop, implement, maintain, and evaluate a quality assessment and performance improvement program. The program must reflect the complexity of the home health organization and services (including those services provided directly or under arrangement). The home health agency must take actions that result in improvements in the home health agencies performance across the spectrum of care. The home health agency's quality assessment and performance improvement program must use objective measures.

(b) The home health agency shall provide at least one (1) of the following services:

(1) Nursing treatment and procedure.

(2) Home health aide services.

(3) Physical therapy.

(4) Speech-language pathology.

(5) Occupational therapy.

(6) Social services.

(c) In all cases involving the provision of home health aide services, the home health agency shall provide case management by a health care professional acting within the scope of his or her practice. Such case management shall include an initial home visit for assessment of a patient's needs to determine the type, appropriateness, and adequacy of requested service, and the development of the patient care plan.

(d) If personnel under contracts are used by the home health agency, there shall be a written contract between those personnel and the home health agency that specifies the following:

(1) That patients are accepted for care only by the primary home health agency.

(2) The services to be furnished.

(3) The necessity to conform to all applicable home health agency policies including personnel qualifications.

(4) The responsibility for participating in developing plans of care.

(5) The manner in which services will be controlled, coordinated, and evaluated by the primary home health agency.

(6) The procedures for submitting clinical notes, scheduling of visits, and conducting periodic patient evaluation.

(7) The procedures for payment for services furnished under the contract.

(e) Services furnished under arrangements are subject to a written contract conforming with the requirements specified in subsection (d) of this rule.

(f) When contracting temporary services from another licensed home health agency, organization, or independent contractor, the personnel records shall be maintained at the office of the employer and shall be available to the home health agency upon two (2) hours' notice.

(g) All personnel providing services shall maintain effective communications to assure that their efforts appropriately complement one another and support the objectives of the patient's care. The means of communication and the results shall be documented in the clinical record or minutes of case conferences.

(h) The home health agency shall coordinate its services with other health or social service providers serving the patient.

(i) A home health agency must develop and implement a policy requiring a notice of discharge of service to the patient, the patient's legal representative, or other individual responsible for the patient's care at least five (5) calendar days before the services are stopped.

(j) The five (5) day period described in subsection (i) of this rule does not apply in the following circumstances:

(1) The health, safety, and/or welfare of the home health agency's employees would be at immediate and significant risk if the home health agency continued to provide services to the patient.

(2) The patient refuses the home health agency's services.

(3) The patient's services are no longer reimbursable based on applicable reimbursement requirements and the home health agency informs the patient of community resources to assist the patient following discharge; or

(4) The patient no longer meets applicable regulatory criteria, such as lack of physician's order, and the home health agency informs the patient of community resources to assist the patient following discharge.

(k) A home health agency must continue, in good faith, to attempt to provide services during the five (5) day period described in subsection (i) of this rule. If the home health agency cannot provide such services during that period, its continuing attempts to provide the services must be documented. *(Indiana State Department of Health; 410 IAC 17-12-2; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2485)*

410 IAC 17-12-3 Patient rights

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. (a) The patient or the patient's legal representative has the right to be informed of the patient's rights through effective means of communication. The home health agency must protect and promote the exercise of these rights as follows:

(1) The home health agency shall provide the patient with a written notice of the patient's right in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The home health agency shall maintain documentation showing that it has complied with the requirements of this section.

(b) The patient has the right to exercise his or her rights as a patient of the home health agency as follows:

(1) The patient's family or legal representative may exercise the patient's rights as permitted by law.

(2) The patient has the right to have his or her property treated with respect.

(3) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the home health agency and must not be subjected to discrimination or reprisal for doing so.

(4) The patient has the right to place a complaint with the department regarding treatment or care furnished by a home health agency.

(5) The patient has the right to be informed about the care to be furnished, and of any changes in the care to be furnished as follows:

(A) The home health agency shall advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(B) The patient has the right to participate in the planning of the care. The home health agency shall advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(C) The home health agency shall advise the patient of any change in the plan of care, including reasonable discharge notice.

(6) The patient has the right to confidentiality of the clinical records maintained by the home health agency. The home health agency shall advise the patient of the agency's policies and procedures regarding disclosure of clinical records.

(7) The patient or patient's legal representative have the right under Indiana law to access the patient's clinical records unless certain exceptions apply. The home health agency shall advise the patient or the patient's legal representative of its policies and procedures regarding the accessibility of clinical records.

(8) The patient has the right to be free from verbal, physical, and psychological abuse and to be treated with dignity.

(c) The home health agency shall investigate complaints made by a patient or the patient's family or legal representative regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the home health agency, and shall document both the existence of the complaint and the resolution of the complaint.

(d) The home health agency shall make available to the patient upon request, a written notice in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment, a listing of all individuals or other legal entities who have an ownership or control interest in the agency as defined in 42 CFR § 420.201, 42 CFR § 420.202, and 42 CFR § 420.206.

(e) The home health agency must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable state law. The home health agency may furnish advanced directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided. *(Indiana State Department of Health; 410 IAC 17-12-3; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2486)*

Rule 13. Home Health Patient Care

410 IAC 17-13-1 Patient care

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25

Sec. 1. (a) Patients shall be accepted for care on the basis of a reasonable expectation that the patient's health needs can be adequately met by the home health agency in the patient's place of residence. Medical care shall follow a written medical plan of care established and periodically reviewed by the physician, dentist, chiropractor, optometrist, or podiatrist as follows:

(1) The medical plan of care shall be developed in consultation with the home health agency staff and shall cover all pertinent diagnoses and include the following:

(A) Mental status.
(B) Types of services and equipment required.
(C) Frequency and duration of visits.
(D) Prognosis.
(E) Rehabilitation potential.
(F) Functional limitations.
(G) Activities permitted.
(H) Nutritional requirements.
(I) Medications and treatments.
(J) Any safety measures to protect against injury.
(K) Instructions for timely discharge or referral.
(L) Therapy modalities specifying length of treatment.
(M) Any other appropriate items.

(2) The total medical plan of care shall be reviewed by the attending physician, dentist, chiropractor, optometrist, or podiatrist, and home health agency personnel as often as the severity of the patient's condition requires, but at least once every two (2) months. The health care professional staff of the home health agency shall promptly alert the person responsible for the medical component of the patient's care to any changes that suggest a need to alter the medical plan of care. A written summary report for each patient shall be sent to the physician, dentist, chiropractor, optometrist, or podiatrist at least every two (2) months.

(b) A home health agency may accept written orders for home health services from a physician, a dentist, a chiropractor, a podiatrist, or an optometrist licensed in Indiana or in any other state. If the home health agency receives an order from a physician, dentist, chiropractor, podiatrist, or optometrist who is licensed in another state, the home health agency shall take reasonable immediate steps to determine that:

(1) the order complies with the laws of the state where the order originated; and

(2) the individual who issued the order examined the patient and is licensed to practice in that state.

(c) All orders issued by a physician, a dentist, a chiropractor, a podiatrist, or an optometrist for home health services must meet the same requirements whether the order originates in Indiana or another state. Orders issued from another state may not exceed the authority allowed under orders from the same profession in Indiana under IC 25.

(d) Home health agency personnel shall promptly notify a patient's physician or other appropriate licensed professional staff and legal representative, if any, of any significant physical or mental changes observed or reported by the patient. In the case of a medical emergency, the home health agency must know in advance which emergency system to contact. *(Indiana State Department of Health; 410 IAC 17-13-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2486)*

Rule 14. Home Health Care Services

410 IAC 17-14-1 Scope of services

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23-1; IC 25-27-1; IC 25-35.6

Sec. 1. (a) The home health agency shall provide nursing services by a registered nurse or a licensed practical nurse in accordance with the medical plan of care as follows:

(1) The registered nurse shall perform nursing duties in accordance with the Indiana nurse practice act (IC 25-23). Except where services are limited to therapy only, for purposes of practice in the home health setting, the registered nurse shall do the following:

(A) Make the initial evaluation visit.
(B) Regularly reevaluate the patient's nursing needs.
(C) Initiate the plan of care and necessary revisions.
(D) Initiate appropriate preventive and rehabilitative nursing procedures.
(E) Prepare clinical notes.
(F) Coordinate services.
(G) Inform the physician and other appropriate medical personnel of changes in the patient's condition and needs, counsel the patient and family in meeting nursing and related needs, participate in in-service programs, and supervise and teach other nursing personnel.
(H) Accept and carry out physician, chiropractor, podiatrist, dentist, and optometrist orders (oral and written).
(I) Assist the physician, chiropractor, podiatrist, dentist, or optometrist in evaluating level of function.
(J) Direct the activities of the licensed practical nurse.
(K) Delegate duties and tasks to licensed practical nurses and other individuals as appropriate.

(2) The licensed practical nurse shall perform duties in accordance with the Indiana nurse practice act (IC 25-23). For purposes of practice in the home health setting, the licensed practical nurse shall do the following:

(A) Provide services in accordance with agency policies.
(B) Prepare clinical notes.
(C) Assist the physician and/or registered nurse in performing specialized procedures.
(D) Prepare equipment and materials for treatments observing aseptic technique as required.
(E) Assist the patient in learning appropriate self-care techniques.
(F) Accept and carry out physician, dentist, chiropractor, podiatrist, or optometrist orders (oral and written).
(G) Inform the physician, dentist, chiropractor, podiatrist, or optometrist of changes in the patient's condition and needs after consulting with the supervising registered nurse.

(b) Any therapy services furnished by the home health agency shall be provided by:

(1) a physical therapist or physical therapist assistant supervised by a licensed physical therapist in accordance with IC 25-27-1; or

(2) an occupational therapist or occupational therapist assistant supervised by an occupation therapist in accordance with IC 25-23.5.

(3) a speech-language pathologist or audiologist in accordance with IC 25-35.6.

(c) The appropriate therapist listed in subsection (b) of this rule shall:

(1) Make an initial evaluation visit to the patient for whom only therapy services are required.

(2) Review the plan of care as often as the severity of the patient's condition requires, but at least every two (2) months.

(3) Assist the physician, chiropractor, podiatrist, dentist, or optometrist in evaluating level of function.

(4) Help develop the plan of care (revising as necessary).

(5) Prepare clinical notes.

(6) Advise and consult with the family and other home health agency personnel.

(7) Participate in in-service programs.

(d) In carrying out the responsibilities identified in subsection (c) of this rule the therapist may:

(1) direct the activities of any therapy assistant; or

(2) delegate duties and tasks to other individuals as appropriate.

(e) Any social services furnished by the home health agency, shall be provided by a social worker, or a social work assistant under the supervision of a social worker, and in accordance with the medical plan of care. The social worker shall do the following:

(1) Assist the physician and other team members in understanding the significant social and emotional factors related to the health problems.
(2) Participate in the development of the plan of care.
(3) Prepare clinical and progress notes.
(4) Work with the family.
(5) Use appropriate community resources.
(6) Participate in discharge planning and in-service programs.
(7) Act as a consultant to other home health agency personnel.
(8) Accept and carry out physician orders for social work services.

(f) This rule does not prohibit the provision of:
(1) homemaker services, including shopping, laundry, cleaning, and seasonal chores;
(2) companion type services, including transportation, letter writing, mail reading, and escort services;
(3) assistance with cognitive tasks, including managing finances, planning activities, and making decisions;
(4) attendant care services; or
(5) any other services for which an individual license, certification, registration, or permit is not required under state law.

(g) Home health aides shall be supervised by a health care professional to ensure competent provision of care. Supervision of services must be within the scope of practice of the health care professional providing the supervision.

(h) Home health aides must receive continuing education. Such continuing education shall total at least twelve (12) hours from January 1 through December 31, inclusive, with a minimum of eight (8) hours in any eight (8) of the following subject areas:
(1) Communications skills, including the ability to read, write, and make brief and accurate oral presentations to patients, caregivers, and other home health agency staff.
(2) Observing, reporting, and documenting patient status and the care or service furnished.
(3) Reading and recording temperature, pulse, and respiration.
(4) Basic infection control procedures and universal precautions.
(5) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.
(6) Maintaining a clean, safe, and healthy environment.
(7) Recognizing emergencies and knowledge of emergency procedures.
(8) The physical, emotional, and developmental needs of and ways to work with the populations served by the home health agency, including the need for respect for the patient, the patient's privacy, and the patient's property.
(9) Appropriate and safe techniques in personal hygiene and grooming that include the following:
(A) Bed bath.
(B) Bath, sponge, tub, or shower.
(C) Shampoo, sink, tub, or bed.
(D) Nail and skin care.
(E) Oral hygiene.
(F) Toileting and elimination.
(10) Safe transfer techniques and ambulation.
(11) Normal range of motion and positioning.
(12) Adequate nutrition and fluid intake.
(13) Medication assistance.
(14) Any other task that the home health agency may choose to have the home health aide perform.

(i) During a home health aide's first year on the state's home health aide registry, the number of hours of training for that aide shall be a prorated portion of the usual twelve (12) and eight (8) hours.

(j) A home health aide continuing education program may be offered by any organization except a home health agency that has a probationary home health agency license.

(k) The training of home health aides pursuant to a continuing education program must be performed by or under the general supervision of a registered nurse. The home health agency shall maintain sufficient documentation to demonstrate that the continuing education requirements are met.

(l) The home health agency shall be responsible for ensuring that, prior to patient contact, the individuals who furnish home health aide services on its behalf meet the requirements of this section as follows:
(1) The home health aide shall:

(A) have successfully completed a competency evaluation program that addresses each of the subjects listed in subsection (h) of this rule; and

(B) be entered on and be in good standing on the state aide registry.

(2) The home health agency shall maintain documentation, which demonstrates that the requirements of this subsection and subsection (h) of this rule were met.

(3) If the home health agency issuing the proof of the aide's achievement of successful completion of a competency evaluation program is not the employing agency, the employing agency shall keep a copy of the competency evaluation documentation in the home health aide's employment file.

(m) The home health aide shall be assigned to a particular patient by a registered nurse (or therapist in therapy only cases). The home health aide may not be assigned to perform additional tasks not included in the original competency evaluation until he or she has successfully been evaluated as competent in that task. The home health aide must report any changes observed in the patient's conditions and needs to the supervisory nurse or therapist.

(n) A registered nurse, or therapist in therapy only cases, shall make the initial visit to the patient's residence and make a supervisory visit at least every thirty (30) days, either when the home health aide is present or absent, to observe the care, to assess relationships, and to determine whether goals are being met. *(Indiana State Department of Health; 410 IAC 17-14-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2487; errata filed Mar 28, 2002, 4:28 p.m.: 25 IR 2522)*

Rule 15. Home Health Clinical Records

410 IAC 17-15-1 Clinical records

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 16-39-7-1

Sec. 1. (a) Clinical records containing pertinent past and current findings in accordance with accepted professional standards shall be maintained for every patient as follows:

(1) The medical plan of care and appropriate identifying information.

(2) Name of the physician, dentist, chiropractor, podiatrist, or optometrist.

(3) Drug, dietary, treatment, and activity orders.

(4) Signed and dated clinical notes contributed to by all assigned personnel. Clinical notes shall be written the day service is rendered and incorporated within fourteen (14) days.

(5) Copies of summary reports sent to the person responsible for the medical component of the patient's care.

(6) A discharge summary.

(7) All entries must be legible, clear, complete, and appropriately authenticated and dated. Authentication must include signatures or a secured computer entry.

(b) Original clinical records shall be retained for the length of time as required by IC 16-39-7 after home health services are terminated by the home health agency. Policies shall provide for retention even if the home health agency discontinues operations.

(c) Clinical record information shall be safeguarded against loss or unauthorized use. Written procedures shall govern use and removal of records and conditions for release of information. Patient's written consent shall be required for release of information not authorized by law. Current service files shall be maintained at the parent or branch office from which the services are provided until the patient is discharged from service. Closed files may be stored away from the parent or branch office provided they can be returned to the office within seventy-two (72) hours. Closed files do not become current service files if the patient is readmitted to service. *(Indiana State Department of Health; 410 IAC 17-15-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2489)*

Rule 16. Incorporation by Reference

410 IAC 17-16-1 Incorporation by reference

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. Chapter IV(B) of "Core Curriculum on Tuberculosis, Fourth Edition, (2000)" is hereby incorporated by reference. Copies of this publication may be obtained by writing to Technical Information Services, Centers for Prevention Services, Centers

for Disease Control, Mail Stop E06, Atlanta, Georgia 30333. Copies may also be obtained from the Indiana State Department of Health, 2 North Meridian Street, Indianapolis, Indiana 46202-3006. *(Indiana State Department of Health; 410 IAC 17-16-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2489)*

ARTICLE 17.1. HOSPICE PROGRAM PROVIDER CERTIFICATION

Rule 1. Certification of Program Providers

410 IAC 17.1-1-1 Definitions

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-22.5; IC 25-23-1-11; IC 25-23-1-12; IC 25-26-13; IC 25-27-1-8; IC 25-35.6-3

Sec. 1. As used in 410 IAC 17.1:

"Attending physician" means the physician who holds a valid license issued pursuant to IC 25-22.5 who is identified by the patient at the time of hospice program admission as having the most significant role in the determination and delivery of medical care for the patient.

"Board" means the Indiana state board of health.

"Bereavement services" means services provided to the family after the hospice patient's death.

"Care plan" means the proposed method developed in writing by the interdisciplinary care team through which the hospice program seeks to provide services which meet the patient's/family's medical, psychosocial and spiritual needs.

"Clergy member" means an individual who has received a degree from an accredited theological school and has fulfilled appropriate denominational seminary requirements; an individual who, by ordination or authorization from the individual's denomination, has been approved to function in a pastoral capacity; or the spiritual counselor of the individual's choice.

"Coordinator of volunteers" means an individual on the hospice program staff who coordinates and supervises the activities of all volunteers.

"Dietary counseling" means counseling given by a qualified dietitian, one who meets the qualifications established by the Committee on Professional Registration of the American Dietetic Association.

"Director" means the person having administrative responsibility for the operation of the hospice program.

"Governing body" means the person or group of persons responsible for the establishment of a hospice program and for development and monitoring of policies and procedures related to all aspects of the hospice program. The governing body ensures that all services provided are consistent with accepted standards of hospice practice.

"Home health aide/nursing assistant" means an individual who renders assistance to patients for personal care and any other duties specified in the care plan as assigned by a registered nurse.

"Hospice patient's family" includes an individual's spouse, sibling, child, parent or significant others as designated by patient.

"Hospice program" means a specialized form of interdisciplinary health care that is designed to alleviate the physical, psychological, social and spiritual discomforts of an individual who is experiencing the last phase of a terminal disease. Services to terminally ill patients and family unit as provided in 410 IAC 17.1 by a hospital, health facility, or home health agency do not constitute a "hospice program" unless that entity has a distinct hospice program.

"Hospice program patient" means a terminally ill patient, as diagnosed by a physician with an unlimited license to practice medicine in Indiana under IC 25-22.5, which illness is anticipated to have a terminal prognosis within six (6) months.

"Hospice staff" means personnel working under the jurisdiction of a hospice, either salaried employee or volunteer, appropriately trained and assigned.

"Identifiable hospice program administration" means an administrative group, individual, or legal entity that has an identifiable organizational structure, accountable to a governing board directly or through a chief executive officer. This administration shall be responsible for the management of all aspects of the program.

"Informed consent" means the agreement in writing to receive hospice program care by a person who can give consent pursuant to IC 16-8-12-1 *[IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* et seq.

"Inpatient beds" means beds provided by existing facilities for use by hospice patients, under written agreement, when they are required for medical management of symptoms or for respite care.

"Interdisciplinary care team" means the following hospice program personnel: physician, registered nurse, social worker, clergy member, the coordinator of volunteers, and appropriate volunteers. Other health care practitioners providing services such

as physical therapy, occupational therapy, speech therapy, dietary counseling, home health aide services or other services may be included on the team when appropriate.

"Licensed practical nurse" means an individual who holds a valid license issued pursuant to IC 25-23-1-12.

"Medical director" means a physician who directs the medical aspects of the hospice's patient care program.

"Occupational therapist" means an individual who is registered as such with the American Occupational Therapy Association.

"Palliative care" means treatment and comfort measures directed toward relief of symptoms, controlling pain and focusing on the special needs of the patient and family as they experience the stress of the dying process, rather than treatment aimed at intervention for the purpose of cure or prolongation of life.

"Patient/family care coordinator" means a registered nurse designated by the hospice to coordinate the provision of hospice program services for each patient/family.

"Pharmacist" means an individual who holds a valid license issued pursuant to IC 25-26-13.

"Physical therapist" means an individual who holds a valid license issued pursuant to IC 25-27-1-8.

"Physician" means an individual who holds a valid license issued pursuant to IC 25-22.5.

"Primary caregiver" means the family member or other person who assumes the overall responsibility for the care of the patient in the home.

"Registered nurse" means an individual who holds a valid license issued pursuant to IC 25-23-1-11.

"Respite care" means care provided to a patient for the purpose of temporary relief to family members or others caring for the patient at home.

"Social worker" means an individual holding a master's degree or a bachelor's degree in social work from a school accredited by the Council on Social Work Education with experience in a health related field and who is capable of providing for hospice patients'/families' psychosocial needs.

"Speech pathologist" means an individual who hold *[sic.]* a valid license issued pursuant to IC 25-35.6-3.

"Volunteer" means an individual, professional or nonprofessional, who has received appropriate orientation and training consistent with acceptable standards of hospice philosophy and practice. This does not include the clergy member. *(Indiana State Department of Health; 410 IAC 17.1-1-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1519; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-1-2 Application

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. An applicant may obtain voluntary certification as follows: The applicant shall submit a certification fee and an application showing the ability to comply with the minimum standards for hospice program certification. The application at a minimum shall contain the following information:

(1) The name of the applicant.

(2) The type of services to be provided.

(3) The location of the program's operation and geographic area served.

(4) The names and business addresses of persons in charge of the program, including governing body, director, and corporate officers or partners.

(5) Composition of medical, paramedical, professional and volunteer staff.

(6) Name and business address of medical director and patient/family care coordinator.

(7) Information related to the provision of inpatient care.

(8) Other information as may be required.

(Indiana State Department of Health; 410 IAC 17.1-1-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1521; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 17.1-1-3 Inspections

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. (a) The hospice program shall provide and make available for inspection policies, administrative and statistical data,

and clinical records required to verify compliance with rules contained in this chapter *[410 IAC 17.1]*.

(b) No certification shall be issued until a representative of the board has conducted a survey of the hospice program for determination of compliance with 410 IAC 17.1.

(c) The certification shall be posted in a conspicuous location accessible to public view within the premises.

(d) Certification of provider expires one (1) year after the date of issuance. It is not assignable or transferable and may be issued only for the premises named in the application. Certification of a provider may be renewed by submitting a renewal application approved by the board and the annual certification fee.

(e) An annual certification fee of one hundred dollars ($100) for each provider certified must be paid to the board prior to inspection. *(Indiana State Department of Health; 410 IAC 17.1-1-3; filed Dec 11, 1987, 2:30 pm: 11 IR 1521; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-1-4 Approval; denial; suspension; revocation

Authority: IC 16-27-1-7
Affected: IC 4-21.5; IC 16-27-1

Sec. 4. The board shall:

(1) approve the certification of an applicant upon the application and after a survey without further evidence; or

(2) deny, suspend, or revoke a certification pursuant to IC 4-21.5 (actions commenced prior to July 1, 1987 shall be governed by IC 4-22-1 *[IC 4-22-1 was repealed by P.L.18-1986, SECTION 2, effective July 1, 1987.*).

(Indiana State Department of Health; 410 IAC 17.1-1-4; filed Dec 11, 1987, 2:30 pm: 11 IR 1521; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 2. Interdisciplinary Team

410 IAC 17.1-2-1 Planned, continuous care

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. An interdisciplinary team must provide hospice program care through a program of planned and continuous care, the medical components of which must be under the direction of a physician as defined in 410 IAC 17.1-1. Hospice program care must provide for the physical, psychological, social, spiritual, and other special needs of the hospice program patients and their families that are experienced during the final stages of terminal illnesses, during dying, and during the period in which the patient's family experiences and adjusts to the patient's death. Hospice program care must be available twenty-four (24) hours a day, seven (7) days a week. *(Indiana State Department of Health; 410 IAC 17.1-2-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1521; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-2-2 Minimum care

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. The interdisciplinary team that provides for the care under Sec. 1 above shall include, at a minimum, the patient's attending physician or designated physician and personnel of the hospice program, including the medical director or physician designated, a nurse, a social worker, a member of the clergy, and a trained individual who offers services to the hospice program without compensation other than reimbursement for that individual's expenses in providing the services. *(Indiana State Department of Health; 410 IAC 17.1-2-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1521; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 3. Administration

410 IAC 17.1-3-1 Written policies

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. The governing body shall establish written policies for all aspects of the hospice program. Such policies shall be available for inspection by the board. *(Indiana State Department of Health; 410 IAC 17.1-3-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1521; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-3-2 Supervision and management

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. (a) The governing body shall designate individuals to serve as director, medical director, patient/family care coordinator, and coordinator of volunteers.

(b) There shall be written policies that specify the authority and responsibilities of these individuals. In the event the position of director or medical director becomes vacant, the board shall be notified, in writing, within 72 hours of the vacancy. *(Indiana State Department of Health; 410 IAC 17.1-3-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1522; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-3-3 Statistical records

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. (a) The hospice program shall maintain statistical records.

(b) Records shall include, but not be limited to: hours worked by staff, including volunteers; patient census information including numbers of referrals, admissions and discharges; patient diagnoses; service location (home or inpatient) and other appropriate statistical data as required for the operation of the hospice.

(c) Records shall be retained for a period in accordance with federal and state laws. *(Indiana State Department of Health; 410 IAC 17.1-3-3; filed Dec 11, 1987, 2:30 pm: 11 IR 1522; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 4. Personnel

410 IAC 17.1-4-1 Policies, records

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. The hospice program shall have written personnel policies. Personnel records shall be established and maintained for hospice program staff providing direct patient/family services which include education, training, previous experience, verification of license when applicable, and other qualifications. *(Indiana State Department of Health; 410 IAC 17.1-4-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1522; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-4-2 In-service education and training

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. (a) Written policies shall be established and implemented which include orientation, volunteer training and in-service education for all hospice program staff. Records on the content of volunteer training sessions and on the subject of in-service shall be maintained by the hospice program; attendance records for both shall be kept.

(b) Training for hospice program staff providing direct patient/family services shall include, but not be limited to, the following:

(1) hospice program philosophy and concepts of care;
(2) physiological and psychological aspects of terminal illness;
(3) symptom management;
(4) family dynamics and coping;
(5) communication and listening;

(6) emergency procedures;
(7) procedure for death occurring in the home;
(8) grief and bereavement; and
(9) documentation and record keeping.

(Indiana State Department of Health; 410 IAC 17.1-4-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1522; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 17.1-4-3 Job descriptions

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. (a) Job descriptions for each hospice program staff position shall be established which include qualifications and specific responsibilities.

(b) Hospice program staff shall be assigned only to duties for which they are trained and competent to perform. Volunteers shall have clearly defined roles and where applicable, meet the same professional standards of practice as required for hospice salaried employees. Volunteers shall function under the supervision of the coordinator of volunteers. *(Indiana State Department of Health; 410 IAC 17.1-4-3; filed Dec 11, 1987, 2:30 pm: 11 IR 1522; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 5. Services

410 IAC 17.1-5-1 Service requirements

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23-1

Sec. 1. The governing body shall ensure through policies and implemented procedures that the following services encompassing the essential elements of hospice program care are provided.

(1) Nursing services available 24 hours a day under the supervision of a registered nurse; provided in accordance with the Indiana Nurse Practice Act (IC 25-23-1) and the care plan; and sufficient to ensure that the nursing needs of each patient are met.

(2) Social work services which may include, but not be limited to, conducting an assessment of the psychosocial needs of the patient/family with the establishment of goals in the care plan to meet those needs; on-going counseling related to death and dying to the patient/family as needed; and assisting the patient/family in the utilization of appropriate community resources.

(3) Additional counseling services shall include spiritual and any other counseling services desired by the patient/family. Spiritual counseling shall include liaison and consultation with the patient/family, clergy and other community based clergy. The hospice shall not impose any spiritual value or belief systems on patients/families. All counseling services shall be in accordance with the care plan.

(4) Bereavement services shall be provided for an appropriate period of time to the family following the death of the patient, generally not less than one (1) year.

(5) Volunteer services for a broad range of activities under the direction of the coordinator of volunteers.

(6) When inpatient care services for symptom management or respite care are provided in a licensed hospital, skilled nursing or comprehensive care facility, the hospice program shall ensure that:

(A) A written agreement is signed by both providers which assures that the inpatient facility will provide care and services to hospice program patients when necessary.

(B) The inpatient provider has policies consistent with the needs of hospice program patients and their families and shall, if necessary, modify policies such as visiting hour restrictions and routine tests to meet those needs.

(C) The hospice program plan of care is furnished to the inpatient provider to ensure that the regimen established is followed as closely as feasible during the inpatient stay.

(D) All inpatient treatment and services are documented in the inpatient medical records and a copy of the discharge summary shall be made part of the hospice program record.

(E) Effective transition from one type of care to another maintained with continuity of care being the primary goal.

(Indiana State Department of Health; 410 IAC 17.1-5-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1522; readopted filed Jul 11, 2001,

2:23 p.m.: 24 IR 4234)

410 IAC 17.1-5-2 Additional services

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. When ordered by the attending physician and specified in the care plan, the following services shall be provided either directly by the hospice program or by contractual arrangement:

(1) Mental health services.
(2) Pharmaceutical services.
(3) Allied health services, to include:
(A) physical therapy;
(B) occupational therapy;
(C) speech therapy;
(D) home health aide;
(E) nutritional assessment and dietary counseling; and
(F) other services when ordered by the attending physician in accordance with the care plan to meet unusual needs.

(Indiana State Department of Health; 410 IAC 17.1-5-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1523; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 17.1-5-3 Other service providers

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. (a) When a hospice program makes arrangements for the provision of services by other agencies and individuals, there shall be a written agreement signed by both providers which includes the following:

(1) the specific services to be provided;
(2) the period of time the contract is to be in effect;
(3) the availability of service;
(4) the financial arrangements;
(5) the provision for supervision of contracted personnel where applicable;
(6) the verification that any individual providing service is appropriately licensed as required by statute;
(7) the assurance that individuals providing services under contractual arrangement meet the same requirements as found in this chapter *[410 IAC 17.1]* for hospice staff; and
(8) the provision for the documentation of services provided in the patient's medical record.

(b) All contracted services shall be provided in accordance with the orders of the attending physician and the care plan.

(c) The hospice program shall assure that all contracted services are provided in accordance with the agreement.

(d) The hospice program shall provide information and education as necessary on the hospice philosophy and concept of care to all agencies and individuals providing contracted services. *(Indiana State Department of Health; 410 IAC 17.1-5-3; filed Dec 11, 1987, 2:30 pm: 11 IR 1523; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-5-4 Direction and coordination

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 4. (a) All hospice program services shall be provided in accordance with the attending physician's orders and coordinated by the patient/family care coordinator in accordance with the written care plan developed by the interdisciplinary care team.

(b) Each patient/family accepted for hospice program care shall receive written information pertaining to services available, including the means of contacting “on call” personnel and other information as necessary. *(Indiana State Department of Health; 410 IAC 17.1-5-4; filed Dec 11, 1987, 2:30 pm: 11 IR 1523; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-5-5 Medical supplies

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 5. The hospice program shall make arrangements for obtaining any necessary supplies or equipment needed by the patient in the home; e.g., dressing, catheters, and oxygen. *(Indiana State Department of Health; 410 IAC 17.1-5-5; filed Dec 11, 1987, 2:30 pm: 11 IR 1524; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 6. Patient/Family Care

410 IAC 17.1-6-1 Acceptance of patients

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. (a) The hospice program shall have written policies which are implemented by the interdisciplinary care team in making decisions regarding acceptance of patients/families and the designation of a primary caregiver.

(b) On acceptance, the hospice program shall ensure its resources are sufficient to meet the needs of the patient/family.

(c) Patients accepted shall be under the care of the attending physician or designee who has determined that hospice program care is appropriate, indicating prognosis, generally not to exceed six (6) months, and so indicates with a signed referral. *(Indiana State Department of Health; 410 IAC 17.1-6-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1524; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-6-2 Provision of care

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. (a) All care and services provided shall be in accordance with the attending physician's or designee's written orders and the care plan. Physician's orders shall be reviewed and signed by the physician at least every two months and maintained in the patient's medical record.

(b) Care and treatments that are required by statute or rule to be rendered by or under the supervision of licensed persons must be carried out by individuals currently licensed, certified, or registered in Indiana.

(c) Care provided by home health aides shall be supervised by licensed registered nurses every two weeks.

(d) The hospice program shall have a written policy implemented which controls the exposure of patients, families and hospice personnel to persons with communicable disease. *(Indiana State Department of Health; 410 IAC 17.1-6-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1524; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 7. Care Plan for Patient/Family

410 IAC 17.1-7-1 Establishment of plan

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. The hospice program shall have policies and procedures which ensure that a written care plan is developed and maintained for each patient/family. The plan shall be established by the interdisciplinary care team in accordance with the orders of the attending physician and be based on the complete assessment of the patient's/family's physical needs and the psychosocial, economic and spiritual needs of the patient. *(Indiana State Department of Health; 410 IAC 17.1-7-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1524; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-7-2 Content of plan

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. The plan shall include the following:
(1) patient's diagnosis and prognosis;
(2) identification of problems and/or needs and the establishment of appropriate goals;
(3) types and frequency of services required to meet the goals; and
(4) identification of persons/disciplines responsible for each service.

(Indiana State Department of Health; 410 IAC 17.1-7-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1524; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 17.1-7-3 Review of plan; team meetings

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. (a) The care plan shall be reviewed by appropriate interdisciplinary care team members and updated at least once monthly.

(b) The interdisciplinary care team and other appropriate personnel shall meet on a frequent and regular basis, at a minimum of once every 30 days, for the purpose of care plan review. Entries shall be recorded in the medical records of those patients whose care plans are reviewed. *(Indiana State Department of Health; 410 IAC 17.1-7-3; filed Dec 11, 1987, 2:30 pm: 11 IR 1524; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 8. Drug and Treatment Orders; Administration

410 IAC 17.1-8-1 Policies and procedures

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. (a) The hospice program shall have written policies and procedures for the administration of drugs and treatments including controlled substances initially approved and annually reviewed by the medical director.

(b) The original order for drugs and treatments shall be signed by the attending physician and incorporated in the patient's medical record.

(c) Verbal orders shall be given to a licensed registered nurse or physician, recorded and signed by the person receiving it and countersigned by the physician within one (1) week.

(d) Changes in drugs and treatments shall be signed by the physician and incorporated in the medical record within one week.

(e) Hospice program nursing staff and/or pharmacist shall monitor the patient's drug regimen frequently to assure optimal symptom control in accordance with physician's orders. *(Indiana State Department of Health; 410 IAC 17.1-8-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1524; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-8-2 Drug disposition

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. (a) The hospice program shall not keep any legend drugs or pharmaceuticals on its premises, unless it is a part of an inpatient licensed health or hospital facility.

(b) Medications are the property of the patient/family and shall be appropriately stored in the home.

(c) Hospice program shall have a policy for the disposal of unused or discontinued medications. *(Indiana State Department of Health; 410 IAC 17.1-8-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1525; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 9. Medical Records

410 IAC 17.1-9-1 Content

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. (a) The hospice program shall have policies and procedures implemented to ensure that a medical record is maintained for each patient and is made available for certification inspection.

(b) The record shall contain pertinent past and current medical and social data and include the following information:

(1) identification data (name, address, telephone, date of birth, sex, marital status);
(2) name of next of kin and/or legal guardian;
(3) names of other family members;
(4) religious preference and church affiliation and clergy, if appropriate;
(5) diagnosis and prognosis as determined by attending physician;
(6) source of referral;
(7) initial assessments;
(8) informed consent for care form;
(9) physician's orders for drugs, treatments, diet, activity and other specific therapy services;
(10) care plan;
(11) clinical notes containing a record of all professional services provided directly or by contract with entries signed by the individual providing the services;
(12) volunteer notes, as applicable, indicating type of contact, activities performed and time spent;
(13) discharge summary to include services provided, or reason for discharge if services are terminated prior to the death of the patient.

(Indiana State Department of Health; 410 IAC 17.1-9-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1525; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 17.1-9-2 Record review

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. Conduct a semi-annual review of randomly selected patient/family records for appropriateness of admission, adequacy of assessment of patient/family needs and quality of services provided. *(Indiana State Department of Health; 410 IAC 17.1-9-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1525; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-9-3 Retention of records

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. (a) The hospice program shall assure that medical records are kept confidential and secure on the certified premises and retained in accordance with federal and state laws.

(b) Bereavement service records shall be maintained in accordance with subsection (a) above. *(Indiana State Department of Health; 410 IAC 17.1-9-3; filed Dec 11, 1987, 2:30 pm: 11 IR 1525; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 10. Evaluation

410 IAC 17.1-10-1 Evaluation required

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. (a) The hospice program shall have policies and a written plan for the implementation of a comprehensive assessment at least annually of its overall program and performance. The quality and appropriateness of care provided shall be assessed with the findings used to verify policy implementation, to identify problems and to establish problem resolution and policy provision as

necessary.

(b) The hospice program shall determine what individuals will carry out the evaluation. Representatives of the governing body, hospice staff, the interdisciplinary care team, and other appropriate professionals shall be used.

(c) The evaluation shall include, but not be limited to, a review of all policies and procedures and a medical record review. *(Indiana State Department of Health; 410 IAC 17.1-10-1; filed Dec 11, 1987, 2:30 pm: 11 IR 1525; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 17.1-10-2 Documentation

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. Documentation of the evaluation must include:

(1) criteria and methods used to accomplish it;

(2) names and credentials of individuals who did the evaluation; and

(3) action taken as a result of findings, including any subsequent policy change.

(Indiana State Department of Health; 410 IAC 17.1-10-2; filed Dec 11, 1987, 2:30 pm: 11 IR 1526; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

ARTICLE 18. VITAL RECORDS

Rule 1. Provisional Certificate of Death

410 IAC 18-1-1 Scope of rule

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37

Sec. 1. It is the express intent of this regulation *[410 IAC 18-1]* to provide an orderly and systematic procedure for the official registration of deceased persons dying in this state when a certification of the cause of death cannot be obtained in time to prevent delay of funeral arrangements and disposition of the remains. It is intended that use of provisional certificate of death shall be limited to those circumstances where the cause of death cannot be obtained prior to scheduled disposition of the remains without undue hardship upon the family of the deceased or the funeral director in charge of interment. *(Indiana State Department of Health; Reg HVR-1,Sec 1; filed Jul 28, 1959, 9:40 am: Rules and Regs. 1960, p. 74; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-1-2 Provisional death certificate information

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37

Sec. 2. A provisional certificate of death shall be prescribed and furnished by the Indiana State Board of Health. Such provisional certificate of death shall require, but not be limited to, the following information: name of deceased, the usual residence of the deceased, the place of death or place where body was found, the time and date of death, the age, sex and race or color of the deceased and the name of the physician last in attendance to the deceased. The provisional certificate of death shall be considered a privilege, not a right, and its uses and limitations shall be administered by the state and local boards of health. *(Indiana State Department of Health; Reg HVR-1,Sec 2; filed Jul 28, 1959, 9:40 am: Rules and Regs. 1960, p. 74; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-1-3 Permit for transportation or disposition of body; exceptions to use of provisional certificate

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37

Sec. 3. The delivery of a provisional certif- icate of death and its acceptance by a local health officer authorized to use the

same, shall entitle the person in charge of interment to a permit for transportation and/or disposition of the body except that a provisional certificate of death shall not be used if disposition of the body is by cremation. If the circumstances suggest that the death is due to other than natural causes, permission of the coroner must be obtained prior to removal of the body or preparation of the body for burial. Upon use of a provisional certificate of death, the person in charge of interment shall present to the local health officer of the jurisdiction in which the death occurred or the body was found, a properly executed certificate of death within seven (7) days of the date of death or discovery of the body. *(Indiana State Department of Health; Reg HVR-1,Sec 3; filed Jul 28, 1959, 9:40 am: Rules and Regs. 1960, p. 74; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-1-4 Authorization of local boards for use of provisional certificate

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37

Sec. 4. Local boards of health shall make application for use of a provisional certificate of death and shall have unrevoked written authorization from the State Board of Health prior to the use of any provisional certificate of death. *(Indiana State Department of Health; Reg HVR-1,Sec 4; filed Jul 28, 1959, 9:40 am: Rules and Regs. 1960, p. 74; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-1-5 Revocation of authorization

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37

Sec. 5. Failure to comply with the provisions of this regulation and/or the laws governing the administration of Vital Statistics, shall be cause to revoke the authority for use of a provisional certificate of death in the local health jurisdiction. Upon discovery of willful or negligent violation or failure to comply with such provisions, the State Board of Health shall notify the local health officer by registered mail that authority to use the provisional certificate of death is revoked and such revocation shall be effective upon receipt. A local health officer shall not be eligible for re-application within one (1) year from the date of revocation of authority to use the provisional certificate of death. *(Indiana State Department of Health; Reg HVR-1,Sec 5; filed Jul 28, 1959, 9:40 am: Rules and Regs. 1960, p. 74; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-1-6 Suspension of provisional certificate privilege; liability

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37

Sec. 6. The local health officer may suspend the privilege of the provisional certificate of death to any funeral home, firm or establishment for failure to present a properly executed certificate of death or for other good and sufficient cause. A suspension of the privilege to use the provisional certificate of death shall not be less than ninety (90) days nor more than twenty-four (24) months. The suspension shall be subject to review and amendment or repeal by the State Board of Health. The funeral home, firm or establishment shall be responsible for the acts of funeral directors or embalmers in its employ and any suspension of privilege shall be binding upon it equally with the person in charge of interment. *(Indiana State Department of Health; Reg HVR-1,Sec 6; filed Jul 28, 1959, 9:40 am: Rules and Regs. 1960, p. 75; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-1-7 Suspension list

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37

Sec. 7. The State Board of Health shall issue on no less than a quarterly basis the name and address of all funeral homes for which the privilege is suspended and the duration of such suspension. All local health officers shall deny the use of the provisional certificate of death to any funeral home named on the suspension list. *(Indiana State Department of Health; Reg HVR-1,Sec 7; filed Jul 28, 1959, 9:40 am: Rules and Regs. 1960, p. 75; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-1-8 Advisory committee; members

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37

Sec. 8. There is hereby created, an Advisory Committee composed of five (5) persons who shall be appointed by the State Health Commissioner and such members shall serve without pay for a three (3) year term or until their successors are appointed. The committee shall include a local health officer, a physician, a representative of the Indiana Funeral Directors Association, a representative of the State Board of Embalmers and Funeral Directors and a representative of the State Board of Health, who shall act as chairman. The committee shall be advisory to the State Board of Health in matters pertaining to administration of the death registration system and this regulation *[410 IAC 18-1]*. *(Indiana State Department of Health; Reg HVR-1,Sec 8; filed Jul 28, 1959, 9:40 am: Rules and Regs. 1960, p. 75; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. Training and Registration of Eye Enucleators

410 IAC 18-2-1 Definitions

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37; IC 29-2-16

Sec. 1. As used in 410 IAC 18-2:

"Approval or approved" means, as applied to a training program in enucleation of eyes, recognition by the board that the program meets or exceeds the minimum standards established by 410 IAC 18-2.

"Board" means the state board of health.

"Eye enucleator" means a person who has successfully completed a training program in the enucleation of eyes, that was approved at the time of training by the board.

"Registered eye enucleator" means a person who:

(1) has successfully completed a training program in the enucleation of eyes that was approved at the time of training by the board, and

(2) is registered currently with the board as an eye enucleator.

"Registration" means the recognition by the board that a person is considered competent to remove eyes or eye tissue under sterile technique and to insure that the removed eye(s) and/or eye tissue are handled properly and protected until they are received by an eye bank. *(Indiana State Department of Health; 410 IAC 18-2-1; filed Aug 19, 1985, 2:54 pm: 9 IR 26; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-2-2 Sponsorship of training program; board approval

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37; IC 29-2-16

Sec. 2. (a) Sponsorship of a training program in eye enucleation must be by a medical facility approved for educational courses that has the professional capability and assumes primary responsibility for the planning and conduct of competency based on didactic and clinical training in eye enucleation.

(b) Prior to accepting students in a training program in eye enucleation, the medical facility will submit the program to the board for review and approval.

(c) Individuals will not be enrolled in a training program in eye enucleation unless the training program has been approved by the board. *(Indiana State Department of Health; 410 IAC 18-2-2; filed Aug 19, 1985, 2:54 pm: 9 IR 26; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-2-3 Instructional time; curriculum; constructive credit

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37; IC 29-2-16

Sec. 3. (a) A training program in eye enucleation must provide sufficient content, instructional time and practical experience

to assure competent performance after completion of the program.

(b) The curriculum shall include, as a minimum:

(1) Anatomy of the eye and the surrounding soft tissue and bony structures.

(2) Physiology of the eye.

(3) Appropriate instruments used and accepted procedures for the removal of the eye or part of the eye.

(4) Sterile technique and sterile procedures required for the safe removal of the eye or part of the eye.

(5) Accepted techniques for the handling, storage, and shipment of removed eyes or parts of eyes to an eye bank to insure sterility and prevent damage to the eye tissue.

(c) An individual who is enrolling in a program may be given constructive credit for specific aspects of the training if there is valid evidence of acceptable training or experience in the specific aspect of training. *(Indiana State Department of Health; 410 IAC 18-2-3; filed Aug 19, 1985, 2:54 pm: 9 IR 26; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-2-4 Faculty

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37; IC 29-2-16

Sec. 4. The training program in eye enucleation will be taught by one or more surgeons or physicians who are knowledgeable about the anatomy and physiology of the eye and surgery pertaining to the eye. *(Indiana State Department of Health; 410 IAC 18-2-4; filed Aug 19, 1985, 2:54 pm: 9 IR 27; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-2-5 Successful completion of training program

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37; IC 29-2-16

Sec. 5. An individual who is enrolled in an approved training program in eye enucleation will be considered to have successfully completed the program only when that individual:

(1) has completed the approved program curriculum (to include constructive credit) as required, and

(2) has demonstrated to the complete satisfaction of the program faculty, without supervision, the ability to:

(A) remove the eye or parts of the eye using accepted procedures under sterile technique with proper respect for the donor's body, and

(B) direct and supervise the transfer of the removed eye or part of the eye so as to be received undamaged and sterile by an eye bank.

(Indiana State Department of Health; 410 IAC 18-2-5; filed Aug 19, 1985, 2:54 pm: 9 IR 27; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 18-2-6 Registration application and issuance

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37; IC 29-2-16

Sec. 6. (a) An applicant for registration as an eye enucleator must:

(1) complete and submit an application on a form approved by the board, and

(2) submit evidence of successful completion of a training program in the enucleation of eyes.

(b) An applicant who complies with the requirements of (a), above, shall be issued a certificate of registration as an eye enucleator. *(Indiana State Department of Health; 410 IAC 18-2-6; filed Aug 19, 1985, 2:54 pm: 9 IR 27; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-2-7 Revocation of registration

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 4-21.5; IC 16-37; IC 29-2-16

Sec. 7. (a) The board may initiate proceedings to revoke the registration of an eye enucleator for any of the following causes:

(1) Fraud or misrepresentation when applying for and receiving registration.

(2) Failure to perform the eye enucleation procedure in compliance with established and accepted standards of performance.

(3) Failure on repeated occasions to perform eye enucleations on request.

(b) Such proceedings will be conducted in accordance with the provisions of IC 4-22-1 *[Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.]. (Indiana State Department of Health; 410 IAC 18-2-7; filed Aug 19, 1985, 2:54 pm: 9 IR 27; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 18-2-8 Eye enucleation advisory committee

Authority: IC 16-19-3-4; IC 16-19-3-5; IC 16-37-1-3
Affected: IC 16-37; IC 29-2-16

Sec. 8. (a) The board shall establish an eye enucleation advisory committee to provide technical advice and recommendations to the board with reference to approval of eye enucleation training programs and the registration of eye enucleators.

(b) This committee shall be composed of one representative from each of the following organizations:

(1) Indiana Academy of Ophthalmology (2) Indiana Funeral Director Association (3) Indiana Hospital Association (4) Indiana Optometric Association (5) Indiana State Nurses Association (6) Indiana University School of Medicine

and one representative each from three recognized eye banks.

(c) The committee shall meet at the request of the state health commissioner.

(d) At the first meeting and each year thereafter, the committee shall elect from its membership a chairman.

(e) After the initial appointment of the committee, each member shall serve a term of three years or until a successor is designated.

(f) To provide continuity, the first term for organizations listed in (b)(1) and (2) shall be for one year; those numbered (b)(3) and (4) shall be for two years; those listed in (b)(5) through (6) and the representatives of the eye banks shall be for three years. *(Indiana State Department of Health; 410 IAC 18-2-8; filed Aug 19, 1985, 2:54 pm: 9 IR 27; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 19. GENERAL PROVISIONS

Rule 1. Operation of Vehicles on the Grounds of the State Board of Health and Special Institutions

410 IAC 19-1-1 Scope of rule

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 1. The purpose of this Rule *[410 IAC 19-1]* is to expedite the safe and orderly conduct of state and public business, to provide parking facilities and to impose reasonable rules on the operation of motor vehicles, bicycles, and other vehicles on the property under control of the State Board of Health and the Special Institutions, as defined in IC 16-7-3-5 *[IC 16-7 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, and shall be enforced as provided herein. *(Indiana State Department of Health; HCP 1 Rule 1, Sec 1; filed Apr 26, 1979, 12:00 pm: 2 IR 685; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 19-1-2 Definitions

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 2. Definitions. As used in this Rule *[410 IAC 19-1]*:

(1) “Grounds” mean all of the land adjacent to and under the administrative control of:

(A) The Indiana State Board of Health in Indianapolis (including SBH Area of Central State Hospital Grounds);

(B) The Indiana Veterans' Home in Lafayette, Indiana;

(C) The Indiana School for the Deaf in Indianapolis;

(D) The Indiana School for the Blind in Indianapolis;

(E) The Indiana Soldiers' and Sailors' Children's Home in Knightstown; and

(F) Silvercrest Children's Development Center in New Albany;

(2) "Superintendent" means the Secretary of the Indiana State Board of Health (State Health Commissioner) and the duly appointed head (superintendents) of the Institutions described in (1)(B) through (F) *[410 IAC 19-1-2(1)(B) through (1)(F)]* of this section.

(3) "Student" means a person who is enrolled in a course of study at one of the Special Institutions.

(Indiana State Department of Health; HCP 1 Rule 1, Sec 2; filed Apr 26, 1979, 12:00 pm: 2 IR 685; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 19-1-3 General regulations

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 3. General Requirements:

(1) All employee, student, or resident vehicles, owned or operated, shall be registered and shall display the appropriate parking tag or decal (registration device) to park in posted parking areas on the grounds;

(2) Pedestrians have the right-of-way at all times;

(3) The Superintendent is authorized to designate parking areas, all parking control signs and markings, and traffic control signs and markings;

(4) The maximum speed limit for motor vehicles on the grounds shall be ten (10) miles per hour, unless otherwise designated and posted;

(5) The driver of a motor vehicle is responsible for finding a proper parking space. A proper parking space for motor vehicles on the grounds is confined to areas designated for that purpose;

(6) Any accident involving a motor vehicle on the grounds must be reported to the appropriate agency's business office. Appropriate law enforcement personnel will be called to investigate;

(7) Parking is prohibited in marked "No Parking Zone", reserved parking areas, on lawns, in construction areas, or any other place which will mar the landscape of the complex, inconvenience or endanger anyone, create a hazard, or interfere with the use of state facilities by others. Violators are subject to having their vehicles towed away at the operator's expense without resort to enforcement procedures;

(8) Yellow curbs, yellow hash marks, and "No Parking" signs designate no parking zones;

(9) Vehicle standing is allowed at any loading or service vehicle dock or zone, entrance to buildings, or emergency zone if the operator is in attendance of the vehicle or is in the process of loading or unloading and can be easily located to move the vehicle should the need arise;

(10) Reserved parking areas may be assigned by the Superintendent when appropriate;

(11) Motor bikes, motorcycles, and motor scooters are subject to all regulations and must be operated on streets designated for normal automobile use;

(12) Any vehicle in violation of this Rule *[410 IAC 19-1]* or any which are apparently abandoned may be towed and stored at the owner's expense. Ultimate action in the case of abandoned vehicles will be in accordance with the Abandoned Vehicle Act (IC 9-9-1) *[IC 9-9-1 was repealed by Acts 1981, P.L.128, SECTION 2, effective July 1, 1981.]*;

(13) The towing charges and service call fee be based on the usual and customary charges for such services in the community wherein the tow occurs;

(14) The towing service called to tow a vehicle is authorized to hold said vehicle until the towing charges are paid to the towing service. In the event the owner of a vehicle appears before the car is towed away, the vehicle will not be released to the owner until payment of the service call fee is made to the driver of the tow truck;

(15) Parking permits issued by the Special Institutions and the State Board of Health shall be mutually recognized so as to authorize parking on any of the grounds with the exception of restricted and metered areas;

(16) A charge of 25 cents per hour is made from 8:00 a.m. to 5:00 p.m., Monday through Friday, or as otherwise posted for parking at metered locations; and

(17) A uniform special or limited time parking pass shall be made available for issuance to specific individuals which will authorize designated day(s) for parking in any parking space with the exception of restricted and metered areas.

(Indiana State Department of Health; HCP 1 Rule 1, Sec 3; filed Apr 26, 1979, 12:00 pm: 2 IR 685; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 19-1-4 Violations

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 4. The following are considered violations of this Rule *[410 IAC 19-1]* and subject the violator to the enforcement procedures as provided in this Rule *[410 IAC 19-1]*:

(1) Parking across lines in designated parking spaces;

(2) Backing into parking spaces where posted. Cars must be parked front first in parking areas that are posted: "Do Not Back In";

(3) Parking against traffic flow;

(4) Parking in posted or marked area; i.e., No Parking, Loading Zone, yellow curbs, fire hydrants, hash marked area, or specifically designated reserved areas including visitor's parking in employee area, employees parking in visitor's areas, or parking in a posted handicapped parking space without specifically designated permit;

(5) Failure to properly display parking tag or decal;

(6) Moving violations, such as exceeding speed limit, failure to observe stop signs, and reckless driving; and

(7) No registration device on vehicle.

(Indiana State Department of Health; HCP 1 Rule 1, Sec 4; filed Apr 26, 1979, 12:00 pm: 2 IR 686; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 19-1-5 Enforcement; penalties

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 5. Any person, which includes but is not limited to employees of the State of Indiana, student or resident of the Institutions or visitor found to be in violation of one or more of the traffic or parking offenses specified in Sec. 4 *[410 IAC 19-1-4]* is subject to having that person's vehicle towed away at the violator's expense and restricted from the use of parking privileges. Violations are subject to the following:

(1) First Violation: Any person who violates any of the subsections contained in Sec. 4 *[410 IAC 19-1-4]* of this Rule will be notified through the use of the Traffic Violation Notice (Sec. 10 *[410 IAC 19-1-10]*) by the security officer responsible for that particular area, and a notation, if an employee of the State Board or Special Institutions is the violator, that a copy of the Traffic Violation Notice will be filed with the agency's business office and with the employee's supervisor;

(2) Second Violation: Any person who violates any of the subsections of Sec. 4 *[410 IAC 19-1-4]* of this Rule two (2) times in any twelve (12) month period and after the issuance of a Traffic Violation Notice (Sec. 10 *[410 IAC 19-1-10]*) may have the vehicle towed away at the owner's expense or may be denied parking privileges for a period not to exceed six (6) months as determined by the Superintendent;

(3) The Superintendent, or his designee, is empowered to authorize the immediate towing of any vehicle which is abandoned as defined by law, any vehicle which is parked or operated in such a manner that it poses a hazard to the safety of others, constitutes an obstruction to traffic, or any vehicle that interferes with the proper and lawful use of the grounds.

(Indiana State Department of Health; HCP 1 Rule 1, Sec 5; filed Apr 26, 1979, 12:00 pm: 2 IR 686; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 19-1-6 Parking appeals committee; application for appeal

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 6. A parking appeals committee shall be established in each Institution and in the State Board of Health and shall consist of three employees appointed by the Superintendent and shall consider written appeals for waiving or revoking of the parking citations.

An appeal must be filed with the Institution's/Board's business office no later than seven days after the traffic violation notice was issued.

The time and place of an in-person appeal will be set at the time the application for appeal is received at the business office.

(Indiana State Department of Health; HCP 1 Rule 1, Sec 6; filed Apr 26, 1979, 12:00 pm: 2 IR 686; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 19-1-7 Grounds for appeals; continuances

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 7. Each individual has the right to appeal the issuance of any parking citation to the Appeals Committee. Requirements for filing appeals are:

(1) Appeals are to be prepared in writing on the "Request for Appeal" form provided by the business office. Written explanations, supporting statements or memoranda must be attached to the "Request for Appeal" form; and

(2) In order for an appeal to be considered by the Appeals Committee, it must be filed with the applicable business office within seven days after the receipt of the violation notice.

The Appeals Committee will advise the individual, by mail, of the decision on the appeal. The decision of the Committee is to be mailed within ten (10) days after the review date.

Continuances for applicants desiring to appear before the Appeals Committee in person:

(1) The individual has the right to have the consideration of the appeal postponed to a later date if the individual chooses to appear in person before the Committee;

(2) Subsequent requests for continuances will be granted only upon showing of good cause;

(3) Requests for continuances must be communicated by telephone or letter to either the business office or a member of the Appeals Committee before the date that the appeal is scheduled to be considered;

(4) If a continuance is granted, the individual will be responsible for contacting either of the above to learn the date, time, and place at which the case will be considered unless the date was set at the time of the request.

The decision of the Appeals Committee is final. The Special Institutions/Board of Health have no other due process open to appellants where they may request a reappeal of their traffic citation. *(Indiana State Department of Health; HCP 1 Rule 1, Sec 7; filed Apr 26, 1979, 12:00 pm: 2 IR 686; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 19-1-8 Registration of vehicle

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 8. Parking Fees and Registration:

(1) All employees, students, and residents may park on the grounds without charge. However, said person shall register the vehicle with the designated officer of the Board/Institution and display the registration device assigned on the designated vehicle;

(2) Registration devices, as approved by the respective Superintendents, shall be positioned on a vehicle in accordance with the instructions issued with the device when the vehicle is registered. The registration device must be clearly visible from the exterior of the vehicle when affixed in accordance with the instructions issued;

(3) The person whose name the vehicle is registered to is held responsible for all violations by all vehicles displaying that person's registration device. A citation is not excused on the plea that another person was driving the vehicle; and

(4) Any employee, student, resident or any other person who severs relationship with the Board/Institution shall within five

(5) days of said separation remove the assigned registration device from the vehicle.

(Indiana State Department of Health; HCP 1 Rule 1, Sec 8; filed Apr 26, 1979, 12:00 pm: 2 IR 687; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 19-1-9 Authorized parking prohibitions

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 9. In an emergency, such as inclement weather and parking lot alterations and, after notification, the Superintendent reserves the right to place uniform conditions upon the right of any person to park in the parking facilities offered. The authorized

prohibitions shall include, but are not limited to, the following:

(1) Assignment of marked or numbered parking spaces to certain qualified employees; or

(2) Authorization to park based upon compliance with car pool requirements whereby said owner has, as passengers, two or more other Board/Institution employees.

(Indiana State Department of Health; HCP 1 Rule 1, Sec 9; filed Apr 26, 1979, 12:00 pm: 2 IR 687; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 19-1-10 Traffic violation notice

Authority: IC 16-19-11-2; IC 16-19-11-3
Affected: IC 16-19-11

Sec. 10. Traffic Violation Notice.

( ) INDIANA STATE BOARD OF HEALTH — TRAFFIC
( ) INDIANA VETERANS' HOME — VIOLATION
( ) INDIANA SCHOOL FOR THE BLIND — NOTICE
( ) INDIANA SCHOOL FOR THE DEAF
( ) INDIANA SOLDIERS' AND SAILORS' CHILDREN'S HOME — No. _____
( ) SILVERCREST CHILDREN'S DEVELOPMENT CENTER

This traffic Violation Notice is issued for the violation of the State Board of Health's and the Special Institutions' traffic regulation (HCP-1) as specified below:

You are directed to appear at the Business Office of the above checked institution within five (5) days of the date shown hereon to either acknowledge the receipt of this Violation Notice or to file an appeal.

Failure to appear in person or appeal this Notice of Violation within the five (5) day period will result in the vehicle being towed without notice for any subsequent violation.

NAME _____ ADDRESS _____
CITY _____ STATE _____
REGISTRATION DEV. NO. _____
VEH. LIC. NO. _____ STATE _____ YEAR _____
MAKE _____ STYLE _____ COLOR _____
( ) A.M.
DATE TIME _____ ( ) P.M.
LOCATION _____

VIOLATION COMMITTED OF SECTION 4 of RULE HCP-1

( ) NO VALID PERMIT
( ) BACKED INTO SPACE
( ) LINE STRADDLING
( ) NO REGISTRATION DEVICE
( ) MOVING VIOLATION
( ) IMPROPER REGISTRATION DEVICE DISPLAYED
( ) FIRE HYDRANT
( ) ON CURB
( ) ON CROSSWALK
( ) METER VIOLATION
( ) YELLOW CURB
( ) DOUBLE-PARKED
( ) POSTED AREA
( ) BLOCKING DRIVE
( ) OTHER

REMARKS: _____

SECURITY OFFICER: _____

DISTRIBUTION:
ORIGINAL: Traffic Violator
COPY: Security Officer's File
Business Office
Division Director

(Indiana State Department of Health; HCP 1 Rule 1, Sec 10; filed Apr 26, 1979, 12:00 pm: 2 IR 687; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

Rule 2. Choke-Saving Methods Placards

410 IAC 19-2-1 Definitions

Authority: IC 16-31-9-3
Affected: IC 16-31-9

Sec. 1. Definitions. As used in this rule *[410 IAC 19-2]*:

(a) "Board" means the State Board of Health.

(b) "Commissioner" means the State Health Commissioner of the State Board of Health.

(Indiana State Department of Health; 410 IAC 19-2-1; filed Oct 11, 1979, 4:45 pm: 2 IR 1565; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Authorizing statute not effective until Jan 1, 1980.

410 IAC 19-2-2 Approval of proposed placards

Authority: IC 16-31-9-3
Affected: IC 16-31-9

Sec. 2. The Commissioner may delegate to appropriate staff members the responsibility for evaluating the appropriateness and completeness of placards containing or displaying one (1) or more choke-saving method(s) for use in "food service establishments," as defined in IC 16-1-41-2 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*. Upon the determination that a proposed placard conforms to the requirements set forth herein, the Commissioner or his designated representative is authorized to approve the proposed placard. *(Indiana State Department of Health; 410 IAC 19-2-2; filed Oct 11, 1979, 4:45 pm: 2 IR 1565; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Authorizing statute not effective until Jan 1, 1980.*

410 IAC 19-2-3 Submission of placards for approval; identification of approval

Authority: IC 16-31-9-3
Affected: IC 16-31-9

Sec. 3. Any food service establishment owner, operator or organization having an interest in food service establishments desiring to obtain approval of a placard displaying one (1) or more choke-saving method(s) that may be used safely and effectively in an emergency by layman to remove food lodged in a person's throat shall submit two (2) copies of the proposed placard to the Division of Health Education, Indiana State Board of Health, 1330 West Michigan Street, Indianapolis, Indiana 46206. These methods must be limited to first-aid procedures and must include techniques which do not require the use of instruments or devices. Upon approval the proposed placard will be identified with an approval number, the date of approval, and the signature of the Commissioner or his designated representative, with one (1) copy of the placard being returned to the submitter. Approved placards may be reproduced for use in any food service establishments. A blank space, at least 3" wide and 1 1/2" high, shall be provided on the lower margin of the proposed placard for the inclusion of the following information:

(a) The sentence, "This placard is deemed to be in compliance with IC 16-1-41 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, and is hereby approved for use in Indiana food service establishments;" and

(b) Approval number; and

(c) Date of Approval; and

(d) Name of Commissioner or designated representative; and

(e) The words, "Indiana State Board of Health."

(Indiana State Department of Health; 410 IAC 19-2-3; filed Oct 11, 1979, 4:45 pm: 2 IR 1565; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Authorizing statute not effective until Jan 1, 1980.

410 IAC 19-2-4 Required information
Authority: IC 16-31-9-3
Affected: IC 16-31-9

Sec. 4. The minimum information required to appear on proposed placards shall include: instruction to call for help when the incident occurs; symptoms of choking; written and pictorial descriptions of at least one (1) first-aid procedure that may be effective for both conscious and unconscious victims; alternate procedure(s) that may be tried; precautions that should be taken; and a recommendation that the victim be checked by a physician after rescue. *(Indiana State Department of Health; 410 IAC 19-2-4; filed Oct 11, 1979, 4:45 pm: 2 IR 1565; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Authorizing statute not effective until Jan 1, 1980.*

410 IAC 19-2-5 Size and design requirements
Authority: IC 16-31-9-3
Affected: IC 16-31-9

Sec. 5. The placards shall be no less than 8½″ × 11″ in size, of a design suitable for posting in food service establishments, and, to the extent practicable, be expressed in words and illustrations which will be understood by laymen and not offensive to restaurant patrons. *(Indiana State Department of Health; 410 IAC 19-2-5; filed Oct 11, 1979, 4:45 pm: 2 IR 1565; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Authorizing statute not effective until Jan 1, 1980.*

410 IAC 19-2-6 Modification of approved placard; resubmission
Authority: IC 16-31-9-3
Affected: IC 16-31-9

Sec. 6. Any change in or revision of an approved placard automatically voids the approval. To obtain approval of any such changed or revised placard, it must be resubmitted in accordance with Section 3 *[410 IAC 19-2-3]* of this Rule. *(Indiana State Department of Health; 410 IAC 19-2-6; filed Oct 11, 1979, 4:45 pm: 2 IR 1565; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) NOTE: Authorizing statute not effective until Jan 1, 1980.*

Rule 3. Nursing Registry Certificate of Registration (Expired)
(Expired under IC 4-22-2.5, effective January 1, 2002.)

ARTICLE 20. STATE HEALTH PLANNING (REPEALED)
(Repealed by Indiana State Department of Health; filed Sep 16, 1983, 3:34 pm: 6 IR 2406)

ARTICLE 20.1. STATE HEALTH PLANNING (REPEALED)
(Repealed by Indiana State Department of Health; filed Oct 7, 1985, 1:44 pm: 9 IR 211)

ARTICLE 20.2. STATE HEALTH PLANNING (REPEALED)
(Repealed by the Indiana State Department of Health; filed November 7, 1986, 3:30 pm: 10 IR 422)

ARTICLE 20.3. STATE CERTIFICATE OF NEED (REPEALED)
(Repealed by Indiana State Department of Health; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1342)

ARTICLE 20.4. STATE CERTIFICATE OF NEED

Rule 1. Definitions

410 IAC 20.4-1-1 Applicability

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 20.4-1-1; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1329)*

410 IAC 20.4-1-2 "Applicant" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 2. "Applicant" means any individual, partnership, corporation, or governmental entity which has filed an application for a CON. *(Indiana State Department of Health; 410 IAC 20.4-1-2; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1329)*

410 IAC 20.4-1-3 "Application" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2; IC 16-29-1

Sec. 3. "Application" means the formal written submission, upon forms approved by the Indiana health facilities council, for CON review and payment of fees required under IC 16-29-1. *(Indiana State Department of Health; 410 IAC 20.4-1-3; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1329)*

410 IAC 20.4-1-4 "Approval" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2; IC 16-29-1; IC 16-29-4

Sec. 4. "Approval" means an authorization by the board, when required under IC 16-29-4 or IC 16-29-1, to undertake a project subject to CON and does not include approval of architectural plans or operational programs for meeting state physical plant and licensing codes although it is required for licensure. *(Indiana State Department of Health; 410 IAC 20.4-1-4; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1329)*

410 IAC 20.4-1-5 "Board" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 5. "Board" means the executive board of the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 20.4-1-5; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1329)*

410 IAC 20.4-1-6 "Certificate of need (CON)" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 6. "Certificate of need (CON)" means a finding made in accordance with this article by the board respecting an application submitted under this article, to certify beds for participation in a state or federal reimbursement program, including programs under Title XVIII or Title XIX of the Social Security Act (42 U.S.C. 1395 et seq. or 42 U.S.C. 1396 et seq.), or to construct or add comprehensive care beds, or to convert beds to comprehensive care beds. *(Indiana State Department of Health; 410 IAC 20.4-1-6; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1329)*

410 IAC 20.4-1-7 "Certified bed" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 7. "Certified bed" means a comprehensive bed which will function as a bed licensed, or to be licensed, under IC 16-28-2 which is certified, or to be certified, for participation in a state or federal reimbursement program, including programs under Title XVIII or Title XIX of the Social Security Act (42 U.S.C. 1395 et seq. or 42 U.S.C. 1396 et seq.). *(Indiana State Department of Health; 410 IAC 20.4-1-7; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-8 "Comparative review" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 8. "Comparative review" means the simultaneous review of two (2) or more applications filed within sixty (60) days after the filing of the first such application which would result in the offering of similar services or facilities in a health service area. *(Indiana State Department of Health; 410 IAC 20.4-1-8; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-9 "Comparative review officer (CRO)" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 9. "Comparative review officer (CRO)" means an individual who is hired on a contractual basis under the authority of this article to review CON applications assigned to the CRO, implement a CON review process, and make draft findings on specific CON applications and their petition for additional comprehensive care beds. *(Indiana State Department of Health; 410 IAC 20.4-1-9; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-10 "Comprehensive bed" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 10. "Comprehensive bed" means a bed in a health care facility that is licensed, or is to be licensed, under IC 16-28-2, or functions as a bed licensed under IC 16-28-2. *(Indiana State Department of Health; 410 IAC 20.4-1-10; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-11 "Construction" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 11. "Construction" means increasing the inventory of reviewable beds in a health facility or service area through activities defined as construction work but does not include the replacement of existing beds. *(Indiana State Department of Health; 410 IAC 20.4-1-11; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-12 "Construction work" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 12. "Construction work" means initiation of and continuous substantial excavation activity or actual building, constructing, carpentering, plumbing, or wiring activities performed in the establishment, modification, or renovation of a facility but does not include planning, design, or survey activities. *(Indiana State Department of Health; 410 IAC 20.4-1-12; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-13 "Conversion" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 13. "Conversion" means changing the classification of an existing bed which is not a comprehensive bed to a comprehensive bed. *(Indiana State Department of Health; 410 IAC 20.4-1-13; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-14 "Cost incurred" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 14. "Cost incurred" means the costs to construct or convert beds as outlined in the CON application, and associated increases in projected rates, if applicable, to the applicant and to the state and the comparative efficiency of those costs in comparison to equivalent costs by similar providers in the health service area. *(Indiana State Department of Health; 410 IAC 20.4-1-14; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-15 "Department" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 15. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 20.4-1-15; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-16 "Director" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 16. "Director" means the individual acting under the authority of, and assigned the responsibilities by, the commissioner to carry out provisions of IC 16-28-2. *(Indiana State Department of Health; 410 IAC 20.4-1-16; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1330)*

410 IAC 20.4-1-17 "Effectiveness" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 17. "Effectiveness" means the degree to which diagnostic, preventive, therapeutic, or other actions achieve the intended results. Effectiveness requires a consideration of outcomes to measure. Usually synonymous with efficacy in common use or the probability of benefits to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use. *(Indiana State Department of Health; 410 IAC 20.4-1-17; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1331)*

410 IAC 20.4-1-18 "Efficiency" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 18. "Efficiency" means the capacity to produce the desired results with minimum energy, time, money, or materials and to have the requisite knowledge and skills to perform in the best possible and least wasteful manner. *(Indiana State Department of Health; 410 IAC 20.4-1-18; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1331)*

410 IAC 20.4-1-19 "Ex parte contact" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 19. "Ex parte contact" means communication between or among a party or parties to a review proceeding and any decision making or recommendation making authority or agent without notice and opportunity for all parties to participate in the communication. *(Indiana State Department of Health; 410 IAC 20.4-1-19; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1331)*

410 IAC 20.4-1-20 "Final order" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-29-1; IC 16-29-4

Sec. 20. "Final order" means action by the board, or an appeals panel appointed by the board, to approve or disapprove a project which is subject to review under IC 16-29-4 or IC 16-29-1. *(Indiana State Department of Health; 410 IAC 20.4-1-20; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1331)*

410 IAC 20.4-1-21 "Health facilities" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-21-2-2; IC 16-28-2

Sec. 21. (a) "Health facility" means any building, structure, institution, or other place for the reception, accommodation, board, care, or treatment extending beyond a continuous twenty-four (24) hour period in any week of more than four (4) individuals in need or desire of such services by reason of physical or mental illness, infirmity, or impairment. However, in the case of reception, accommodation, board, care, or treatment in a household or family, for compensation of a person related by blood to the head of the household or family (or to the spouse of the head of the household or family) within the degree of consanguinity of first cousins, the premises in which the person is received, boarded, accommodated, cared for, or treated do not constitute a health facility.

(b) "Health facility" does not include the following:

(1) Hotels, motels, or mobile homes when used as such.

(2) Hospitals or mental hospitals, except for that part of a hospital that provides long term care services and functions as a health facility, in which case that part of the hospital is licensed under IC 16-21-2-2 but in all other respects is subject to this article.

(3) Institutions operated by the federal government.

(4) Foster homes or day care centers.

(5) Schools for the deaf or blind.

(6) Day schools for the retarded.

(7) Day care centers.

(8) Children's homes and child placement agencies.

(9) Offices of the practitioners of the healing arts.

(10) Any institution in which health care services and private duty nursing services are rendered in accordance with the practice and tenets of the religious denomination known as the Church of Christ Scientist or any offices of Christian Science practitioners.

(11) Industrial clinics providing only emergency medical services or first aid for employees.

(12) A residential facility as defined in IC 16-13-21-1 *[IC 16-13 was repealed by P.L.2-1992, SECTION 897, effective February 14, 1992.]*.

(Indiana State Department of Health; 410 IAC 20.4-1-21; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1331)

410 IAC 20.4-1-22 "Health service area" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 22. "Health service area" means the geographic area designated as being appropriate for the effective planning and development of health services. In the case of long term comprehensive care beds, the county of location is the service area. For intermediate care facility for the mentally retarded beds, the service area is the subarea of location within one (1) of the three (3) 1974 governor-designated Indiana health service areas: northern, central, or southern. *(Indiana State Department of Health; 410 IAC 20.4-1-22; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1331)*

410 IAC 20.4-1-23 "Indiana health facilities council" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-1-1

Sec. 23. "Indiana health facilities council" refers to the entity established by IC 16-28-1-1. *(Indiana State Department of Health; 410 IAC 20.4-1-23; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1331)*

410 IAC 20.4-1-24 "Intermediate care facility for the mentally retarded" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 24. "Intermediate care facility for the mentally retarded" means a health facility with beds licensed under IC 16-28-2 or used as beds licensed under IC 16-28-2 which serves persons with mental retardation. *(Indiana State Department of Health; 410 IAC 20.4-1-24; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)*

410 IAC 20.4-1-25 "Noncertified bed" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 25. "Noncertified bed" means a comprehensive bed licensed, or to be licensed under IC 16-28-2 or used as a bed licensed under IC 16-28-2 which is not certified, or proposed to be certified, for participation in a state or federal reimbursement program, including programs under Title XVIII or Title XIX of the Social Security Act (42 U.S.C. 1395 et seq. or 42 U.S.C. 1396 et seq.). A noncertified bed is the same as a private pay bed. *(Indiana State Department of Health; 410 IAC 20.4-1-25; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)*

410 IAC 20.4-1-26 "Party" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 26. "Party" means the following:

(1) State department.

(2) The person, or persons in the case of comparative review, submitting an application for CON review.

(3) Any person determined by the Indiana health facilities council, the board or an appeals panel appointed by the state board, the CRO, or the administrative law judge to be aggrieved by an order issued under this article.

(Indiana State Department of Health; 410 IAC 20.4-1-26; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)

410 IAC 20.4-1-27 "Person" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 4-21.5; IC 16-28-2

Sec. 27. "Person" means an individual, firm, partnership, corporation, association, company, and the legal successors thereof. *(Indiana State Department of Health; 410 IAC 20.4-1-27; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)*

410 IAC 20.4-1-28 "Project excepted from review" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 28. "Project excepted from review" means those projects identified in 410 IAC 20.4-2-4 *[sic.]*. *(Indiana State Department of Health; 410 IAC 20.4-1-28; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)*

410 IAC 20.4-1-29 "Project subject to review" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 29. "Project subject to review" means those projects identified in 410 IAC 20.4-2-3. *(Indiana State Department of Health;*

410 IAC 20.4-1-29; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)

410 IAC 20.4-1-30 "Proposal" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 30. "Proposal" means the beds or facility proposed in an application for CON review. *(Indiana State Department of Health; 410 IAC 20.4-1-30; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)*

410 IAC 20.4-1-31 "Quality care services" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 31. "Quality care services" means that each patient must receive, and each facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with the comprehensive assessment and plan of care. Based on that assessment, a facility must assure that a patient's abilities in activities of daily living do not diminish unless such diminution is unavoidable because of the resident's clinical condition. Patients are to receive appropriate treatment and services to maintain or improve their ability to carry out daily activities. Activities of daily living include the ability to bathe, dress, groom, transfer, ambulate, use the toilet, eat, and use speech or another functional communication system. Patients who are unable to carry out activities of daily living must receive necessary services to maintain good nutrition, grooming, and personal and oral hygiene. *(Indiana State Department of Health; 410 IAC 20.4-1-31; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)*

410 IAC 20.4-1-32 "Specialized services" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2; IC 16-29-2

Sec. 32. "Specialized services" means a series of services identified under IC 16-29-2 that are excluded from this article. The specialized services will include services for patients who are ventilator dependent, who have a progressive neuromuscular disease, or who have been infected by human immunodeficiency virus (HIV). *(Indiana State Department of Health; 410 IAC 20.4-1-32; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1332)*

410 IAC 20.4-1-33 "Sponsored" defined

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 33. "Sponsored" means:

(1) the sponsor organization is financially responsible for the obligations of either the legal entity which owns, or the legal entity which operates, the comprehensive care beds; or

(2) the sponsor organization is and will remain responsible for the satisfactory delivery of care in the beds sponsored by it.

(Indiana State Department of Health; 410 IAC 20.4-1-33; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1333)

Rule 2. Applicability

410 IAC 20.4-2-1 State health plan

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-30-2-4; IC 16-42; IC 16-43; IC 16-46

Sec. 1. (a) The department shall develop and promote a state health plan and recommend to the governor and the general assembly means by which programs and activities can be developed and implemented to effectively and efficiently meet the identified needs. The department shall submit annually, to the governor and to the general assembly, a report of these health needs

and the board's recommendations. Each report must be submitted by November 1 of each year.

(b) The report required by subsection (a) must address, on a county-by-county basis, the health needs of the state concerning the provision of the following types of services:

(1) Public health services described in IC 16.

(2) Disease treatment services described in IC 16-46.

(3) Food and drug control services described in IC 16-42 and IC 16-43.

(4) All other services within the jurisdiction of the department. Bed need projections will be published as required by IC 16-30-2-4.

(Indiana State Department of Health; 410 IAC 20.4-2-1; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1333)

410 IAC 20.4-2-2 Scope of coverage

Authority: IC 16-28-1-12; IC 16-29-1-13

Affected: IC 4-21.5-3-5; IC 4-21.5-3-7; IC 6-2.1-3-20; IC 6-2.1-3-21; IC 16-21-2-2; IC 16-24-1; IC 16-28-2; IC 16-29-1; IC 16-29-4-3

Sec. 2. (a) Projects subject to review include, but are not limited to, the following:

(1) The conversion of existing health facility beds to intermediate care facility for the mentally retarded beds.

(2) An increase by any means, including space reallocation and new construction, in the number of intermediate care facility for the mentally retarded beds in a facility.

(3) The construction of comprehensive care beds which are to be licensed, or will function as if licensed, under IC 16-28-2.

(4) The conversion of existing beds to comprehensive care beds which are to be licensed, or will function as if licensed, under IC 16-28-2.

(5) An increase by any means, including space reallocation, in the number of noncertified comprehensive care beds in a facility if those beds will function essentially as beds licensed under IC 16-28-2.

(6) An increase by any means, including space reallocation, in the number of certified comprehensive care beds in a health facility if those beds will function essentially as beds licensed under IC 16-28-2.

(7) Any request made by, on behalf of, or through an existing or proposed health facility, licensed and regulated under IC 16-21-2-2, IC 16-28-2, IC 16-24-1, or IC 12-11-2 *[IC 12-11-2 was repealed by P.L.272-1999, SECTION 66, effective July 1, 1999.]*, that proposed or existing beds be used as beds licensed under IC 16-28-2 and certified to participate in state or federal reimbursement programs, including programs under Title XVIII or Title XIX of the Social Security Act (42 U.S.C. 1395 et seq. or 42 U.S.C. 1396 et seq.).

(b) Except with respect to the conversion of beds under IC 16-29-4-3, a project to construct, add, or convert comprehensive care beds is presumed to be subject to the review required by this article unless the Indiana health facilities council determines that the project is exempt or excepted by law from review. Any person desiring to construct, or to add comprehensive care beds, or to convert comprehensive care beds without the review and approval required by this article, must obtain the determination of the Indiana health facilities council that the project is exempt or excepted from review. A person who constructs, adds, or converts comprehensive care beds without having obtained such review and approval, or without having petitioned timely for a determination of exemption or exception from review and approval, or in contravention of a determination by the Indiana health facilities council that the project is not exempt or excepted by law from the review and approval required by this article, is in breach of this article and becomes an unqualified applicant for a license under IC 16-28-2.

(c) Petitions to the Indiana health facilities council for a determination that a project is exempt or excepted from review must be filed with the Indiana health facilities council before construction work on a project is commenced, unless construction work on a project was commenced prior to the effective date of this article, in which case such petitions for a determination of exemption or exception must be filed within thirty (30) days of the effective date of this article.

(d) A petition for a determination that a project is exempt or excepted from review must include the following:

(1) All the reasons the petitioner claims that the project is exempt or excepted from review.

(2) One (1) or more affidavits which set forth sworn statements of fact, made under penalty of perjury, which evidence the basis of the claim that the project is exempt or excepted from review, and which attest to the genuineness and truthfulness of all documentation supporting the affidavit and the petition.

(3) Documents which evidence, are referable to, and which establish each of the sworn statements of fact set forth in the petition.

(4) If the petition claims that a project is exempt or excepted from review under IC 16-29-1-9 through IC 16-29-1-11, an affidavit which sets forth sworn statements of fact made under penalty of perjury that:

(A) if the comprehensive care beds are exempt because they are sponsored by a religious or fraternal organization:

(i) that the religious or fraternal organization is and will continue to be financially responsible for the mortgages, notes, wages, taxes, and other obligations of either the legal entity which owns the beds or the legal entity which operates the beds; or

(ii) is in lieu of the foregoing provision, that the religious or fraternal organization owned, operated, or controlled comprehensive care beds licensed under IC 16-28-2 prior to May 6, 1989, and, as a condition subsequent to obtaining a determination of exemption or exception, that the religious or fraternal organization will own, operate, or, in like degree and in the same or substantially similar manner, control the beds which are the subject of the petition;

(B) the comprehensive care beds will be used to serve members of the religious or fraternal organization;

(C) the organization, if a religious organization:

(i) is an Indiana nonprofit corporation;

(ii) was exempt by virtue of its status as a religious organization from gross income taxation under IC 6-2.1-3-20 on or before December 31, 1986, and continues to be exempt; and

(iii) has conducted worship since December 31, 1986;

(D) the organization, if a fraternal organization:

(i) was exempt from gross income taxation under IC 6-2.1-3-21 on or before December 31, 1986, and continues to be exempt; and

(ii) owned, operated, or sponsored a health care facility licensed under IC 16-28-2 on December 31, 1986;

(E) the organization has complied and will continue to comply with the requirements of IC 16-29-1-9 through IC 16-29-1-11; and

(F) a notice has been published in a newspaper of general circulation in the county for which the project has been proposed and has been provided to all the licensees of comprehensive care beds in that county of the filing of the petition.

(e) Upon a determination by the Indiana health facilities council as to whether a project is exempt or excepted from review, the Indiana health facilities council shall issue a notice of such determination under IC 4-21.5-3-5. Upon receipt of the finding, the director shall certify that the applicant meets the statutory requirements under IC 16-29-1-9 or IC 16-29-1-10 and process the application for licensure accordingly.

(f) To qualify for a review of the Indiana health facilities council's determination, a person must comply with IC 4-21.5-3-7. If a petition for a review is not filed under IC 4-21.5-3-7 within the fifteen (15) day period, the determination of the Indiana health facilities council is final.

(g) Each application for a CON shall be processed and reviewed under the provisions contained in this article. *(Indiana State Department of Health; 410 IAC 20.4-2-2; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1333)*

410 IAC 20.4-2-3 Exception to coverage

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-21-2; IC 16-28-2; IC 16-29-1; IC 16-29-2; IC 16-29-3-1; IC 25-4; IC 25-31

Sec. 3. (a) Requirements of this article do not apply to the following activities, referred to hereafter as projects excepted from review:

(1) The construction, development, or other establishment of a Christian Science sanitarium operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts.

(2) Comprehensive care beds that are owned, operated, or sponsored by a religious organization as described by IC 16-29-1-9 if the beds are to be used to serve members of the religious organization.

(3) Comprehensive care beds that are owned or operated by an Indiana nonprofit corporation that is owned by a religious organization described in IC 16-29-1-9 and used to serve members of that religious organization.

(4) Comprehensive care beds that are owned, operated, or sponsored by a fraternal organization as described by IC 16-29-1-10 if the comprehensive care beds are used to serve members of that fraternal organization.

(5) The replacement of existing facilities without an increase in the number of comprehensive care beds which will function

as beds licensed under IC 16-28-2.

(6) The replacement of existing facilities without an increase in beds which are certified to participate in Title XVIII or Title XIX of the Social Security Act (42 U.S.C. 1395 et seq. or 42 U.S.C. 1396 et seq.).

(7) The conversion, as authorized by IC 16-29-3-1, by a hospital licensed under IC 16-21-2, of:

(A) up to thirty (30) acute care beds to skilled level certified comprehensive long term care beds beginning January 1, 1986; and

(B) up to an additional twenty (20) acute care beds to either intermediate level certified comprehensive beds or skilled level certified comprehensive long term care beds, beginning June 1, 1989, if those beds will function essentially as beds licensed under IC 16-28-2.

(8) The construction, as authorized by IC 16-29-1-8, by a facility licensed under IC 16-28-2, of a maximum of fifteen (15) noncertified comprehensive care beds.

(9) The construction, as authorized by IC 16-29-1-8, by a hospital licensed under IC 16-21-2, of a maximum of ten (10) noncertified comprehensive care beds.

(10) The construction or renovation of a comprehensive care bed that will be solely used to provide specialized services under IC 16-29-2. Review under IC 16-29-2 is excluded from this article.

(b) The owner of a CON which has not expired or been voided may sell or otherwise transfer that certificate without additional CON approvals if:

(1) the certificate is not used outside of the county or, in the case of an intermediate care facility for the mentally retarded proposal, the service area with respect to which it was issued;

(2) the total number of beds constructed under the CON does not exceed the number originally approved; and

(3) the department is given notice and documentation of the transfer.

(c) Comprehensive care beds that were exempted from review prior to May 5, 1989, are subject to certificate of need review and approval unless those comprehensive care beds were licensed as such prior to the effective date of this article.

(d) Affirmations of exceptions and exemptions, affidavits of truthfulness, and counter assertions shall be received by the Indiana health facilities council. The Indiana health facilities council shall decide if a project is excepted or exempted from CON review. *(Indiana State Department of Health; 410 IAC 20.4-2-3; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1334)*

Rule 3. General Provisions

410 IAC 20.4-3-1 Computation of time and filing

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 1. Any time period provided for in this article shall be computed in accordance with the Indiana Rules of Trial Procedures. *(Indiana State Department of Health; 410 IAC 20.4-3-1; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1335)*

410 IAC 20.4-3-2 Application content

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2; IC 16-30-1-1

Sec. 2. (a) An application for CON under this article shall be filed with the secretary of the Indiana health facilities council upon forms approved by the Indiana health facilities council. The application shall contain such information as the Indiana health facilities council deems necessary.

(b) The application shall include information regarding the need for the project, including the following:

(1) Justification for the project.

(2) Evidence of consistency of the project with the goals of the state health plan.

(3) Rationale for the project if it is not consistent with the state health plan.

(4) Alternatives to the project.

(5) Specific location of the project.

(6) Data regarding the utilization of existing facilities in the county proposed to be served.

(c) The application shall provide financial information about the project, including, but not limited to, the following:

(1) Pro forma financial statements for the first three (3) years of the project's operation.

(2) Debt service requirements.

(3) Sources of financing.

(4) Projected rates for the facility with evidence that the Medicaid rates used are reimbursable under the Medicaid rate-setting criteria.

(d) The application shall include the health personnel requirements for the operation of the project, including the following:

(1) A list of all categories of personnel required for the project, the number of personnel to be added or reduced for the project, and plans for recruiting new personnel.

(2) Data on the availability of health personnel in the service area which shall include at least the response to inquiries made by the applicant to each facility, hospital, home health agency, employment agency, and nurse training institution in the area.

(e) The application shall include information regarding the impact of the project upon the service area, including impact on other providers.

(f) The application shall include information to illustrate and document the experience or capacity of the applicant to provide quality, effective, and efficient care, including, but not limited to, the following:

(1) A description of past or current adverse licensure action, if any, against any facility owned, operated, or managed by the applicant.

(2) A list of facilities owned, operated, or managed by the applicant.

(3) Letters of recommendation and reference.

(4) Letters of support.

(g) The application shall include a timetable for start-up and completion of the project.

(h) The application shall include a properly notarized affidavit of truthfulness and proper submission signed by the applicant and owner. The affidavit shall indicate that copies of the application and attachments are accurate. In the case of a corporate applicant, the president or chief executive of the corporation shall sign the form on behalf of the corporation; in the case of a partnership, all partners shall sign; in the case of a limited partnership, all general partners shall sign; in the case of a trust, all trustees shall sign; in the case of an estate, the executor or administrator shall sign; in the case of any governmental unit, its managing officer shall sign; and, in the case of a receivership, the receiver of record shall sign and also submit a certified letter of appointment. *(Indiana State Department of Health; 410 IAC 20.4-3-2; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1335)*

410 IAC 20.4-3-3 Review responsibilities; applicant

Authority: IC 16-28-1-12; IC 16-29-1-13

Affected: IC 16-28-2; IC 16-29-1-7; IC 16-29-4; IC 25-4; IC 25-31

Sec. 3. (a) An application for review under IC 16-29-1 or IC 16-29-4 shall be submitted to the secretary of the Indiana health facilities council.

(b) To defray the costs of hearings and other procedural requirements, applicants shall pay the associated costs as follows:

(1) The applicant shall pay, upon filing an application, or upon supplementing a pending application as described in this article, the following:

(A) A one thousand five hundred dollar ($1,500) deposit.

(B) A nonrefundable one thousand dollar ($1,000) filing fee.

(2) Upon the completion of administrative proceedings but prior to the issuing of a final order by the board, the remaining associated costs will be assessed and billed to the applicant, or applicants in the case of comparative review.

(3) If the one thousand five hundred dollar ($1,500) deposit, or sum of deposits from applicants in the case of a comparative review, exceeds the procedural and administrative costs of review, the excess deposit amount will be refunded to the applicant or applicants on a prorated basis.

(c) An application submitted for review may be withdrawn prior to the board's final order if the applicant files written notice with the Indiana health facilities council.

(d) An applicant who causes an application to be withdrawn shall forfeit the entire one thousand dollar ($1,000) filing fee. Portions of the one thousand five hundred dollar ($1,500) expense deposit will be forfeited as follows:

(1) If an application is withdrawn within sixty (60) days of its submission, the applicant shall forfeit the filing fee and an amount equal to the sum of expenses caused by the review of the application.

(2) If an application is withdrawn sixty-one (61) days, or later, after its submission, the applicant shall forfeit the filing fee

and remain liable for an amount equal to the entire deposit or an amount equal to the applicant's share of expenses caused by the review, whichever is greater.

(e) The applicant must file a new application and pay the new application fee and deposit in order to initiate review of any project previously withdrawn.

(f) An applicant may modify a filed application at any time until a CRO is assigned and, thereafter, only with the approval of the assigned CRO. Any modifications must be reflected throughout the content of the application as appropriate.

(g) Within five (5) days of the date an application is submitted and date stamped by the secretary of the Indiana health facilities council, the applicant shall cause an advertisement to be published in a newspaper having a general circulation in the county in which the proposed project is to be located. This advertisement must contain the name of the applicant and a description of the proposed project, including the specific location and the estimated cost of the project.

(h) Within five (5) days of the date an application is filed for review, the applicant shall notify, in writing, by United States mail or personal service, the following:

(1) All existing health facilities in the project's service area.

(2) All applicants with pending applications for the same service area.

(3) Persons holding valid CONs for the service area proposed to be served.

(i) Proof of notice complying with the provisions of this section shall be the burden of the applicant and shall be submitted to the Indiana health facilities council.

(j) Following the issuance of an approval, the holder of the approval shall submit a six (6) month progress report on a form prescribed by the department each six (6) months until the department acknowledges that the project is complete.

(k) In accordance with IC 16-29-1-7, all projects which receive final approval become void eighteen (18) months after the determination becomes final unless:

(1) construction plans for the project are approved by the department and the department of fire and building services;

(2) the applicant has completed construction of the project's foundation in conformity with the approved plans as certified by an independent architect licensed under IC 25-4 or an independent professional engineer licensed under IC 25-31; and

(3) construction work on the project is continuous and in conformity with the approved plans.

(Indiana State Department of Health; 410 IAC 20.4-3-3; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1336)

410 IAC 20.4-3-4 Review responsibilities; secretary, Indiana health facilities council

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 4-21.5; IC 16-29-1; IC 16-29-4

Sec. 4. (a) The secretary of the Indiana health facilities council shall receive and date stamp applications for projects subject to review under IC 16-29-4 and IC 16-29-1.

(b) The secretary shall collect, deposit, and administer the fees paid under section 3 of this rule, as required by law, and maintain appropriate records.

(c) When an application is filed, the secretary shall notify the Indiana health facilities council and assure that a CRO from the approved list is assigned to the project.

(d) The secretary shall require a response to be submitted to every request on the application as filed.

(e) Past and current licensure and certification survey status reports for each health facility in Indiana owned, operated, or managed by an applicant shall be made available upon request to the CRO to the Indiana health facilities council by the secretary, if requested.

(f) The secretary shall assign a CRO to each application submitted for review and have the CRO compensated from the application filing fee and deposit.

(g) The secretary shall monitor the review progress of each application and report to the Indiana health facilities council any action or inaction by the CRO which appears to impede efficient, impartial review.

(h) The secretary shall have copies of the Indiana health facilities council's proposed findings and recommended order distributed according to the notice requirements of IC 4-21.5.

(i) The secretary shall receive petitions for review of the Indiana health facilities council's proposed findings and recommended orders under IC 4-21.5.

(j) The activities of the secretary shall be governed by the ex parte contacts policy under section 12 of this rule. *(Indiana State Department of Health; 410 IAC 20.4-3-4; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1337)*

410 IAC 20.4-3-5 Review responsibilities; CRO

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-28-2

Sec. 5. (a) The secretary of the health facilities council shall assign a CRO to each application filed for review.

(b) Once assigned to a project, the CRO shall be responsible for coordination of the review procedures set forth in this article.

(c) The CRO shall have the authority to assess the completeness of assigned applications and to require additional information from the applicant as needed within time deadlines set by the CRO. The CRO shall also have the authority to accept or reject any information submitted and to reject applications which, in the CRO's assessment, are not complete or do not meet the requirements set by the CRO for the submission of additional information.

(d) If, within a single sixty (60) day time period, two (2) or more applications for projects that would result in the offering of similar services and facilities in a health service area affected by the project are filed, the CRO shall review them comparatively. A sixty (60) day time period will commence when the first reviewable application for a service area is filed and will end sixty (60) days from that date.

(e) The CRO may seek technical assistance in the review of applications as the officer deems appropriate.

(f) The CRO shall give written notification of review to the applicant and to any other party by mail. At a minimum, the written notification shall contain the following items:

(1) The date of commencement of the review.

(2) The proposed schedule for the review.

(3) A list of any applications which will be comparatively reviewed with the application.

(4) Instructions for the submission of comments to the CRO about the application.

(g) The CRO shall assure that each project received by the Indiana health facilities council and assigned to him or her is tracked and that appropriate documentation of status and action is maintained.

(h) The CRO shall conduct a public meeting in the county in which the project is proposed to be located. To conduct the public meeting, the CRO shall do the following:

(1) The CRO shall publish a notice of the meeting in a newspaper of general circulation in the county in which the proposed project is to be located. The notice, which shall be published at least ten (10) days before the meeting, shall include the date, time, and place of the meeting and contain a brief summary of the proposed project, including the specific location and the estimated cost of the project.

(2) At least five (5) days before the meeting, the CRO shall provide a copy of the published notice by first class mail to all existing and proposed health facilities that are providing, or have notified the Indiana health facilities council of their intent to provide, the same or similar services in the health service area in which the proposed project is to be located.

(3) The CRO shall determine how the public meeting is to be conducted and shall open the meeting with an explanation of procedures.

(4) The CRO shall have a transcript of the meeting made and placed in the project file to be used by the CRO, the Indiana health facilities council, and the board in making recommended and final orders on the project.

(5) The CRO shall prepare, for each application heard, proposed findings of fact and a recommended order which will be forwarded to the Indiana health facilities council at the most immediate regularly scheduled meeting of the Indiana health facilities council for which inclusion on the agenda and appropriate notice can be accomplished. The proposed findings shall address each of the review factors and considerations in section 10 of this rule.

(6) The CRO must present preliminary findings and a recommended order to the Indiana health facilities council, and be available to represent the CRO's position in subsequent appeals.

(i) The activities of the CRO shall be governed by the ex parte contacts policy under section 12 of this rule. *(Indiana State Department of Health; 410 IAC 20.4-3-5; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1337)*

410 IAC 20.4-3-6 Review responsibilities; Indiana health facilities council

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 4-21.5-1-2; IC 16-28-2; IC 16-28-10-1; IC 16-30-2-2

Sec. 6. (a) The Indiana health facilities council may recommend, before the conversion of existing health facility beds to intermediate care facilities for the mentally retarded beds or the construction of a new intermediate care facilities for the mentally

retarded facility, that the board issue a preliminary approval of the proposed project if the Indiana health facilities council determines that there is an insufficient number of available beds to care for all persons who are determined under IC 12-11-2 *[IC 12-11-2 was repealed by P.L.272-1999, SECTION 66, effective July 1, 1999.]* to be appropriate for placement in an intermediate care facility for the mentally retarded.

(b) The Indiana health facilities council shall review all applications for approval to construct or add, by any means, comprehensive care beds or beds which will function as beds licensed under IC 16-28-2 as described in 410 IAC 20.4-2-2. After reviewing an application, or applications in the case of a comparative review, the Indiana health facilities council shall make proposed findings based on information prepared by the department in accordance with IC 16-30-2-2 and any other relevant information as to the need for the proposed beds, quality care services, or cost incurred. Only after finding that the beds are necessary and adequate documentation of the applicant's experience or capacity to provide quality, effective, and efficient care has been supplied, the Indiana health facilities council shall recommend that the board approve additional comprehensive beds.

(c) The Indiana health facilities council shall receive, and accept or reject, all affidavits of truthfulness and any other requests for determinations of reviewability.

(d) The Indiana health facilities council shall appoint a roster of CROs who:

(1) shall not be employees of the department and need not be administrative law judges within the meaning of IC 4-21.5-1-2; and

(2) shall assist the Indiana health facilities council in its assessment of applications and be responsible for:

(A) coordinating the review processes;

(B) conducting community-based public meetings held under this article; and

(C) preparing proposed findings of fact and a recommended order for the Indiana health facilities council's consideration.

(e) The Indiana health facilities council shall monitor reviews to prevent any action or inaction of a CRO from impeding efficient and impartial review of an assigned application.

(f) The Indiana health facilities council shall receive the proposed findings and recommended order of the CRO.

(g) The Indiana health facilities council may seek assistance in the review of the proposed findings and recommended order of the CRO as the Indiana health facilities council deems appropriate.

(h) After completing its review of the CRO's proposed findings and recommended order and other information as the Indiana health facilities council deems appropriate, the Indiana health facilities council shall:

(1) adopt the proposed findings and recommended order of the CRO; or

(2) reject the proposed findings and recommended order of the CRO and formulate and formally adopt:

(A) proposed findings for each review factor set out in section 11 of this rule; and

(B) a revised recommended order.

(i) The Indiana health facilities council shall provide copies of the Indiana health facilities council's proposed findings and recommended order, including instructions for filing a petition for review, according to administrative law requirements of IC 4-21.5.

(j) If no petition for review is granted and/or no hearing is held, the proposed findings and recommended order of the Indiana health facilities council shall be forwarded to the department as the official proposed findings and recommended order.

(k) If a petition for review is granted, an administrative law judge will conduct a hearing in accordance with IC 4-21.5 and IC 16-28-10-1.

(l) In its conduct of its review responsibilities, the Indiana health facilities council shall be governed by the ex parte contacts policy under section 12 of this rule. *(Indiana State Department of Health; 410 IAC 20.4-3-6; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1338)*

410 IAC 20.4-3-7 Review responsibilities; aggrieved party

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 4-21.5; IC 16-28-2

Sec. 7. An aggrieved party to the official proposed findings and recommended order must submit a petition for review to the secretary of the Indiana health facilities council, in writing, within fifteen (15) days after the recommended order is served. *(Indiana State Department of Health; 410 IAC 20.4-3-7; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1339)*

410 IAC 20.4-3-8 Review responsibilities; administrative law judge

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 4-21.5-1; IC 16-28-10-1

Sec. 8. (a) Except as provided in subsection (b), an administrative hearing that complies with IC 4-21.5 must be held in the course of the CON process if a petition for review of the Indiana health facilities council action is granted.

(b) No administrative hearing will be held if:

(1) no petitions for review are granted; or

(2) all filed and granted petitions for review, if any, are withdrawn.

(c) The board shall designate an independent hearing officer to hold the administrative hearing. The hearing officer who has all the duties and powers given to the board in connection with the administrative hearing and shall be an administrative law judge within the meaning of IC 4-21.5-1, shall be admitted to the practice of law in the state of Indiana, but shall not be:

(1) an employee of the state;

(2) a member of the Indiana health facilities council; or

(3) the CRO assigned to the project which is the subject of the hearing.

(d) A record of the proceedings of all administrative hearings shall be made.

(e) The cost of appointing an administrative law judge shall be paid by the applicant if the administrative law judge finds in favor of the state. If the administrative law judge finds in favor of the applicant, the cost of appointing the administrative law judge shall be paid by the state.

(f) Following the hearing, the administrative law judge shall prepare and file proposed findings of fact and a recommended order as required by IC 4-21.5 and IC 16-28-10-1 to all parties to the review and to any person who so requests.

(g) If no objections are filed and no petition for review granted, the proposed findings and recommended order of the administrative law judge shall be forwarded to the board as the official proposed findings and recommended order.

(h) If objections are filed and a petition for review is granted, the board shall appoint an appeals panel consisting of three (3) members to review the order of the administrative law judge.

(i) The administrative law judge shall be governed by the ex parte contacts policy under section 12 of this rule and the provisions of IC 4-21.5 in conducting the administrative hearing and associated procedures. *(Indiana State Department of Health; 410 IAC 20.4-3-8; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1339)*

410 IAC 20.4-3-9 Review responsibilities; appeals panel

Authority: IC 16-29-1-12; IC 16-29-1-13
Affected: IC 4-21.5; IC 16-28-10-2

Sec. 9. (a) If objections are filed and a petition for review is granted, proceedings for the review of a proposed finding and recommended order of the administrative law judge shall be conducted by an appeals panel appointed by the board under IC 16-28-10-2.

(b) The appeals panel is the ultimate authority under IC 4-21.5. An order resulting from an appeals panel's proceeding shall be a final order as described under section 10 of this rule.

(c) The cost of the proceedings conducted by the panel, including the fees of the panel members, shall be paid by the applicant if the panel finds in favor of the state. If the panel finds in favor of the applicant, the cost shall be paid by the state.

(d) The appeals panel shall be governed by the ex parte contacts policy under section 12 of this rule and the provisions of IC 4-21.5 in conducting the review procedures. *(Indiana State Department of Health; 410 IAC 20.4-3-9; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1339)*

410 IAC 20.4-3-10 Review responsibilities; executive board

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 4-21.5; IC 16-29-1-7; IC 16-29-4; IC 16-30-2

Sec. 10. (a) Findings and final orders, as required by law, shall be issued for each project subject to review under IC 16-29-4 and IC 16-29-1.

(b) The board shall receive the proposed findings and recommended order, or recommended orders in the case of a

comparative review, of the Indiana health facilities council adopted under section 6 of this rule, and after reviewing the record:

(1) adopt the findings and recommended order of the Indiana health facilities council; or

(2) reject the proposed findings and recommended order of the Indiana health facilities council and formulate and formally adopt:

(A) findings for each review factor set out in this section; and

(B) a revised order which shall be the final order.

(c) The board shall receive the proposed findings and recommended order, or recommended orders in the case of a comparative review, of the administrative law judge adopted under section 8 of this rule, and after reviewing the record:

(1) adopt the proposed findings and recommended order of the administrative law judge; or

(2) reject the proposed findings and recommended order of the administrative law judge and formulate and formally adopt:

(A) findings for each review factor set out in this section; and

(B) a revised order which shall be the final order.

(d) For each application approved, specific written findings shall be made concerning the need for and appropriateness of additional comprehensive care and intermediate care facilities for the mentally retarded beds in the health service area, consistency with the annual assessment of health needs under IC 16-30-2, quality care services, and cost incurred.

(e) For each application disapproved, written findings shall be made stating the basis on which the project was disapproved, including the need for and appropriateness of additional comprehensive care and intermediate care facilities for the mentally retarded beds in the service area, consistency with the annual assessment of health needs under IC 16-30-2, quality care services, and cost incurred.

(f) The written findings and final determination of the board shall be sent to the Indiana health facilities council, to the applicant, to the counsel of record (if any), and to affected persons by certified mail, return receipt requested. The written findings and final order of the board shall be available upon request.

(g) In its conduct of its review responsibilities, the board and the department shall be governed by the ex parte contacts policy under section 12 of this rule.

(h) The secretary of the Indiana health facilities council shall monitor the progress of the holder of the CON in meeting the time table for project development. An approval is void eighteen (18) months after it becomes final unless the applicant has satisfied the requirements of IC 16-29-1-7. *(Indiana State Department of Health; 410 IAC 20.4-3-10; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1340)*

410 IAC 20.4-3-11 Review factors

Authority: IC 16-29-1-12; IC 16-29-1-13
Affected: IC 16-28-2; IC 16-30-2-2

Sec. 11. (a) The agents responsible for conducting review and the Indiana health facilities council under this article shall consider the following:

(1) A proposed project's consistency with the annual assessment of health needs under IC 16-30-2-2 using the following factors in making proposed findings, recommended orders, and final orders:

(A) The availability of alternative, less costly, or more effective methods of providing services.

(B) The availability of resources, including health personnel, management personnel, and funds for capital and operating needs or sources to meet the identified need.

(C) The availability of alternative uses of resources for the provision of other health care services.

(D) The capacity of existing market conditions to improve quality assurance, cost containment, and responsiveness to consumer preferences.

(E) The capacity of the existing market conditions to improve capital allocations for long term care, control long term care expenditures, and to better meet the long term care needs and preferences of residents of the health service area of application.

(F) The competitive factors of the free enterprise system, with the goal of encouraging competition and efficiency in the utilization of health resources.

(G) The comparative efficiency of proposed costs in comparison to equivalent costs of similar projects in the health service area.

(2) Information required to be provided under 410 IAC 20.4-4-1.

(3) The need for additional beds.

(4) Current availability of personnel and whether the applicant has demonstrated ability to staff the project proposed in the application.

(5) The reimbursability of proposed and forecasted rates. In cases of comparative review, rates of reimbursement shall not be considered as a factor in the review if the applicants demonstrate that forecasted rates are reimbursable under Medicare and/or Medicaid.

(6) The experience of the applicant as a health care provider. Documentation may include past and current licensure status, federal and state survey reports, statements of community or consumer support for the project or lack of support, and any other relevant information provided.

(7) The project's economic feasibility, including the following:

(A) Evidence that the assumptions used in financial planning and projections are based on the actual experience of the applicant or other providers.

(B) Evidence that the applicant has considered the reimbursement policies of major payers and their impact on revenue and future capital requirements.

(8) The utilization of existing beds in the service area shall be considered as follows, except in the case of intermediate care facilities for the mentally retarded bed conversions:

(A) If the existing utilization rate for all certified comprehensive care beds in the county of application is less than ninety percent (90%), or if the addition of the certified beds proposed in the application will reduce the existing utilization rate for all certified comprehensive care beds in the county of application below ninety percent (90%), there is a presumption that the certification of the beds is not necessary.

(B) If the existing utilization rate for all noncertified comprehensive care beds in the county of application is less than ninety percent (90%), or if the addition of the noncertified beds proposed in the application will reduce the existing utilization rate for all noncertified comprehensive care beds in the county of application below ninety percent (90%), there is a presumption that additional noncertified beds are not necessary.

(9) The department shall consult with the division of aging and rehabilitative services *[division of disability, aging, and rehabilitative services]* of the office of the secretary of family and social services on the need for intermediate care facilities for the mentally retarded beds as identified under requirements of the Omnibus Budget Reconciliation Act of 1987, P.L.100-203.

(b) An agency responsible for conducting review under this article shall be governed by the ex parte contacts policy under section 12 of this rule. *(Indiana State Department of Health; 410 IAC 20.4-3-11; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1340)*

410 IAC 20.4-3-12 Ex parte contacts

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 4-21.5; IC 16-28-2

Sec. 12. (a) Following the commencement of any procedural, administrative, or judicial hearing under this article and prior to the time when a final order on an application is issued by the board and all appeals are exhausted, there shall be no ex parte contacts relative to the project among the applicant or a person acting on behalf of the applicant or holder of an approval, any person opposed to the issuance or in favor of the withdrawal of an approval, and the comparative hearing officer, a member of the Indiana health facilities council, a member of the appeals panel or the board, or an administrative law judge. Contacts between the applicant or persons acting on behalf of the applicant or holder of an approval and a person employed or engaged by the board, department, or Indiana health facilities council exercising any responsibility respecting the application or its withdrawal are permitted if contacts are made through counsel for the department and are for the purpose of exchanging information or interviews with witnesses.

(b) Except during the proceedings of a hearing, there shall be no ex parte contact relative to any application between a person acting in the capacity of a review officer or administrative law judge under this article and a person employed by the Indiana health facilities council or the department and exercising any responsibility respecting any application. However, contacts are permitted if agreed to by all parties to the hearing proceedings and an opportunity is afforded for all parties to be involved or represented by counsel.

(c) Provisions of this section do not preclude aid received from any person employed or engaged by the department acting in that capacity provided that a staff assistant may not communicate information of a type that would be prohibited under subsection (a) or would furnish, augment, diminish, or modify the evidence in a record. *(Indiana State Department of Health; 410 IAC 20.4-3-*

12; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1341)

Rule 4. Data Reporting

410 IAC 20.4-4-1 Scope

Authority: IC 16-28-1-12; IC 16-29-1-13
Affected: IC 16-29-4; IC 16-30-2-4

Sec. 1. (a) Each provider of long term care services of the types which are subject to review under IC 16-29-4 or IC 16-29 shall provide to the department, on forms specified by the department, quarterly census data which includes, but is not limited to, patient days of each facility grouped by age, sex cohort, payer classification, and category defined by the department, such as distinct part bed or skilled nursing facility bed.

(b) The data collected shall be used, with other relevant information, to assess the need for additional licensed beds. *(Indiana State Department of Health; 410 IAC 20.4-4-1; filed Dec 5, 1997, 3:30 p.m.: 21 IR 1342)*

ARTICLE 21. REPORTING

Rule 1. State Cancer Registry

410 IAC 21-1-1 Definitions

Authority: IC 16-38-2-10
Affected: IC 16-38-2

Sec. 1. As used in 410 IAC 21-1:

"Cancer registry" means a mechanism by which data relating to all cases of malignant disease that occur in Indiana residents is recorded and, necessary and appropriate information is compiled concerning those cases as determined by the board, in order to conduct epidemiologic surveys of cancer and to apply appropriate preventive and control measures.

"Confirmed case" means the best evidence available for determining the nature of malignant disease using the following methods and codes: 1 = positive histology; 2 = positive exfoliative histology in the absence of positive histology; (3 is vacant) 4 = positive microscopic confirmation not otherwise specified (NOS); (5 is vacant) 6 = direct visualization without microscopic confirmation; 7 = radiography without microscopic confirmation; 8 = clinical diagnosis (other than 6 or 7) including gross examination at autopsy; and 9 = unspecified whether or not microscopically confirmed, unknown. This is a priority series with code 1 taking precedence. Each number takes priority over all higher numbers (i.e., 1 over 4, and 5 over 9 etc.).

"Data set" means all clinical, pathological *[sic.,]* therapeutic and demographic information defined in 410 IAC 21-1-3 and 410 IAC 21-1-4.

"ICD-O" means International Classification of Diseases for Oncology, 1976, World Health Organization publication, Organisation Mondiale De La Sante, 1211, Geneva 27, Switzerland.

"Indiana resident" means an individual domiciled in the state of Indiana.

"Malignant disease" means confirmed cases of cancer enumerated in the ICD-O excluding superficial, squamous and basal cell carcinomas of the skin.

"Patient" means any individual who is ill, or undergoing diagnosis or treatment for disease by a dentist, medical laboratory, physician or hospital.

"Person" means an individual, association, partnership, corporation, or governmental entity.

"State board" means the Indiana state board of health. *(Indiana State Department of Health; 410 IAC 21-1-1; filed Nov 7, 1986, 3:30 pm: 10 IR 420; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-2 General requirements

Authority: IC 16-38-2-10
Affected: IC 5-15-5.1-5; IC 16-38-2

Sec. 2. (a) All physicians, dentists, hospitals and medical laboratories shall report all confirmed cases of cancer occurring in Indiana residents who have been diagnosed or treated in Indiana, to the state board cancer registry.

(b) Any health care provider reporting to a public or private cancer registry on September 1, 1985 shall make available to the state cancer registry, all data as required under 410 IAC 21-1-3 (hospitals) or 410 IAC 21-1-4 (physicians, dentists and medical laboratories) upon the effective date of 410 IAC 21-1.

(c) The state board shall assure state cancer registry computer compatibility for any health care provider who on or before the effective date of 410 IAC 21-1 elects to transmit the required data by way of a computerized mechanism.

(d) Any health care provider who, after the effective date of 410 IAC 21-1, establishes a computerized mechanism for the purpose of transmitting abstracted data sets via computer link up, tape transfer, or direct interface, shall be responsible for assuring system compatibility with the state board cancer registry.

(e) Any health care provider who elects to transfer abstracted data sets to the state cancer registry in paper form, shall utilize an abstract form designed or approved by the state board pursuant to IC 5-15-5.1-5.

(f) All manually prepared data sets shall be mailed or delivered by the health care provider to the state cancer registry.

(g) All health care providers not reporting to a public or private cancer registry on September 1, 1985, shall begin submitting data on cases diagnosed on or after January 1, 1987 to the state cancer registry as set out in 410 IAC 21-1-3 (hospitals) or 410 IAC 21-1-4 (physicians, dentists and medical laboratories), no later than six (6) months following the date of such diagnosis.

(h) Reports of confirmed cases of malignant disease shall be submitted to the state cancer registry within six (6) months following a confirmed diagnosis. *(Indiana State Department of Health; 410 IAC 21-1-2; filed Nov 7, 1986, 3:30 pm: 10 IR 420; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-3 Hospitals

Authority: IC 16-38-2-10
Affected: IC 16-38-2

Sec. 3. (a) All hospitals shall submit abstracted data sets to the state board cancer registry which shall include but not be limited to the following data items:

(1) site code
(2) accession number
(3) sequence number
(4) accession year
(5) social security number
(6) medical record number
(7) full name (including maiden name)
(8) home address, city, county, state and zip code
(9) phone number
(10) date of birth
(11) sex
(12) race
(13) class of case
(14) admission date
(15) follow-up physician
(16) discharge date
(17) date of initial diagnosis
(18) topography code
(19) paired organ involvement
(20) histology code
(21) tumor grade
(22) diagnostic confirmation
(23) tumor size (largest dimension)
(24) number of positive nodes
(25) number of nodes examined

(26) sites of distant metastasis
(27) general summary stage
(28) TNM stage
(29) AJCC stage group
(30) TNM staging basis
(31) date and method of first course of treatment
(32) subsequent therapies/treatments (dates and methods)

(b) Available updated information regarding all elements enumerated in 410 IAC 21-1-3(a) shall be reported to the state board cancer registry each twelve (12) month period following the initial reporting of the disease. *(Indiana State Department of Health; 410 IAC 21-1-3; filed Nov 7, 1986, 3:30 pm: 10 IR 421; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-4 Physicians, dentists and medical laboratories

Authority: IC 16-38-2-10
Affected: IC 16-38-2

Sec. 4. (a) Any physician, dentist or medical laboratory who diagnoses a case of malignant disease when such case is not referred to a hospital for further diagnosis or treatment, shall submit required data sets to the state cancer registry. Such data sets shall include but not be limited to the following available data items:

(1) patient's full name (including maiden name)
(2) patient's address (including city, county *[sic.]* state and zip code)
(3) social security number
(4) date of birth
(5) sex
(6) race
(7) date of diagnosis
(8) topography
(9) morphology
(10) diagnostic confirmation
(11) hospital referred to
(12) physician, dentist or laboratory license number
(13) physician, dentist or laboratory name, address and phone number

(b) Physicians, dentists and medical laboratories whose offices are located within the confines of a hospital or, who are employed or contracted by a hospital and who diagnose or treat patients for malignant disease, shall not be required to report cases of malignant disease under 410 IAC 21-1-4. Such cases shall be reported in accordance with 410 IAC 21-1-3. *(Indiana State Department of Health; 410 IAC 21-1-4; filed Nov 7, 1986, 3:30 pm: 10 IR 421; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-5 Security and confidentiality of data

Authority: IC 16-38-2-10
Affected: IC 5-14-3-10; IC 16-38-2

Sec. 5. (a) The state board shall assure confidentiality of patient record data when entering, retrieving, reviewing and utilizing such data.

(b) The state board shall take all precautions and security measures necessary in order to protect the cancer registry data from intrusion or misuse by unauthorized individuals, and to preserve the right to privacy of individual patients maintained on the registry.

(c) Pursuant to IC 5-14-3-10, any public employee or official, or any employee or officer of a contractor or subcontractor of a public agency who knowingly or intentionally discloses the identity of a patient maintained on the state cancer registry system to a person not authorized to receive such information, commits a Class A misdemeanor. Any public employee shall be disciplined in accordance with the personnel policies of the agency by which he is employed if he intentionally, knowingly, or recklessly discloses or fails to protect the identity of patients maintained on the state cancer registry system.

(d) A person who reports information to the cancer registry system in accordance with 410 IAC 21-1, is immune from any civil or criminal liability that might otherwise be imposed because of release of what is otherwise confidential information. *(Indiana*

State Department of Health; 410 IAC 21-1-5; filed Nov 7, 1986, 3:30 pm: 10 IR 422; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 21-1-6 Cancer registry reports
Authority: IC 16-38-2-10
Affected: IC 16-38-2

Sec. 6. (a) The state board shall make available to all hospitals licensed under IC 16-10-1 *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, a comprehensive annual report which outlines the trends of malignant disease in Indiana and focuses on specific elements of special study regarding the disease.

(b) Hospitals, physicians, dentists, laboratories and other persons may request and be provided with special reports from the state cancer registry, providing the data requested does not disclose the identity of a patient. *(Indiana State Department of Health; 410 IAC 21-1-6; filed Nov 7, 1986, 3:30 pm: 10 IR 422; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. State Traumatic Injury Registry (Repealed)
(Repealed by Indiana State Department of Health; filed Oct 24, 1996, 4:00 p.m.: 20 IR 752)

Rule 3. Birth Problems Registry

410 IAC 21-3-1 Applicability
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 21-3-1; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757)*

410 IAC 21-3-2 "Indiana resident" defined
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 2. "Indiana resident" means an individual whose current address is within the state of Indiana. *(Indiana State Department of Health; 410 IAC 21-3-2; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757)*

410 IAC 21-3-3 "Person" defined
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 3. "Person" means an individual, association, partnership, corporation, or government entity. *(Indiana State Department of Health; 410 IAC 21-3-3; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757)*

410 IAC 21-3-4 "Registry" defined
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 4. "Registry" means the Indiana birth problems registry administered by the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 21-3-4; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757)*

410 IAC 21-3-5 "Severe disability" defined
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 5. "Severe disability" means a severe physical disability or developmental delay that:
(1) results from injury, infection, or disease;
(2) is chronic in nature; and
(3) requires long term health care.
(Indiana State Department of Health; 410 IAC 21-3-5; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)

410 IAC 21-3-6 "Stillbirth" defined
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 6. "Stillbirth" means a birth after twenty (20) weeks of gestation that is not a live birth. *(Indiana State Department of Health; 410 IAC 21-3-6; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)*

410 IAC 21-3-7 Persons required to report
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 7. The following persons shall report a diagnosed birth problem to the birth problems registry:
(1) Hospitals.
(2) Birthing centers.
(3) Health facilities.
(4) Physicians.
(5) Psychiatric hospitals.
(6) Dentists.
(7) Oral surgeons.
(8) Registered or licensed practical nurses.
(9) Midwives.
(10) Optometrists.
(11) Podiatrists.
(12) Chiropractors.
(13) Physical therapists.
(14) Psychologists.
(15) Local health departments.
(16) Health maintenance organizations.
(Indiana State Department of Health; 410 IAC 21-3-7; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)

410 IAC 21-3-8 Reporting requirements
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 8. (a) The following shall be reported by a person who must report as required by section 7 of this rule to the registry:
(1) Every birth problem listed in section 9 of this rule that has been diagnosed in a child before that child's second birthday.
(2) Every birth problem listed in section 9 of this rule that was diagnosed at the time of a child's death up to two (2) years of age or at expulsion or extraction of a fetus after twenty (20) weeks of gestation.
(b) Reports to the registry must be made within sixty (60) days of diagnosis.
(c) Only diagnoses of birth problems in children who are Indiana residents shall be reported.
(d) The registry shall provide the required forms for birth problems reporting. *(Indiana State Department of Health; 410 IAC 21-3-8; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)*

410 IAC 21-3-9 Reportable birth problems

Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 9. The following categories, along with those conditions identified in the International Classification of Diseases–Ninth Revision, Clinical Modification, 1998 (ICD-9-CM), are birth problems:

(1) A structural deformation.

(2) A developmental malformation.

(3) A genetic, inherited, or biochemical disease.

(4) Birth weight less than two thousand five hundred (2,500) grams.

(5) A condition of a chronic nature, including central nervous system hemorrhage or infection of the central nervous system, that may result in a need for long term health care.

(6) Stillbirth.

(7) Any other severe disability that is recognized in a child after birth and before the child becomes two (2) years of age.

(8)

ICD-9-CM Codes	Name
155–208	Neoplasms
216–216.9	Neoplasms
230–234	Neoplasms
246.1	Dyshormonogenic goiter
250	Diabetes mellitus
257.8	Other testicular dysfunction
279	Disorders involving the immune mechanism
282	Hereditary hemolytic anemias
284.0	Constitutional aplastic anemia
286.0–286.5	Coagulation defects
287.3	Primary thrombocytopenia
288	Diseases of white blood cells
289.6	Familial polycythemia
330	Cerebral degenerations usually manifest childhood
335	Anterior horn cell disease
359	Muscular dystrophies and myopathies
362.21	Retrolental fibroplasia
362.7	Hereditary retinal dystrophies
365.14	Glaucoma of childhood
378	Strabismus and other disorders of binocular eye movement
379.51	Congenital nystagmus
524.0–524.1	Anomalies of jaw
	Congenital anomalies
740–742	Central nervous system
743–744	Orofacial
745–747	Cardiovascular
748	Respiratory
749–750.29	Orofacial
750.3–751	Gastrointestinal
752–753	Genitourinary
754–756	Musculoskeletal
757	Integument

758	Chromosome and syndromes
759	Other and unspecified congenital anomalies

(Indiana State Department of Health; 410 IAC 21-3-9; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)

ARTICLE 22. CHILD CARE FACILITIES

Rule 1. Exempted Day Nurseries (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 22-1) to the Division of Family and Children (470 IAC 3-4.4) by P.L.9-1991, SECTION 129, effective July 1, 1992.

Rule 2. Registered Day Care Ministries (Transferred)

NOTE: Transferred from the Indiana State Department of Health (410 IAC 22-2) to the Division of Family and Children (470 IAC 3-4.5) by P.L.9-1991, SECTION 129, effective July 1, 1992.

ARTICLE 23. GRANTS

Rule 1. Indiana Medical and Nursing Grant Fund (Repealed)

(Repealed by Indiana State Department of Health; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3761)

Rule 2. Health Care Professional Recruitment and Retention Program

410 IAC 23-2-1 Definitions

Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 23-2-1; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3759)*

410 IAC 23-2-2 "Department" defined

Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 2. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 23-2-2; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3759)*

410 IAC 23-2-3 "Fiscal body" defined

Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 3. "Fiscal body" means:
(1) county council, for a county not having a consolidated city;
(2) city county council, for a consolidated city or county having a consolidated city;
(3) common council, for a city other than a consolidated city;
(4) town council, for a town;
(5) township board, for a township; or
(6) governing body or budget approval body, for any other political subdivision.

(Indiana State Department of Health; 410 IAC 23-2-3; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3759)

410 IAC 23-2-4 "Fund" defined
Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 4. "Fund" means the Indiana health care professional recruitment and retention fund. *(Indiana State Department of Health; 410 IAC 23-2-4; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3759)*

410 IAC 23-2-5 "Lending institution" defined
Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 5. "Lending institution" means an institution that makes or holds education loans. *(Indiana State Department of Health; 410 IAC 23-2-5; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3759)*

410 IAC 23-2-6 "Shortage area" defined
Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 6. "Shortage area" means a county, city, town, census tract, or township designated by the department as underserved by health care professionals. *(Indiana State Department of Health; 410 IAC 23-2-6; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3759)*

410 IAC 23-2-7 "Student loan" defined
Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 7. "Student loan" means a loan insured or guaranteed under a federal or state program of private insurance that is made to assist a student in obtaining postsecondary education and is:

(1) made to any Indiana student, or either one (1) or both parents or the legal guardian of the student, for the purpose of attending an Indiana or non-Indiana institution;

(2) made to any non-Indiana student, or one (1) or both parents or the legal guardian of the student, for the purpose of attending an Indiana institution; or

(3) made or owned by any lending institution or their affiliate with offices located in Indiana or in a state which an Indiana bank or an Indiana bank holding company is entitled under Indiana law to acquire a bank or holding company.

(Indiana State Department of Health; 410 IAC 23-2-7; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3760)

410 IAC 23-2-8 Federal designation
Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 8. The department shall annually adopt the federal designation of the counties, towns, census tracts, and townships in Indiana that are underserved by specific types of health professionals as determined by the department. The department shall rank these areas according to the degree each is underserved by health care professionals. *(Indiana State Department of Health; 410 IAC 23-2-8; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3760)*

410 IAC 23-2-9 Fund established
Authority: IC 16-46-5-19
Affected: IC 16-46-5; IC 25-22.5-9

Sec. 9. (a) The Indiana health care professional recruitment and retention fund is established. The purpose of this fund is to provide loan repayment for student loans incurred by health care professionals to encourage full-time delivery of health care in shortage areas. The department shall administer the fund.

(b) The fund consists of the following:
(1) Appropriations made by the general assembly.
(2) Repayments by loan recipients from the Indiana medical and nursing distribution loan fund under IC 25-22.5-9.
(3) Gifts to the fund.
(4) Grants from public or private sources.
(c) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund.
(d) Money in the fund does not revert to the state general fund.
(e) The fund shall be used for loan repayment under this document. *(Indiana State Department of Health; 410 IAC 23-2-9; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3760)*

410 IAC 23-2-10 Applicants

Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 10. (a) Applicants may choose only from those areas appearing on the department's annual list, unless an applicant can provide the department with sufficient evidence and documented support that an area not appearing on the department's list is a medically underserved area.

(b) A health care professional must apply for a loan repayment on an application form supplied by the department. Applications from health care professionals will be accepted until November 1. Funding decisions will be made by the department by December 1.

(c) Health care professionals participating in the student loan repayment program must meet the following conditions:
(1) Be a U.S. citizen.
(2) Have no outstanding contractual obligation for health professional service to the U.S. government, or a state or other entity, unless the service obligation will be completely satisfied before the contract has been signed. Be aware that certain bonus clauses in employment contracts may impose a service obligation.
(3) Not be in breach of a health professional service contract to the U.S. government, state or local government, or other entity.
(4) Not have a judgment lien against their property for a debt to the United States.
(5) Perform their service obligation at a site designated as eligible by the department.
(6) Provide full-time primary health care service, which is defined as a minimum of forty (40) hours per week for at least forty-five (45) weeks per year at an eligible site. At least thirty-two (32) of the forty (40) hours per week must be spent providing clinical service. These services must be conducted during normally scheduled clinic hours in the ambulatory care setting office(s), with the remaining hours spent providing inpatient care to patients of the eligible site and/or in practice related administrative activities, with administrative activities not to exceed twenty percent (20%) of their full-time tour. Time spent "on-call" is not considered part of the full-time tour. Obstetrician/gynecologists and certified nurse midwives are expected to spend not less than twenty-one (21) hours per week providing ambulatory care services during normally scheduled office hours, with the remaining hours spent providing inpatient care to patients of the eligible site and/or in practice related administrative activities, with administrative activities not to exceed twenty percent (20%) of their full-time tour.
(7) Charge for their professional services at the usual and customary prevailing rates in the area in which such services are provided, except that if a person is unable to pay such charge, such person shall be charged at a reduced rate or not charged any fee.
(8) Agree to provide primary health services to any individual seeking care. The program participants must agree not to discriminate on the basis of the patient's ability to pay for such care on the basis that payment for such care will be made pursuant to Medicare or Medicaid.
(9) Agree that they will:
    (A) accept assignment under Medicare (Section 1842(b)(3)(B)(ii) of the Social Security Act) for all services for which payment under Part B of Title XVIII; and
    (B) enter into an appropriate agreement with the state agency that administers the state plan for medical assistance under Title XIX to provide services to individuals entitled to medical assistance under the plan.
(10) Pay the amount specified in the program contract default provisions for failure to complete their service obligation for any reason.

(d) To be eligible for loan repayment for student loans, a health care professional must meet all of the following conditions:
(1) Hold an unlimited license to practice a health care profession in Indiana that has been declared by the department to be eligible for loan repayment in a specified fiscal year.
(2) Either:
(A) completed at least one (1) year of health care professional practice in a shortage area; or
(B) worked at least one (1) year at a community or migrant health center or maternal and child health clinic in a shortage area.
(3) Practice in a health care profession that has been declared eligible by the department for loan repayment in a specified fiscal year.
(Indiana State Department of Health; 410 IAC 23-2-10; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3760)

410 IAC 23-2-11 Eligibility
Authority: IC 16-46-5-19
Affected: IC 16-46-5-7

Sec. 11. The department shall consider each application and determine the eligibility of the applicant for the program under which the application is submitted and the extent to which the shortage area or eligible entity located in a shortage area is underserved, according to the rank given the shortage area under IC 16-46-5-7. *(Indiana State Department of Health; 410 IAC 23-2-11; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3761)*

410 IAC 23-2-12 Amount awarded
Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 12. Amounts awarded may not exceed the documented amount of the student loans incurred by the health care professional. *(Indiana State Department of Health; 410 IAC 23-2-12; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3761)*

410 IAC 23-2-13 Annual report
Authority: IC 16-46-5-19
Affected: IC 16-46-5

Sec. 13. The department shall file an annual report with the governor and the general assembly on the following:
(1) The receipt, disbursement, and use of funds.
(2) The identification of shortage areas.
(3) The number of applications for loan repayments by the following categories:
(A) Profession.
(B) Specialty.
(C) Underserved are to be served.
(4) The number and amount of loan repayments provided by the department.
(Indiana State Department of Health; 410 IAC 23-2-13; filed Jun 27, 2002, 1:35 p.m.: 25 IR 3761)

ARTICLE 24. LOCAL HEALTH SERVICES

Rule 1. Definitions

410 IAC 24-1-1 Applicability
Authority: IC 16-19-3-4
Affected: IC 16-46-1

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 24-1-1; filed*

Mar 12, 1991, 3:00 p.m.: 14 IR 1622; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 24-1-2 "Board" defined
Authority: IC 16-19-3-4
Affected: IC 16-46-1

Sec. 2. "Board" means the Indiana state board of health. *(Indiana State Department of Health; 410 IAC 24-1-2; filed Mar 12, 1991, 3:00 p.m.: 14 IR 1622; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 24-1-3 "Department" defined
Authority: IC 16-19-3-4
Affected: IC 16-46-1

Sec. 3. "Department" means the local health department. *(Indiana State Department of Health; 410 IAC 24-1-3; filed Mar 12, 1991, 3:00 p.m.: 14 IR 1622; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 24-1-4 "Household" defined
Authority: IC 16-19-3-4
Affected: IC 16-46-1

Sec. 4. "Household" means a group of related or unrelated individuals who are not residents of an institution, but who are living in one (1) dwelling as one (1) economic unit. *(Indiana State Department of Health; 410 IAC 24-1-4; filed Mar 12, 1991, 3:00 p.m.: 14 IR 1622; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 24-1-5 "Individual" defined
Authority: IC 16-19-3-4
Affected: IC 16-46-1

Sec. 5. "Individual" means a person or household. *(Indiana State Department of Health; 410 IAC 24-1-5; filed Mar 12, 1991, 3:00 p.m.: 14 IR 1622; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 24-1-6 "Poverty income guideline" defined
Authority: IC 16-19-3-4
Affected: IC 16-46-1

Sec. 6. "Poverty income guideline" means the poverty income guidelines published annually in the Federal Register, by the Secretary of Health and Human Services, pursuant to 42 U.S.C. 9902(2) and 42 U.S.C. 9847, which provides an update of the poverty income guidelines to account for last year's increase in prices as measured by the Consumer Price Index. *(Indiana State Department of Health; 410 IAC 24-1-6; filed Mar 12, 1991, 3:00 p.m.: 14 IR 1622; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. Local Health Maintenance Fund

410 IAC 24-2-1 Fee collection
Authority: IC 16-19-3-4
Affected: IC 16-46-1

Sec. 1. (a) If a department has authority under an ordinance to charge fees for local health maintenance services, the department shall establish a cost per unit of service and set fees in compliance with the ordinance. The fee shall be reasonable and shall not exceed the cost of the service.

(b) The fees charged by a department for licenses, permits, and inspections are not services subject to IC 16-1-43-3 *[IC 16-1*

was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]. (Indiana State Department of Health; 410 IAC 24-2-1; filed Mar 12, 1991, 3:00 p.m.: 14 IR 1622; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 24-2-2 Establishment of a fee schedule

Authority: IC 16-19-3-4
Affected: IC 16-46-1

Sec. 2. (a) The fee schedule for local health maintenance services shall consist of the following:

(1) Members of households whose annual income is between zero (0) and one hundred eighty-five percent (185%) of the poverty income guideline may be charged a maximum of thirty percent (30%) of the cost for local health maintenance services.

(2) Members of households whose annual income is between one hundred eighty-five percent (185%) and two hundred twenty percent (220%) of the poverty income guideline may be charged a maximum of fifty percent (50%) of the cost for local health maintenance services.

(3) Members of households whose annual income is between two hundred twenty percent (220%) and two hundred fifty percent (250%) of the poverty income guideline may be charged a maximum of seventy-five percent (75%) of the cost for local health maintenance services.

(4) Members of households whose annual income exceeds two hundred fifty percent (250%) of the poverty income guideline may be charged a maximum of the full cost of the service.

(b) The poverty income guidelines, used to calculate fees, shall be published annually in the Indiana Register.

(c) Assignment of annual income levels shall be based on the individual's annual household gross income and size. The department may, when computing the fee to be assessed, consider extenuating circumstances such as substantial financial debt, substantial assets, and family members with extraordinary medical bills. *(Indiana State Department of Health; 410 IAC 24-2-2; filed Mar 12, 1991, 3:00 p.m.: 14 IR 1622; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

ARTICLE 25. ARTIFICIAL INSEMINATION

Rule 1. Definitions

410 IAC 25-1-1 Applicability

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 25-1-1; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 25-1-2 "Artificial insemination" defined

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 2. As used in this article, "artificial insemination" means the introduction of semen into the vagina or cervix of a woman by means other than through the act of coitus. *(Indiana State Department of Health; 410 IAC 25-1-2; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 25-1-3 "Confirmatory test" defined

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-12-4; IC 16-41-14

Sec. 3. As used in this article, "confirmatory test" has the meaning set forth in IC 16-8-7-1 *[IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-12-4.]. (Indiana State Department of Health; 410 IAC 25-1-3; filed Sep*

15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 25-1-4 "Donor insemination" defined

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 4. As used in this article, "donor insemination" means artificial insemination by a donor. *(Indiana State Department of Health; 410 IAC 25-1-4; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 25-1-5 "Person" defined

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 5. As used in this article, "person" means an individual, corporation, business, partnership, or association. *(Indiana State Department of Health; 410 IAC 25-1-5; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 25-1-6 "Practitioner" defined

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 6. As used in this article, "practitioner" means any person who performs donor insemination or receives, processes, or stores semen intended for donor insemination. *(Indiana State Department of Health; 410 IAC 25-1-6; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. Artificial Insemination

410 IAC 25-2-1 Artificial insemination by donor where donor is the husband of the recipient

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 1. This rule does not apply to a donor who is the husband of a recipient. *(Indiana State Department of Health; 410 IAC 25-2-1; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 25-2-2 Artificial insemination by donor where donor and recipient are not in a mutually monogamous relationship

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 2. When artificial insemination by a donor is to be performed and the donor and recipient are not in a mutually monogamous relationship, the practitioner must ensure that the following are done:

(1) Each semen donor must initially undergo an appropriate medical history and physical examination. The following laboratory tests must be performed before the donor provides a donation:

(A) Serologic test for human immunodeficiency virus type 1 antibodies. If the initial screening test yields positive results, a confirmatory test for human immunodeficiency virus type 1 antibodies must be performed.

(B) Serologic tests for hepatitis B surface antigen and hepatitis B core antibodies.

(C) Serologic test for hepatitis C antibodies.

(D) Serologic test for human T-lymphotropic virus type I antibodies.

(E) Serologic test for cytomegalovirus antibodies.

(F) Serologic test for syphilis.

(G) Urethral culture for Chlamydia trachomatis.

(H) Urethral culture for Neisseria gonorrhoeae.

The results of these procedures, combined if necessary with additional test results, must indicate the individual's semen does not contain human immunodeficiency virus type 1, hepatitis B virus, hepatitis C virus, human T-lymphotropic virus type I, cytomegalovirus, Treponema pallidum, Chlamydia trachomatis, or Neisseria gonorrhoeae before he begins providing semen specimens for artificial insemination.

(2) Each individual semen specimen collected must be held a minimum of one hundred eighty (180) days. Then, before this specimen can be used for artificial insemination, the donor must be retested with the following tests:

(A) Serologic test for human immunodeficiency virus type 1 antibodies. If the initial screening test yields positive results, a confirmatory test for human immunodeficiency virus type 1 antibodies must be performed.

(B) Serologic tests for hepatitis B surface antigen and hepatitis B core antibodies.

(C) Serologic test for hepatitis C antibodies.

(D) Serologic test for human T-lymphotropic virus type I antibodies.

(E) Serologic test for cytomegalovirus antibodies.

No semen specimen may be used for artificial insemination if the results of these tests, combined if necessary with other evidence, indicate the specimen may contain human immunodeficiency virus type 1, hepatitis B virus, hepatitis C virus, human T-lymphotropic virus type I, or cytomegalovirus.

(3) In addition to the tests specified in subdivision (2), the following tests must continue to be performed at six (6) month intervals as long as the donor continues to provide semen for artificial insemination:

(A) Serologic test for syphilis.

(B) Urethral culture for Chlamydia trachomatis.

(C) Urethral culture for Neisseria gonorrhoeae.

No semen specimen may be used for artificial insemination if the results of these tests, combined if necessary with other evidence, indicate the specimen may contain Treponema pallidum, Chlamydia trachomatis, or Neisseria gonorrhoeae.

(4) Each recipient of semen shall undergo the following tests before artificial insemination procedures are initiated. The following tests shall be repeated at least annually as long as artificial insemination procedures are continuing:

(A) Serologic test for human immunodeficiency virus type 1 antibodies. If the initial screening test yields positive results, a confirmatory test for human immunodeficiency virus type 1 antibodies must be performed.

(B) Serologic tests for hepatitis B surface antigen and hepatitis B core antibodies.

(C) Serologic test for hepatitis C antibodies.

(D) Serologic test for human T-lymphotropic virus type I antibodies.

(E) Serologic test for syphilis.

(F) Cervical cultures for Neisseria gonorrhoeae.

(G) Cervical cultures for Chlamydia trachomatis.

The results of these procedures, combined if necessary with additional evidence, must indicate the individual is not infected with human immunodeficiency virus type 1, hepatitis B virus, hepatitis C virus, human T-lymphotropic virus type I, Treponema pallidum, Neisseria gonorrhoeae, or Chlamydia trachomatis before artificial insemination is performed.

(5) A serologic test for rubella antibodies shall be performed on the recipient before artificial insemination procedures are initiated. If the test is negative, it is recommended that rubella vaccine be administered unless a valid medical contraindication exists. If rubella vaccine is given, artificial insemination procedures should not begin until at least three (3) months after the time of the vaccination.

(Indiana State Department of Health; 410 IAC 25-2-2; filed Sep 15, 1992, 11:00 a.m.: 16 IR 700; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 25-2-3 Artificial insemination by donor where donor and recipient are in a mutually monogamous relationship

Authority: IC 16-19-3-4; IC 16-41-14-6

Affected: IC 16-41-14

Sec. 3. When artificial insemination by a donor is to be performed and the recipient indicates she is in a mutually monogamous relationship with the donor, the practitioner must ensure that a serologic test for human immunodeficiency virus type 1 antibodies is performed on the donor initially and at least annually as long as artificial insemination procedures are continuing. If at any time the initial screening test yields positive results, a confirmatory test for human immunodeficiency virus type 1 antibodies must be

performed. The results of this test must indicate the donor is not infected with human immunodeficiency virus type 1 before he can provide semen for artificial insemination. *(Indiana State Department of Health; 410 IAC 25-2-3; filed Sep 15, 1992, 11:00 a.m.: 16 IR 701; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 25-2-4 Additional laboratory tests

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-14

Sec. 4. The practitioner may choose to perform additional laboratory tests on the donor or recipient, or both, to rule out the presence of infectious disease. *(Indiana State Department of Health; 410 IAC 25-2-4; filed Sep 15, 1992, 11:00 a.m.: 16 IR 701; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 25-2-5 Investigations and enforcement

Authority: IC 16-19-3-4; IC 16-41-14-6
Affected: IC 16-41-9-12; IC 16-41-14

Sec. 5. The Indiana state department of health, or its designated agent, may enter upon private property to inspect and investigate possible violations of IC 16-8-7.5 *[IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-14.]* and this rule. The Indiana state department of health may commence an action under IC 16-1-9.5-10 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* to enforce IC 16-8-7.5 *[IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993. See IC 16-41-14.]* and this rule. *(Indiana State Department of Health; 410 IAC 25-2-5; filed Sep 15, 1992, 11:00 a.m.: 16 IR 702; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

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