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**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

Proposed Rule
LSA Document #03-216

DIGEST

Amends 410 IAC 15-1.5-8, 410 IAC 15-1.7-1, 410 IAC 15-2.5-7, and 410 IAC 15-2.7-1 to update the requirement for the Life Safety Code for hospitals and ambulatory outpatient surgical centers. Effective 30 days after filing with the secretary of state.

410 IAC 15-1.5-8 **410 IAC 15-2.5-7**
410 IAC 15-1.7-1 **410 IAC 15-2.7-1**

SECTION 1. 410 IAC 15-1.5-8 IS AMENDED TO READ AS FOLLOWS:

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~~ **meet** 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 that~~ **which that** may be conducive to the harborage or breeding of insects, rodents, or other vermin.

(2) No condition shall be created or maintained ~~which that~~ **which that** 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 **(2000 Edition)**.

(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~~ 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 backflow 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~~ **ensure** 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 that~~ 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 or** buildings, 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 **the following**:

- (A) Asepsis.
- (B) Cross-infection. ~~and~~
- (C) Safe practice.

(2) Refuse and garbage shall be collected, transported, sorted, and disposed of by methods **which that** 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 that** includes representatives from administration, patient services, and support services.

(3) The safety program **which that** 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)

SECTION 2. 410 IAC 15-1.7-1 IS AMENDED TO READ AS FOLLOWS:

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~~ **2000** 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 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 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*)

SECTION 3. 410 IAC 15-2.5-7 IS AMENDED TO READ AS FOLLOWS:

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 (**2000 Edition**).

(D) Water supply and sewage disposal services shall be obtained from municipal or community services.

(E) As early in the construction, addition, ~~and/or 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 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 that** may be conducive to the harboring or breeding of insects, rodents, or other vermin.

(2) No condition may be created or maintained **which that** 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 or** instruction, **or both**, 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 or** buildings, 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 that** 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 that** 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)

SECTION 4. 410 IAC 15-2.7-1 IS AMENDED TO READ AS FOLLOWS:

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~~ **2000** 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 (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.

(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 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 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)*

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on February 23, 2004 at 10:30 a.m., at the Indiana State Department of Health Building, 2 North Meridian Street, Yoho Board Room, 3rd Floor, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on proposed amendments to update the requirement for the Life Safety Code for hospitals and ambulatory outpatient surgical centers. Copies of these rules are now on file at the Health Care Regulatory Services Commission, Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Gregory A. Wilson, M.D.
State Health Commissioner
Indiana State Department of Health