
**INDIANA
STATE DEPARTMENT OF HEALTH**

TITLE 410 INDIANA ADMINISTRATIVE CODE

**ARTICLE 15.2 AMBULATORY SURGERY CENTER
LICENSURE RULES**

Rule 2.1 thru 2.7 and Interpretive Guidelines

12/23/2008

TITLE 410, INDIANA ADMINISTRATIVE RULES
 ARTICLE 15.2 AMBULATORY SURGERY CENTER
 LICENSURE RULES
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ARTICLE 15.2 AMBULATORY SURGERY CENTER RULES AND GUIDELINES

TAG	RULE 2	Guidance to Surveyors
	Rule 2.1. Definitions	
	<p>410 IAC 15-2-1-1 Applicability Authority: IC 16-21-1-7 Affected: IC 16-21-1</p>	
	<p>Sec. 1. The definitions in this rule apply throughout this rule. (<i>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</i>)</p> <p>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</p> <p>Sec. 2. "Ambulatory outpatient surgical center" means a center as defined in IC 16-18-2-14. (<i>Indiana State Department of Health; 410 IAC 15-2-1-2; filed Dec 1, 1999, 3:44 p.m.; 23 IR 781</i>)</p>	<p>"Ambulatory outpatient surgical center" means a public or private institution that meets the following conditions:</p> <ol style="list-style-type: none"> (1) Is established, equipped, and operated primarily for the purpose of performing surgical procedures and services. (2) Is operated under the supervision of at least one (1) licensed physician or under the supervision of the governing board of the hospital if the center is affiliated with a hospital. (3) Permits a surgical procedure to be performed only by a physician, dentist, or podiatrist who meets the following conditions: <ol style="list-style-type: none"> (A) Is qualified by education and training to perform the surgical procedure. (B) Is legally authorized to perform the procedure. (C) Is privileged to perform surgical procedures in at least one (1) hospital within the county or an Indiana county adjacent to the county in which the ambulatory outpatient surgical center is located. (D) Is admitted to the open staff of the ambulatory outpatient surgical center. (4) Requires that a 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. (5) Provides at least one (1) operating room and, if anesthetics other than local infiltration anesthetics are administered, at least one (1) post-anesthesia recovery room. (6) Is equipped to perform diagnostic x-ray and laboratory examinations required in connection with any surgery to be performed. (7) Does not provide accommodations for patient stays of longer than twenty-four (24) hours. (8) Provides full-time services of registered and licensed nurses for the professional care of the patients in the post-anesthesia recovery room. (9) Has available the necessary equipment and trained personnel to handle foreseeable emergencies such as a defibrillator for cardiac arrest, a tracheotomy set for airway obstructions, and a blood bank or other blood supply. (10) Maintains a written agreement with at least one (1) hospital for immediate acceptance of patients

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	<p>410 IAC 15-2-1-3 "Authenticate" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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:</p> <ul style="list-style-type: none"> (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. <p>(Indiana State Department of Health; 410 IAC 15-2-1-3; filed Dec 1, 1999, 3:44 p.m.; 23 IR 781)</p>	<p>who develop complications or require postoperative confinement.</p> <p>(1) Provides for the periodic review of the center and the center's operations by a committee of at least three (3) licensed physicians having no financial connections with the center.</p> <p>(12) Maintains adequate medical records for each patient.</p> <p>(13) Meets all additional minimum requirements as established by the state department for building and equipment requirements.</p> <p>Meets the rules and other requirements established by the state department for the health, safety, and welfare of the patients.</p> <p>"Authenticate" means the author or responsible individual validates an entry in a record by:</p> <ul style="list-style-type: none"> (a) A full signature including first initial, last name, and discipline; or (b) Written initials if full signature appears on the same page; (c) A unique identifier such as a number or computer key; or <p>A signature stamp.</p>
	<p>410 IAC 15-2-1-4 "Center" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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)</p>	<p>"Center" refers to an ambulatory outpatient surgical center.</p>
	<p>410 IAC 15-2-1-5 "Commissioner" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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)</p>	<p>"Commissioner" refers to the State Health Commissioner or the designee of the State Health Commissioner.</p>

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	<p>410 IAC 15-2-1-6 "Council" defined Authority: IC 16-21-1-7 Affected: IC 16-18-2-84; IC 16-21-1</p> <p>Sec. 6. "Council" means the body defined in IC 16-18-2-84(1). (<i>Indiana State Department of Health</i>; 410 IAC 15-2-1-6; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)</p>
	<p>410 IAC 15-2-1-7 "Dentist" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>Sec. 7. "Dentist" means any person holding an unlimited license to practice dentistry in the state of Indiana. (<i>Indiana State Department of Health</i>; 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)</p>
	<p>410 IAC 15-2-1-8 "Department" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>Sec. 8. "Department" means the Indiana state department of health. (<i>Indiana State Department of Health</i>; 410 IAC 15-2-1-8; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)</p>
	<p>410 IAC 15-2-1-9 "Division" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>Sec. 9. "Division" means the division of acute care of the department. (<i>Indiana State Department of Health</i>; 410 IAC 15-2-1-9; filed Dec 1, 1999, 3:44 p.m.: 23 IR 781)</p>
	<p>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</p> <p>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. (<i>Indiana State Department of Health</i>; 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)</p>

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<p>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</p> <p>Sec. 11. "Health care provider" means a provider as defined in IC 16-18-2-14. (<i>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</i>)</p>	<p>"Health Care Provider" means:</p> <ol style="list-style-type: none"> (1) An individual, partnership, corporation, professional corporation, facility, or institution licensed or legally authorized by this state to provide health care or professional services as a licensed physician, a psychiatric hospital, a hospital, a health facility, an emergency ambulance service (IC 16-31-3), a dentist, a registered or licensed practical nurse, a midwife, an optometrist, a podiatrist, a chiropractor, a physical therapist, a respiratory care practitioner, an occupational therapist, a psychologist, a paramedic, an emergency medical technician, or an occupational emergency technician, or a person who is an officer, employee, or agent of the individual, partnership, corporation, professional corporation, facility or institution acting in the course and scope of the person's employment. (2) A college, university, or junior college that provides health care to a student, a faculty member, or an employee and the governing board or a person who is an officer, employee or agent of the college, university or junior college acting in the course and scope of the person's employment. (3) A blood bank, community mental health center, community mental retardation center, community health center, or migrant health center. (4) Home health agency (as defined in IC 17-27-1-2). (5) A health maintenance organization (as defined in IC 27-13-1-19). (6) A health care organization whose members, shareholders or partners are health care providers under subdivision (1). (7) A corporation, partnership or professional corporation not otherwise qualified under this subsection that <ol style="list-style-type: none"> (A) Provides health care as one (1) of the corporation's partnerships or professional corporation's functions; (B) Is organized or registered under state law; and (C) Is determined to be eligible for coverage as a health care provider under IC 34-18 for the corporation's partnerships or professional corporation's health care function. <p>Coverage for a health care provider qualified under this subdivision is limited to its health care functions and does not extend to other causes of action.</p>	<p>"Health care worker" refers to a person who provides services whether as individual health care providers, volunteers, students, or employees of a center.</p>
<p>410 IAC 15-2-1-12 "Health care worker" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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. (<i>Indiana State Department of Health; 410 IAC 15-2-1-12; filed Dec 1, 1999, 3:44 p.m.; 23 IR 782</i>)</p>	<p>Coverage for a health care provider qualified under this subdivision is limited to its health care functions and does not extend to other causes of action.</p>	<p>"Health care worker" refers to a person who provides services whether as individual health care providers, volunteers, students, or employees of a center.</p>

	<p><u>410 IAC 15-2-1-13</u> "Licensed health professional" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1; IC 25-23-1-27.1</p> <p>Sec. 13. "Licensed health professional" means an individual as defined in IC 25-23-1-27.1. (<i>Indiana State Department of Health</i>; <i>410 IAC 15-2-1-13</i>; <i>filed Dec 1, 1999, 3:44 p.m.</i>; <i>23 IR 782</i>)</p>	<p>"Licensed health professional" means</p> <ol style="list-style-type: none"> (1) A registered nurse; (2) A licensed practical nurse; (3) A physician with an unlimited license to practice medicine or osteopathic medicine; (4) A licensed dentist; (5) A licensed chiropractor; (6) A licensed optometrist; (7) A licensed pharmacist; (8) A licensed physical therapist; (9) A certified psychologist; (10) A licensed podiatrist; or <p>A licensed speech-language pathologist or audiologist.</p>
	<p><u>410 IAC 15-2-1-14</u> "Medical staff" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>Sec. 14. "Medical staff" means a group that is responsible to the governing board for the following:</p> <ol style="list-style-type: none"> (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: <ol style="list-style-type: none"> (A) The quality and necessity of care provided. (B) The preventability of complications and deaths occurring in the center. <p>(<i>Indiana State Department of Health</i>; <i>410 IAC 15-2-1-14</i>; <i>filed Dec 1, 1999, 3:44 p.m.</i>; <i>23 IR 782</i>)</p>	
	<p><u>410 IAC 15-2-1-15</u> "Pharmacist" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1; IC 25-26-13</p> <p>Sec. 15. "Pharmacist" means an individual licensed under IC 25-26-13. (<i>Indiana State Department of Health</i>; <i>410 IAC 15-2-1-15</i>; <i>filed Dec 1, 1999, 3:44 p.m.</i>; <i>23 IR 782</i>)</p>	<p>"Pharmacist" means a person licensed by law to practice Pharmacy in Indiana.</p>

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	<p>410 IAC 15-2-1-16 "Physician" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1; IC 25-22.5-5</p> <p>Sec. 16. "Physician" means an individual licensed under IC 25-22.5-5. (<i>Indiana State Department of Health; 410 IAC 15-2-1-16; filed Dec 1, 1999, 3:44 p.m.; 23 IR 782</i>)</p>	<p>"Physician" means any person who holds</p> <ul style="list-style-type: none"> ▪ the degree of doctor of medicine or of osteopathic medicine approved by the board or its equivalent and an unlimited license to practice medicine or osteopathic medicine in Indiana.
	<p>410 IAC 15-2-1-17 "Podiatrist" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>Sec. 17. "Podiatrist" is any person holding an unlimited license to practice podiatry in the state of Indiana. (<i>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</i>)</p>	
	<p>410 IAC 15-2-1-18 "Practitioner" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1; IC 25-1-9-2</p> <p>Sec. 18. "Practitioner" means an individual as defined in IC 25-1-9-2. (<i>Indiana State Department of Health; 410 IAC 15-2-1-18; filed Dec 1, 1999, 3:44 p.m.; 23 IR 782</i>)</p>	<p>"Practitioner" means an individual who holds:</p> <ol style="list-style-type: none"> (1) An unlimited license, certificate, or registration; (2) A limited or probationary license, certification, or registration; (3) A temporary license, certificate, registration, or permit; (4) An intern permit; or <p>A provisional license, issued by the board regulating the profession in question, including a certificate of registration issued under IC 25-30.</p>
	<p>410 IAC 15-2-1-19 "Registered nurse" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1; IC 25-23-1</p> <p>Sec. 19. "Registered nurse" means an individual licensed under IC 25-23-1. (<i>Indiana State Department of Health; 410 IAC 15-2-1-19; filed Dec 1, 1999, 3:44 p.m.; 23 IR 782</i>)</p>	<p>"Registered Nurse" means a person who holds a valid license issued under this chapter, and who bears primary responsibility and accountability for nursing practices based on specialized knowledge, judgement, and skill derived from the principles of biological, physical, and behavioral sciences.</p>
	<p>410 IAC 15-2-1-20 "Supplier" defined Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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. (<i>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</i>)</p>	<p>"Supplier" for Health Care Financing Administration (HCFA) only (<i>now named Centers for Medicare and Medicaid Services (CMS)</i>), means an agency for diagnosis and therapy, such as a laboratory, a clinic, and a physical therapist office rather than sustained patient care. This definition includes an Ambulatory Out-patient Surgical Center.</p>

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	<p>Rule 2.2. Compliance 410 IAC 15-2.2-1 Compliance with rules Authority: IC 16-21-1-7 Affected: IC 16-21-1</p>	
Q0010	<p>Sec. 1. (a) All centers shall be licensed by the department and shall comply with all applicable federal, state, and local laws and rules.</p>	(a) Verify that the center has a current license.
Q0012	<p>(b) Components required for licensure as a center are the following:</p> <ol style="list-style-type: none"> (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. 	(b) Verify that the center has or provides under arrangement the services required for licensure. Verify that there are contracts or agreements for those required services the center provides under arrangement.
Q0014	(c) Optional services, not required for licensure, must comply with all rules for that service.	(c) Obtain a list of the optional services provided by the center or under arrangement.
Q0020	<p>(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:</p> <ol style="list-style-type: none"> (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. <p>(Indiana State Department of Health; 410 IAC 15-2.2-1; filed Dec 1, 1999, 3:44 p.m.; 23 IR 782)</p>	(d) Verify that the plan covers at least those items required in the rules. Determine that the responsibility for reviewing and reporting is outlined. Determine that the policies and procedures address the requirements for reporting.
	<p>410 IAC 15-2.2-2 Survey procedures Authority: IC 16-21-1-7 Affected: IC 16-21-1; IC 16-21-2-6</p>	
Q0024	Sec. 2. (a) The center shall fully cooperate with licensure and complaint investigation inspections conducted by representatives of the department.	(a) Document situations that are significant and/or contribute to a pattern of non-cooperation.
Q0026	(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	(b) Review selected documents, registers, and reports as necessary.

TAG	RULE
Q0028	<p>bylaws and regulations of the facility.</p> <p>(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:</p> <p>(1) Items to include, but not be limited to, the following:</p> <ul style="list-style-type: none"> (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.
Q0030	<p>(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.</p>
Q0032	<p>(3) Reports on patient services rendered must be submitted to the department as specified by the commissioner on forms provided by the department.</p>
Q0034	<p>(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. <i>(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)</i></p>

(c)(1)(A) through (H) Review those current documents during the survey process that have a direct and relative bearing on the quality of care as required by the regulations. It is not necessary to review documents that were covered during the previous year's licensure inspection.

(c)(2) Review the register to verify that it contains the required information.

(c)(3) Verify that reports have been submitted to the department as requested.

(d) No survey requirement.

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	<p>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</p>	
Q0038	<p>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.</p>	(a) Verify through file review at the Division that the current application is on file.
Q0040	<p>(b) A license is not transferable or assignable, and is issued only for the premises named in the application.</p>	(b) Verify that the license covers the premises and locations named in the application.
Q0042	<p>(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.</p>	(c) If multiple buildings/sites, verify single governing body, administrative control, and medical staff.
Q0048	<p>(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.</p>	(d) If there has been a change of ownership, verify that a reapplication has been filed with the Division.
Q0050	<p>(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.</p>	(e) Determine that this information is on file in the division prior to the pre-occupancy survey.
Q0052	<p>(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.</p>	(f) All buildings under the license shall comply with 15-2.5-7 unless a waiver is granted. Verify the waivers before citing.
Q0054	<p>(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)</p>	(g) No survey requirements.

TAG	RULE
Q0056	<p>410 IAC 15-2-3-2 Posting of license Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>Sec. 2. (a) The license must be conspicuously posted on the premises.</p>
Q0058	<p>(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. (<i>Indiana State Department of Health; 410 IAC 15-2-3-2; filed Dec 1, 1999, 3:44 p.m.; 23 IR 783</i>)</p>
	<p>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</p>
	<p>Sec. 3. (a) The commissioner may take any of the following actions on any of the grounds listed in subsection (b):</p> <ol style="list-style-type: none"> (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.
	<p>(b) The commissioner may take action under subsection (a) on any of the following grounds:</p> <ol style="list-style-type: none"> (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.
	<p>(c) IC 4-21.5 applies to an action under this section.</p>
	<p>(d) A licensee or an applicant for a license aggrieved by an action under this rule may request review under IC 4-21.5.</p> <p>(e) The department shall appoint an appeals panel consisting of three (3) members as follows:</p> <ol style="list-style-type: none"> (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.

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	(f) An employee of the department may not be a member of the panel.	(f) No survey requirements.
	(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. (<i>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</i>)	(g) No survey requirements.
	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.	(a) No survey requirements.
	(b) The complaints will be assigned a priority for investigation according to division policy.	(b) No survey requirements.
	(c) The complaint investigation will be unannounced and may evolve into a full survey.	(c) All complaint investigations are unannounced and are investigated either on site, or by phone, or by mail. If the complaint survey is being conducted during the licensing survey, inform the center that the complaint has been filed and that it will be investigated during the survey. Conduct the investigation of the complaint, document the outcome for the complaint report, and indicate any non-compliance on the complaint report and the licensure survey, if applicable. When on a complaint investigation, if significant non-compliances are discovered to warrant a full survey, notify the center and contact the division for concurrence.
	(d) The division shall notify the center of the results of the investigation in writing.	(d) No survey requirements.
	(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.	(e) No survey requirements.
	(f) Upon recommendation of the division, the survey report will be forwarded to the commissioner for action under section 3 of this rule. (<i>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</i>)	(f) No survey requirements.

TAG	RULE
	<p>Rule 2.4. Governing Body</p> <p>410 IAC 15-2.4-1 Governing body, powers and duties Authority: IC 16-21-1-7 Affected: IC 16-21-1</p>
Q0100	<p>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:</p>
Q0102	<p>(1) Ensure that the center:</p> <p>(A) meets all rules and regulations for licensure and for certification, if applicable; and</p> <p>(B) makes available to the commissioner or representatives of the department upon request all reports, records, minutes, documentation, information, and files required for licensure.</p>
Q0103	<p>(a)(1)(B) Are the reports, records, minutes, documentation, information and files supplied to the commissioner (or the commissioner's representative, the surveyor) if requested?</p> <p>In the case of quality review, determine by review of reports on occurrences and review of outcome documentation that the information reported to the QA&I program is what is contained in the medical record (factual and accurate) and that appropriate action was taken and is appropriately reported. (It is not the intent to be privy to all the activities and information occurring from report to outcome, just that center policy and procedure was followed. We are looking at the process, i.e., what went in and what came out, not the content of what occurred during the process. Was the outcome appropriate?)</p>
Q0104	<p>(a)(2) Review the bylaws and determine if the governing body functions in accordance with the bylaws. Determine if the committees or committee functions required by the bylaws are established and functioning. Review the minutes of the governing body meetings (since the last survey) to determine if the information required by the bylaws to be reported to the governing body is being reported.</p>
Q0106	<p>(a)(3) Determine and document the date of adoption of the bylaws and the last date of review. (These dates may not necessarily be on the bylaws document itself but could be reflected in the minutes of the governing body meetings.)</p>
Q0108	<p>(a)(4) Review records to verify entries covering medical staff and governing body communication and actions on pertinent issues.</p>
Q0110	<p>(a)(5) Review minutes of the governing body meetings (since the last survey) to verify reports on required areas and quarterly review.</p>

TAG	RULE	Guidance to Surveyors
Q0112	(b) The governing body is responsible for conduct of the medical staff activities related to the center. The governing body shall do the following:	(b) Verify that the bylaws establish the responsibility of the governing body for the conduct of the medical staff.
Q0114	(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.	(b)(1) It is the responsibility of the governing body to determine, with the advice of the medical staff, the categories of practitioners appointed to the medical staff. Review medical staff bylaws to insure the determination of categories of practitioners for medical staff privilege.
Q0116	(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.	(b)(2)(A thru D) Review the governing body minutes and confirm that the governing body appoints all members to the medical staff in accordance with established policies, based on the practitioner's scope of clinical expertise, and that the action taken is appropriate and is documented.
Q0122	(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.	(b)(3) Verify that the medical staff operates under current bylaws, rules and regulations that have been approved by the governing body. Verify that any revisions or modifications in medical staff bylaws, rules, and regulations have been approved by the medical staff and governing body and documented in the minutes.
Q0124	(4) Ensure that the medical staff is accountable and responsible to the governing body for the quality of care provided to patients.	(b)(4) Verify that the governing body is periodically appraised concerning medical staff evaluation of patient care services provided by the center.
Q0126	(5) Ensure that criteria for selection for medical staff membership are individual character, competence, education, training, experience, and judgment.	(b)(5) & (6) Determine that the governing body utilizes a reasonable alternative to board certification as a means of obtaining medical staff membership. In addition to matters of board certification, determine that the review process also considers criteria such as training, character, competence and judgement. (A center is not prohibited from requiring board certification when considering a practitioner for medical staff membership. Rather, the intent is that a center may not rely solely on the fact that a practitioner is or is not board certified in making a judgement on medical staff membership.)
Q0128	(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.	(b)(6) see above
Q0130	(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.	(b)(7) Verify the Center policy on admissions and ensure that patients are admitted in accordance with this policy and the requirements of the rule.

TAG	RULE	
Q0132	(8) Ensure surgical procedures are performed only by a physician, dentist, or podiatrist who is privileged to perform such procedures according to medical staff bylaws, regulations, and/or policies and procedures.	(b)(8) Verify by reviewing the documentation in the patient record that the surgical procedure is performed only by those practitioners allowed under state statute and with privileges to do so from the governing body.
Q0134	(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.	(b)(9) Review the authorized procedures and determine that no procedures are performed that are not authorized by the governing body. During the records check, verify that there are no lengths of stay that exceed 24 hours as designated in accordance with the center admission policy. (The admission policy may start the 24 hours from the patient's arrival at the center, but in no event, later than the on-site administration of pre-operative medication or admission to the surgical suite, whichever comes first, as noted in the patient's medical record.)
Q0140	(c) The governing body is responsible for managing the center. The governing body shall do the following:	(c) Verify that the bylaws establish the responsibility of the governing body for managing the center.
Q0142	(1) Develop criteria, which include, but are not limited to, defining educational and experience requirements for the chief executive officer.	(c)(1) Verify that the governing body has established criteria defining the experience, education, etc., requirements for chief executive office (CEO) and that the CEO meets the criteria requirements.
Q0144	(2) Delineate in writing the responsibility and authority of the chief executive officer.	(c)(2) Verify the documentation of the CEO's responsibility and authority.
Q0146	(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.	(c)(3) Verify the CEO's attendance and representation at the appropriate meetings.
Q0148	(4) Require that the chief executive officer designate in writing an administrative officer to serve during his or her absence.	(c)(4) Verify the designation of administrative authority in the absence of the CEO.
Q0150	(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)(5) (A through P) Verify that the current policies and programs/procedures cover the requirements listed by the rule or center policy, whichever is more restrictive.
Q0152	(C) Orientation of all new employees, including contract and agency personnel, to applicable center and personnel policies.	(c)(5)(B) Verify procedure time and the time records of employees involved to determine that they are not on duty elsewhere when scheduled for coverage at the center.
Q0153	(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	
Q0154		

TAG	RULE	
Q0156	<p>certification and keep documentation of same so that it can be made available upon request.</p> <p>(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.</p>	
Q0160	<p>(F) Establishing criteria for each manager, including, but not limited to, the following:</p> <ul style="list-style-type: none"> (i) Definition of educational requirements. (ii) Experience requirements. (iii) Professional certification, licensing, or registration, where appropriate. 	
Q0162	<p>(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.</p>	
Q0164	<p>(H) A post offer physical examination and employee health monitoring in accordance with the center's infection control program.</p>	
Q0166	<p>(I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p>	<p>(c)(5)(I) Review policies and procedures in each service for update and verify that they are reviewed/revised in accordance with center policy or triennially, whichever is less. In accordance with the center policy, each policy may be initialed or signed individually and dated on review/revision or a face sheet on all policies may be used with initials/signatures and date of review/revision.</p>
Q0168	<p>(J) Establishing a policy and procedure for communication with physicians concerning a patient emergency.</p>	<p>(c)(5)(J) Verify that a policy and procedure exists that outlines who contacts the appropriate practitioner on patient emergencies and the action to be taken if that practitioner is not available i.e., who to contact next and in what order until assistance is obtained.</p>
Q0170	<p>(K) Establishing criteria to determine the delineation of privileges.</p>	
Q0172	<p>(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.</p>	
Q0176	<p>(M) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities</p>	

TAG	RULE	
Q0178	<p>and verifying in-service in special procedures.</p> <p>(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.</p>	
Q0182	<p>(O) Annual implementation of internal and external disaster preparedness plans with documentation of outcome.</p>	
Q0184	<p>(P) Development, implementation, and monitoring of a safety management program to include, but not be limited to, the following:</p>	
Q0186	<p>(i) Periodic equipment inspections.</p>	
Q0188	<p>(ii) Insect, rodent, or other vermin control.</p>	
Q0190	<p>(iii) Instructions for operating and maintaining the building or building portion and equipment.</p>	
Q0192	<p>(iv) Chemical substances use and storage.</p>	
Q0194	<p>(v) Surgical waste and similar material disposal.</p>	
Q0196	<p>(vi) General housekeeping precautions.</p>	
Q0200	<p>(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:</p>	<p>(d) Verify that the bylaws establish the responsibility of the governing body for assuring the provision of quality patient care in the center.</p>
Q0210	<p>(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.</p> <p>(2) Ensure the following:</p> <p>(A) The center develops, implements, and maintains written medical staff policies and procedures for emergencies, initial treatment, and transfer.</p> <p>(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:</p> <p>(i) Timely assessment.</p> <p>(ii) Basic life support.</p> <p>(iii) Proper transfer mode.</p>	<p>(d)(1) Practitioners other than doctors of medicine or osteopathy may join the medical staff if the practitioners are appropriately licensed and medical staff membership is in accordance with state law and allowed by center policy.</p> <p>Verify that patients are under the care of a licensed practitioner member of the medical staff in accordance with that practitioner's privileges.</p> <p>(d)(2)(A&B) Determine that the medical staff has policies and procedures to cover emergencies, assessment, treatment, and referral. Determine that the policies cover transfer of patient and record.</p>
Q0212		

Q0214	(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.	(d)(3) Verify that the governing body has adopted a policy on appraisal of physician limited practice problems. (It may be that the center does not require criminal history checks. This is acceptable as long as there is a policy to that effect.)
Q0216	(4) Ensure that there is a center-wide, quality assessment and improvement program that evaluates the provision of patient care and outcome.	(d)(4) Verify that there is a QA&I program approved by the governing body that is center-wide and that requires the evaluation of the provision of patient care and the outcome of patient care.
Q0220	(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:	(e) Verify that the bylaws establish the responsibility of the governing body for assuring that the center services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by center employees or indirectly by contract or arrangement.
Q0222	(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.	(e)(1) Verify that the contracted services are provided in accordance with current statutes, rules, and regulations. When touring these services observe for compliance.
Q0224	(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.	(e)(2) Arrangements to take into consideration include services provided through formal contracts, joint ventures, informal agreements, shared services, or lease arrangements. Determine that the patient care services provided under arrangement are subject to the same center QA&I program evaluation as other services provided directly by the center.
Q0226	(3) Ensure that the center maintains a list of all contracted services, including the scope and nature of the services provided.	(e)(3) Review the list of contracted services and verify that there is a delineation of contractor responsibility. The "list" of services may be maintained electronically, on hard copy, or other acceptable manner as long as there is easy access for review and the required information is available.
Q0228	(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.	(e)(4) Verify that the transfer agreement is current. During Physician record review verify hospital admitting privileges of those physicians, dentists and podiatrists doing surgery at the center. Anesthesiologists need not have staff privileges at a hospital unless the anesthesiologist is the physician performing the surgical procedure.
Q0230	(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. <i>(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)</i>	(e)(5) Confirm that the governing body has appointed a committee as required by the rule and that the governing body has specified the frequency of the meetings. This may be done as part of another committee as long as there is "no financial interest" in the center on the part of the reviewing physicians. Review documentation to insure the committee fulfills its responsibilities.

TAG	RULE	
Q0300	<p>410 IAC 15-2.4-2 Quality assessment and improvement Authority IC 16-21-1-7 Affected IC 16-21-1</p> <p>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:</p>	<p>(a) Verify that the center has developed a QA&I program to meet its needs. The methods used by each center for self-assessment (QA&I) are flexible and a wide variety of techniques may be used to gather information to be monitored. These may include document-based review (e.g.: review of medical records, computer profile data, continuous monitors, patient care indicators or screens, incident reports, etc.); direct observation of clinical performance and of operating systems and interview with patients and/or staff. Determine that the information gathered by the center is based on criteria and/or a measure generated by the medical and professional/technical staffs and reflects center practice patterns, staff performance, and patient outcomes. Review the QA&I plan and verify that it has been reviewed and approved according to center policy. Verify that the plan is continuous.</p>
Q0310	<p>(1) All services, including services furnished by a contractor.</p>	<p>(a)(1) Verify that the QA&I plan covers all the services listed as required and those services the center has that are optional. Verify that those services provided under arrangement participate in the QA&I. To avoid duplication of effort and assure adequate attention to problems of the center, determine that mechanisms are in place to assure appropriate communication across departments and services.</p>
Q0320	<p>(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.</p>	<p>(a)(2) Verify that the QA&I plan covers all the services listed as required and those services the center has that are optional. Verify that those services provided under arrangement participate in the QA&I. To avoid duplication of effort and assure adequate attention to problems of the center, determine that mechanisms are in place to assure appropriate communication across departments and services.</p>
Q0326	<p>(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.</p>	<p>(a)(3) Verify that the review of surgical services performed goes through the medical staff, that it documents appropriateness against criteria and standards adopted by the medical staff, and that it documents outcome.</p>
Q0328	<p>(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)</p>	<p>(b) Review the documentation of action taken by the center to improve those areas where problems have been found. Determine that the action taken is delineated out and the responsibility for action outlined. Determine that the method of follow-up and responsibility for that follow-up is outlined. Determine that the expected impact on the patient care outcome is stated and that the outcome was effective and is reported in accordance with the center plan.</p> <p>In the case of quality review, determine by review of reports on occurrences and review of outcome documentation, that the information reported to the QA&I Program is what is contained in the medical record (factual and accurate) and that appropriate action was taken and is appropriately reported. (It is not the intent to be privy to all the activities and information occurring from report to outcome, just that center policy and procedure was followed. We are looking at the process, what went in and what came out, not the content of what occurred during the process.)</p>

	<p>410 IAC 15-2-4-2.2 Reportable events Authority: IC 16-19-3-4; IC 16-21-1-7 Affected: IC 16-19-3; IC 16-21-1; IC 25</p>	
Q0332	<p>Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following:</p> <p>(1) A process for determining the occurrence of the following reportable events within the center:</p> <p>(A) The following surgical events:</p> <ul style="list-style-type: none"> (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: <ul style="list-style-type: none"> (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; (ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. (iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. <p>Excluded are emergent situations:</p> <ul style="list-style-type: none"> (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; 	<p>or both</p> <p>or both</p>

death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infant discharged to the wrong person.

(ii) Patient death or serious disability associated with patient elopement.

(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self inflicted injuries that were the reason for admission to the center.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

(AA) drug;

(BB) dose;

(CC) patient;
 (DD) time;
 (EE) rate;
 (FF) preparation; or
 (GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.
 (iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

(AA) Pulmonary or amniotic fluid embolism.
 (BB) Acute fatty liver of pregnancy.
 (CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.
 (v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.
 (vii) Patient death or serious disability resulting from joint movement therapy performed in the center.

(viii) Artificial insemination with the wrong donor sperm or wrong egg.

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in

the center. Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient: (AA) contains the wrong gas; or (BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.

(iv) Patient death or serious disability associated with a fall while being cared for in the center.

(v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the center.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the center.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.

Q0334

(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.

(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the center in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:

- (1) The report shall:
- (A) be made to the department;
 - (B) be submitted not later than fifteen (15) working days after the serious adverse event is determined to have occurred by the center's quality assessment and improvement program;
 - (C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and
 - (D) identify the reportable event, the quarter of Occurrence and the center, but shall not include any identifying information for any:
 - (i) patient;
 - (ii) individual licensed under IC 25; or
 - (iii) center employee involved;
- or any other information.
- (2) A potential reportable event may be identified by a center that:
- (A) receives a patient as a transfer; or
 - (B) admits a patient subsequent to discharge; from another health care facility subject to a reportable event requirement. In the event that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.
- (3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.
- (4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.
- (d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The

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	<p>department's public report will be issued annually.</p> <p>(e) Any reportable event listed in subsection (a)(1) that: (1) is determined to have occurred within the center between: (A) January 1, 2009; and (B) the effective date of this rule; and (2) has not been previously reported;</p> <p>must be reported within five (5) days of the effective date of this rule. <i>(Indiana State Department of Health; 410 IAC 15-2.4-2.2)</i></p>	
	<p>Rule 2.5: Required Ambulatory Outpatient Surgical Center Services</p> <p>410 IAC 15-2.5-1 Infection control program Authority: IC 16-21-1-7 Affected: IC 16-21-1-1</p>	
Q0400	<p>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.</p>	<p>(a) Tour the center, observe the environment, and interview the infection control officer/practitioner(s) to determine that the infection control program is being enforced. Determine that there is a qualified person(s) to meet the needs anticipated by the center.</p>
Q0404	<p>(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.</p>	<p>(b) Determine that center policies or other appropriate documents demonstrate that the center has an active infection control program. Review minutes of the infection control committee (since the last survey). Determine if there have been problems and follow a problem from discovery to solution to see if there has been proper documentation and satisfactory outcome. Determine if the problem has been presented to the QA&I in accordance with the center plan. Review center and department/service policies to determine that the program is both center-wide and department/service specific.</p>
Q0406	<p>(c) The infection control program must identify and evaluate trends or clusters of center generated infections or communicable diseases.</p>	<p>(c) Verify that there is a method established to identify clusters of center generated infections or communicable diseases and that the evaluation is reported or acted upon in accordance with center policy.</p>
Q0408	<p>(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.</p>	<p>(d) Verify that the IC officer/practitioner has training or experience in disease transmission and infection control principles. Determine that the IC officer/practitioner is responsible for all elements of the infection control program as outlined by the Infection Control Committee in the center policies and procedures. Verify that the program is integrated by the CEO, Medical staff, and the Nurse Executive in the center's QA&I and in service training programs.</p>
Q0410	<p>(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</p>	<p>(e)(1) Verify that corrective action has been implemented in problem areas and that documentation concerning corrective actions and outcomes is maintained.</p>
Q0412	<p>(2) provide for appropriate infection control input into</p>	<p>(e)(2) Verify that there is documentation of involvement by infection control in plans for</p>

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Q0414	<p>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.</p> <p>(f) The center shall establish a committee to monitor and guide the infection control program in the center as follows:</p> <p>(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:</p> <p>(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (d).</p> <p>(B) A representative from the medical staff.</p> <p>(C) A representative from the nursing staff.</p> <p>(D) Consultants from other appropriate services within the center as needed.</p> <p>(2) The infection control committee responsibilities must include, but are not limited to, the following:</p> <p>(A) Establishing techniques and systems for identifying, reviewing, and reporting infections in the center.</p> <p>(B) Recommending corrective action plans, reviewing outcomes, and assuring resolution of identified problems.</p> <p>(C) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.</p> <p>(D) Written reports of quarterly meetings.</p> <p>(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:</p> <p>(i) Sanitation.</p> <p>(ii) Universal precautions, including infectious waste management.</p> <p>(iii) Cleaning, disinfection, and sterilization.</p>	<p>construction and renovation and protection of patients/staff during construction and renovation if construction or renovation has/is/ or will be taking place.</p> <p>(f) The infection control committee responsibilities do not need to be accomplished by a separate committee. They may be incorporated into another committee so long as the required review and actions pertaining to the infection control function are documented in the minutes of the committee doing the review. The infection control committee may delegate to a qualified person the responsibility for the operational elements of the infection control program. If the committee has delegated this responsibility, verify that an IC officer/practitioner(s) has been designated to be responsible. Review the minutes and verify.</p> <p>(f)(1) Verify the composition of the committee and the meeting schedule by reviewing the minutes.</p> <p>(A) Verify that the IC officer/practitioner (s) is a member of the committee.</p> <p>(B&C) Verify that there are provisions for representation from Medical Staff, Nursing, & Administration. Determine that they participate.</p> <p>(D) Verify that there are provisions for participation of other department/service representatives when necessary.</p> <p>(f)(2)(A) Verify that the infection control officer/practitioner(s) maintains a log/documentation of incidents related to infections and communicable diseases. Determine that laboratory culture reports are monitored to detect infection trends. Verify that there are surveillance protocols based on the IC program requirements including feedback and intervention.</p> <p>(f)(2)(B) Review the minutes for committee input and action.</p> <p>(f)(2)(C) Determine that there is an active, on-going employee health program, including documentation of incidents and follow-up. Check the TB and blood and body fluid program for compliance.</p> <p>(f)(2)(D) Verify by reviewing the reports of meeting minutes.</p>
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Q0434	(iv) Aseptic technique, invasive procedures, and equipment usage.	biological monitoring is used to check the sterilization processes. Verify that the results of bacteriological tests are evaluated and any necessary corrective action taken.
Q0436	(v) Reuse of disposables.	(f)(2)(E)(iv) Verify infection control review of nursing policies on aseptic technique and invasive procedures. Determine that the equipment usage is in accordance with current standards of infection control practice.
Q0438	(vi) A patient isolation system.	(f)(2)(E)(v) Verify that center policy addresses the use and re-use of disposables in accordance with the product manufacturer's recommendations on allowing re-use.
Q0440	(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.	(f)(2)(E)(vi) Verify that there is a center isolation system to cover OSHA requirements, universal precautions, and other methods of transmission (i.e., airborne). Verify that there has been monitoring of compliance by center staff in accordance with center policy on isolation.
Q0442	(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.	(f)(2)(E)(vii) Verify written protocol to determine appropriate employee post exposure management to minimize the risk of secondary spread of infection.
Q0444	(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.	(f)(2)(E)(viii) Review the documentation of history of or immunity to Rubella, Rubeola, and Chicken Pox.
Q0446	(x) A program of linen management.	(f)(2)(E)(ix) Review the policies that cover attire and hygiene. Observe the employees for neatness and good general hygiene. Review the Operating Room dress code and observe for compliance.
Q0450	(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:	(f)(2)(E)(x) Review the procedures and linen handling program to verify compliance with center policy. Determine that written procedures for linen and laundry personnel address handling processing, and transporting of clean and soiled linen. Determine that soiled linen is contained in a bag impervious to moisture at the source of generation. Determine that clean linen is delivered to the designated area in a manner that prevents contamination and in accordance with center policy.
Q0452	(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.	(g) Review policies and procedures for sterilization of equipment and supplies. Verify that equipment and supplies are sterilized in accordance with acceptable standards of practice or manufacturers recommendations and applicable state laws and rules. Verify that sterilization services is directed by a person qualified by education and experience and has met the center's competency requirements.
Q0454	(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	(g)(2) Review policies and procedures. Verify policies and procedures are being followed by personnel.

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	<p>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.</p>	
Q0466	<p>(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.</p>	
Q0472	<p>(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.</p>	
Q0480	<p>(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.</p>	
Q0486	<p>(2) Central clean linen storage space must be provided as follows:</p>	
Q0488	<p>(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</p>	
Q0490	<p>(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</p>	

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Q0494	<p>handled.</p> <p>(B) If laundry is processed in the center:</p> <ul style="list-style-type: none"> (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. <p><i>(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)</i></p>	
Q0504	<p>410 IAC 15-2.5-2 Laboratory services Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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.</p>	<p>(a) Determine which services are provided directly by the center and which are provided through a contractual agreement.</p>
Q0506	<p>(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.</p>	<p>(b) Review the policy on who can order tests and examinations and review a sampling of orders to determine that the center policy is being observed.</p>
Q0508	<p>(c) A written description of available laboratory services, reference values, critical values, and expected turnaround time shall be available to the patient care staff.</p>	<p>(c) Verify the existence of a written description of the laboratory services provided. Verify that the description of the service is accurate and current and that the items required by regulation are covered.</p>
Q0510	<p>(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.</p>	<p>(d) Determine if there is a requirement for and a policy on frozen section service. Verify that this service is provided as required and if provided on site is in compliance with current CLIA regulations for high complexity pathology testing.</p>
Q0514	<p>(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:</p> <ul style="list-style-type: none"> (1) Microscopic examination only. (2) Macroscopic examination only. (3) Both microscopic and macroscopic examinations. 	<p>(e) Verify that the requirements concerning which tissue specimens removed during surgical procedures require macroscopic and/or microscopic examination are covered in the medical staff rules and regulations and that the requirements are being carried out.</p>
Q0522	<p>(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</p>	<p>(f) Verify current CLIA certificate and expiration date of center lab or status of facility that performs tests under contract. If center lab, verify that the deficiencies cited on the last CLIA survey have been addressed and that proficiency testing records reflect satisfactory results.</p>

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Q0524	(g) Laboratory supervisory and testing personnel qualifications must be consistent with the work assignments and in compliance with 42 CFR 493.	(g) Review the personnel records of the director and a sample of laboratory personnel records to assure they are in compliance with current CLIA regulations for complexity of testing performed.
Q0526	(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.	(h) Verify that non-laboratory personnel performing out-of-laboratory tests have been properly trained in those tests and are annually updated. Determine that documentation of performance certification is available in the employee file.
Q0530	(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.	(i) If the ASC policy (commensurate with procedures performed) is that if blood is needed the patient is transferred to the hospital, the required hospital transfer agreement meets this requirement. Otherwise, verify that the center 1) has an agreement with a licensed blood center and/or transfusion service to come on site for transfusion or 2) has an agreement with a transfusion service to provide testing/blood or 3) meets requirements as a transfusion service.
Q0534	(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. (<i>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</i>)	If center transfuses blood or blood products, policies addressing administration of the blood and blood products must be available and approved by medical staff. Verify that there is a center procedure for reporting transfusion reactions if transfusion is performed on site.
Q0604	410 IAC 15-2-5-3 Medical records, storage, and administration Authority: IC 16-21-1-7 Affected: IC 16-21-1	
Q0606	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	(a) Verify that the medical records service is structured appropriately to meet the needs of the center and the patients. (b) Verify that there is an established system which addresses at least the following activities of the medical records services: ▪ timely processing, coding/indexing, and retrieval of records; ▪ protecting the confidentiality of medical information; and ▪ compiling and retrieval of data for QA&I activities.
	(b)(1) Review the personnel file of the director for compliance with the requirements. If there is a consultant, verify credentials and review reports from the consultant. Determine if the	

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	<p>recommendations of the consultant must be maintained.</p>	<p>recommendations and outcomes are recorded.</p>
Q0610	<p>(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.</p>	<p>(b)(2) Review a sampling of other medical record service personnel records. Review written job descriptions and staffing schedules to determine if staff is carrying out all designated responsibilities.</p>
Q0612	<p>(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.</p>	<p>(c) Verify that there is an established system which addresses timely processing, coding/indexing, and retrieval of medical records.</p>
Q0614	<p>(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.</p>	<p>(c)(1) Review the policies for requirements on accurate and timely documentation. Verify that the records are readily accessible either in hard copy or electronically and that information can be retrieved promptly and in accordance with center policy.</p>
Q0616	<p>(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.</p>	<p>(c)(2) If the center has a unit record system, verify that it is functioning properly and that the files are current. Verify that it covers all aspects of the information system necessary to complete the record. If the center does not utilize the unit records system, verify that there is a system to retrieve all patient informational elements in a timely manner from different locations.</p> <p>(c)(3) Verify that the center has a policy on "what is an entry". Verify that there is a policy that the author of each entry authenticates his or her entry. A responsible individual of the same discipline may authenticate the entry, if allowed by the center and medical staff policies.</p> <ul style="list-style-type: none"> ▪ Verify that the policy includes authenticated signatures, written initials, codes, mechanical signatures and signature stamps. If used: <ol style="list-style-type: none"> 1) verify that computer code signatures, mechanical signatures and signature stamps are authorized by the governing body; 2) verify that the codes and stamps are maintained under adequate safeguards; 3) verify that the policies cover review by the author of the transcribed reports prior to authentication and <ol style="list-style-type: none"> 4) verify that policies and procedures provide for: <ol style="list-style-type: none"> a) appropriate sanctions for unauthorized or improper use of computer codes, mechanical signatures, or signature stamps; b) a signed statement from the individual whose signature the code or stamp represents is the only one who has the code or stamp and is the only one who will use it and; c) no delegation of the use of such code or stamp to another individual. <p>Verify that there is a system established for author identification, i.e., signature sheets, lists, signature in personnel files, signature cards, etc.</p>
Q0618	<p>(4) Medical records must be retained in their original or legally reproduced form as required by federal or state law.</p>	<p>(c)(4) Verify that medical records are retained in their original or legally reproduced form in hard copy, microfilm/microfiche or computer memory banks in accordance with center policy. Current state law requires health records be kept a minimum of 7 years. (IC 16-39-7-1)</p>
Q0620	<p>(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the center policies.</p>	<p>(c)(5) Verify that the center policy allows facsimile orders, reports, and documents and if so that plain paper is required.</p>
Q0622	<p>(6) The center shall have a system of coding and indexing medical records which allows for timely</p>	<p>(c)(6) Verify that the center uses a coding and indexing system that permits timely retrieval of patient records by diagnosis and procedure, by physician, and by condition on discharge.</p>

	retrieval of records by diagnosis and procedure, physician, and condition on discharge, in order to support continuous quality assessment and improvement activities.	
Q0624	<p>(7) The center shall ensure the confidentiality of patient records. The center must develop, implement, and maintain the following:</p> <p>(A) A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.</p> <p>(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.</p>	<p>(c)(7)(A&B) Verify that only authorized persons are permitted access to records maintained by the center. Verify that the center has a policy to grant patients direct access to his/her medical record if the practitioner responsible for the patient's care determines that direct access is not likely to have an adverse effect on the patient.</p> <ul style="list-style-type: none"> ▪ Verify that medical records are released only for patient care evaluation, utilization review, treatment, QA&I programs, in-house educational purposes, or as dictated by center policy. <p>Other than the above, verify that copies of medical records are released outside the center only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by statutes.</p>
Q0630	<p>(d) The medical record must contain sufficient information to:</p> <ol style="list-style-type: none"> (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. 	<p>(d) Review a sample of active and closed patient records (since the last licensing survey) for completeness and accuracy in accordance with center policy. The sample should be at least 10% of the current daily patient surgical load but not fewer than 30 records, except on initial surveys.</p>
Q0640	<p>(e) All entries in the medical record must be as follows:</p> <ol style="list-style-type: none"> (1) Legible and complete. 	<p>(e) Review a sampling of medical record entries. If there are isolated instances of noncompliance bring them to the attention of the center. If a pattern develops on a specific person authorized to make entries or on specific items concerning the entries that are not in compliance with policy/regulations cite as a noncompliance.</p>
Q0644	<p>(2) Made only by authorized individuals as specified in center and medical staff policies.</p>	<p>(e)(1) Determine if there is a procedure for verifying entries with questionable legibility/readability.</p>
Q0646	<p>(3) Authenticated and dated in accordance with section 4(b)(3)(N) of this rule.</p>	<p>(e)(2) Review the policies to verify that they specify which individuals/categories of staff/professionals are allowed to make medical record entries.</p>
Q0648	<p>(f) All patient records must document and contain, at a minimum, the following:</p> <ol style="list-style-type: none"> (1) Patient identification. 	<p>(e)(3) Verify authentication within the time frame approved by the medical staff and center policy not to exceed 30 days from the date of the procedure.</p>
Q0650	<p>(2) Appropriate medical history and results of a physical examination completed within the time frames in section 4(b)(3)(M) of this rule.</p>	<p>(f) Review a sampling of the current and closed patient surgical records. Verify that the required items are included where appropriate.</p>
Q0652	<p>(3) Preoperative diagnostic studies recorded in the record before surgery, if performed.</p>	
Q0654	<p>(4) Any allergies and abnormal drug reactions.</p>	
Q0656	<p>(5) Entries related to anesthesia administration.</p>	
Q0658	<p>(6) Evidence of appropriate informed consent for</p>	

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	<p>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.</p>	
Q0660	(7) Discharge diagnosis.	
Q0662	(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.	
Q0664	(9) A written or dictated report describing techniques, findings, and tissue removed or altered.	
Q0666	(10) Signatures of physicians and health care workers who treated or cared for the patient.	
Q0668	(11) Condition on discharge, disposition of the patient, and time of dismissal.	
Q0670	(12) Final progress note, including instructions to the patient and family, with dismissal diagnosis.	(f)(12) Verify that the medical record includes a final progress note made by the physician. The final progress note is to include instructions to the patient and family and discharge diagnosis.
Q0672	(13) A copy of the transfer form, if the patient is referred to a hospital or other facility.	
Q0676	(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. <i>(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)</i>	(g) Verify that medical records are retained in their original or legally reproduced form in hard copy, microfilm/microfiche or computer memory banks in accordance with center policy. Current law requires health records be kept a minimum of 7 years, (IC 16-39-7-1) readily accessible, i.e., on site, available upon request or as needed for survey or review. If medical records are stored off-site and there is no legally reproducible copy on-site, verify facility has an approved waiver under rule IC 15-2.2-2(c). (Allow for a reasonable time to retrieve documents stored off-site.)
Q0700	<p>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</p> <p>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:</p>	(a) Review the bylaws of the medical staff to insure it is established in accordance with the governing body bylaws.
Q0704	(1) Conduct outcome-oriented performance evaluations of its member at least biennially.	(a)(1) Verify that the medical staff appraisal system is outcome oriented and that the procedures evaluate the demonstrated competence of a member as established by the medical staff QA&I

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Q0706	<p>(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.</p>	<p>program. Verify the member's adherence to medical staff by laws and rules and regulations.</p> <p>(a)(2) Verify that there is a mechanism established to examine credentials of prospective members by the medical staff. Verify that the credentials examined include at least:</p> <ul style="list-style-type: none"> ▪ a request for clinical privileges; ▪ current licensure; ▪ training and professional education; ▪ documented experience; and ▪ supporting references of competence.
Q0708	<p>(3) Make recommendations to the governing body on the appointment or reappointment of the applicant for a period not to exceed two (2) years.</p>	<p>(a)(3) Verify that the medical staff makes recommendations to the governing body for new members and re-appointments that are specific to type of appointment and extent of clinical privileges, and that the governing body takes final appropriate action.</p>
Q0710	<p>(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:</p> <p>(A) A completed, signed application.</p> <p>(B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable.</p> <p>(C) A current copy of the individual's credentials as follows:</p> <p>(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.</p> <p>(ii) Indiana controlled substance registration showing number as applicable.</p> <p>(iii) Drug Enforcement Agency registration showing number as applicable.</p> <p>(iv) Documentation of experience in the practice of medicine.</p> <p>(v) Documentation of specialty board certification as applicable.</p> <p>(vi) Documentation of privilege to perform surgical procedures in a hospital in accordance with IC 16-18-2-14(3)(C).</p> <p>(D) Category of medical staff appointment and delineation of privileges approved.</p> <p>(E) A signed statement to abide by the rules of the center.</p>	<p>(a)(4) Verify that a separate file is maintained for each member of the medical staff and applicant. Review a representative number of files including in the sample the file of special categories of staff member, i.e., Dentists, Podiatrists, Allied Health Professionals, CRNA's, etc.</p> <p>(a)(4)(A&B) Review the sample files for application and the required information.</p> <p>(a)(4)(C)(i) Verify that all practitioners are currently licensed in compliance with state laws. If there is any practice limitation, review the documentation and determine that the action taken is in accordance with medical staff policy.</p> <p>(a)(4)(C)(ii&iii) View the copies or acceptable list.</p> <p>(a)(4)(C)(iv&v) Review the application for required information.</p> <p>(a)(4)(C)(vi) Verify hospital appointment and surgical privileges. The physician may be privileged to perform different procedures at the hospital than at the center. All that is required by statute is that the physician "is privileged to perform surgical procedures in at least one hospital within the county or an Indiana county adjacent to the county in which the ambulatory outpatient surgical center is</p>

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	<p>(F) Documentation of current health status as established by center and medical staff policy and procedure and federal and state requirements.</p> <p>(G) Other items specified by the center and medical staff.</p>	<p>located".</p> <p>(a)(4)(D) Verify that the request for appointment and privileges is addressed in the appointment and that documentation explains the differences, if any.</p> <p>(a)(4)(E) This statement may be found on the medical staff application.</p> <p>(a)(4)(F) Verify that infection control policy or medical staff rule addresses practitioner health status.</p> <p>(a)(4)(G) Review the record for required information.</p> <p>(b) The medical staff shall regulate itself by bylaws and rules and regulations, or policies and procedures, that are consistent with acceptable medical staff practices. Verify that the bylaws are enforced, revised as necessary, and reviewed as required.</p> <p>(b)(1) Verify governing body approval by citing a signed, dated copy of the bylaws, rules and regulations, or documentation in the minutes of a governing body meeting that the bylaws, rules and regulations were presented and approved. Verify adherence to rules and regulations (see(a)(4)(E) above).</p> <p>(b)(2) Verify review at least every three years by citing dated, signed copy or documentation of review and approval in medical staff and governing body meeting minutes.</p> <p>(b)(3)(A) Verify that the bylaws describe the organizational structure of the medical staff; delineate accountability to the governing body; describe who is responsible for regularly scheduled review and evaluation of the clinical work of the members of the medical staff; describe the formation of leadership in the staff; and lay out rules and regulations of the medical staff to make clear what are acceptable standards of patient care for all medical and surgical services.</p> <p>(b)(3)(B) Verify the schedule of meetings and that the meetings are held at least as required with the required attendance.</p> <p>(b)(3)(C) Review a sample of the minutes since the last survey.</p> <p>(b)(3)(D) Verify the existence of a procedure for appointment or election of the chief, president, or chairperson.</p> <p>(b)(3)(E) Verify that the bylaws specify the role and responsibilities of each category (e.g., active, courtesy, etc.) of practitioner on the medical staff.</p> <p>(b)(3)(F) Verify that the bylaws describe the qualifications such as licensure, specific training, experience, current competence, and health status to be met by a candidate for appointment to the medical staff. Verify the requirement for hospital admitting and surgical privileges.</p> <p>(b)(3)(G) Verify the bylaws contain criteria for granting, withdrawing, and modifying clinical privileges to various categories of the medical staff and that a procedure exists for applying these criteria.</p>
Q0728	(b) The medical staff shall adopt and enforce bylaws and rules to carry out its responsibilities. These bylaws and rules must be as follows:	
Q0730	(1) Be approved by the governing board.	
Q0732	(2) Be reviewed at least triennially.	
Q0734	(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.	
Q0736	(B) Meeting requirements of the medical staff to include, at a minimum, the following: (i) Frequency, at least quarterly. (ii) Attendance.	
Q0742	(C) A provision for maintaining records of all meetings of the medical staff and its committees.	
Q0744	(D) A procedure for designating an individual practitioner with current privileges as chief, president, or chairperson of the staff.	
Q0746	(E) A statement of duties and privileges for each category of the medical staff.	
Q0748	(F) A description of the medical staff applicant qualifications.	
Q0750	(G) Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.	

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Q0752	(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.	(b)(3)(H,I,J,&K) Verify that the bylaws cover these requirements.
Q0754	(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.	
Q0756	(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.	
Q0764	(K) A process for appeals of decisions regarding medical staff membership and privileges.	
Q0766	(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.	(b)(3)(L) Verify that the medical staff has adopted a definition of emergency care. Verify that a timely response is addressed i.e., within what time frame and that there is a clear protocol on who responds, in what order they are contacted to respond, and how they may respond, if appropriate.
Q0772	(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	(b)(3)(M)(i&ii) Verify that the bylaws require an H&P be done for each patient by a physician or where appropriate, another practitioner granted such privileges by the medical staff in accordance with state law. The H&P must be consistent with the requirements of the medical staff taking into account the complexity of the procedure to be performed. (b)(3)(M)(iii) If the H&P is done prior to admissions and within the time frame specified by the

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	and changes noted in the record on admission in accordance with center policy.	medical staff, look for an updating entry or progress note made on admission that covers the vital signs, documents the systems stability or change, and other pertinent information required by the medical staff rules and regulations.
Q0780	(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.	(b)(3)(N) Verify that there is a policy on written and verbal orders. The medical staff may define the categories of diagnostic or therapeutic verbal orders associated with any potential hazard to the patient and determine the time required for those orders to be authenticated, not exceeding the thirty (30) day limit.
Q0782	(O) A provision for personnel authorized to take a verbal order.	(b)(3)(O) Verify that the policy covers what categories of professionals may receive verbal orders and the procedures for entering and verifying those orders.
Q0784	(P) A requirement that the final diagnosis be documented along with completion of the medical record within thirty (30) days following discharge.	(b)(3)(P) Verify that there is a procedure for notifying practitioners on completing records before the 30-day limit, not after 30 days. Review the number of delinquent records (i.e. those not completed within 30 days) and cite if that number exceeds 50% of the average monthly discharge. Do not count those records that are beyond the control of the center, i.e., pathology report, or CDC report.
Q0786	(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 non physician practitioners.	(b)(3)(Q) If the center allows patient care by practitioners other than physicians, verify that there are medical staff policies and procedures to cover the physician oversight and review of the non-physician practitioners.
Q0788	(R) A requirement that a physician shall be available to the center during the period any patient is present in the center.	(b)(3)(R) Verify that there is a physician immediately available by phone, during the period a patient is in the center, to respond to patients requiring emergency care and then available on the premises within an acceptable period of time, if necessary, and in accordance with medical staff policies.
Q0790	(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:	(c) If anesthesia is administered then assess the service whether or not it is an organized or separate service. An appropriately qualified physician shall be appointed and given the authority and responsibility by the medical staff, for directing the administration of all anesthesia in the center. The director is responsible for planning, directing, supervising all activities of the service, and monitoring of the QA&I of anesthesia patient care.
Q0800	(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:	(c)(1) Review the policies and procedures to determine if the service incorporates the minimum policies required.
Q0802	(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	(c)(1)(A) Review the medical staff policy on the requirements for specialized training and experience in the administration of anesthesia. Insure that the center has a definition for local infiltration anesthetic.

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Q0804	<p>remain present in the facility during the surgical procedure, except when only a local infiltration anesthetic is administered.</p> <p>(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.</p>	<p>(c)(1)(B) Review the written policies and procedures on all types of anesthesia authorized by the medical staff for use in the center.</p>
Q0816	<p>(C) Personnel permitted to administer anesthesia. Anesthesia must only be administered by an individual privileged by the medical staff and who is a:</p> <ul style="list-style-type: none"> (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. 	<p>(c)(1)(C) Review the medical staff policies and insure that the privileging for administration of anesthesia is appropriate.</p>
Q0824	(D) Safety rules to be followed.	
Q0826	(E) Safety training required of personnel.	
Q0828	(F) The delineation of preanesthesia, intra-operative, and post-anesthesia responsibilities as follows:	<p>(c)(1)(F) Determine that the policies designate who is responsible for the pre, intra, and post anesthesia requirements.</p>
Q0830	(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	<p>(c)(1)(F)(i) Determine that the preoperative anesthesia evaluation includes a notation of anesthesia risk, anesthesia, drug and allergy history, any potential anesthesia problems identified, and the patient's condition prior to induction of anesthesia.</p>

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Q0832	<p>surgery.</p> <p>(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.</p>	<p>(c)(1)(F)(ii) Determine that there is monitoring and documentation of monitoring intra-operatively in accordance with current acceptable standards of practice and medical staff policies. Determine that the intra-operative anesthesia record, documenting all pertinent events taking place during anesthesia, includes: name, dosage, route and time of administration of drug and anesthesia agents; I.V. fluids; blood or blood products, if applicable; oxygen flow rate; continuous recording of patient status noting blood pressure, heart and respiration rate, and is in accordance with medical staff policy.</p>
Q0834	<p>(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.</p>	<p>(c)(1)(F)(iii) Determine that the postanesthesia recovery record contains information in accordance with center policies and procedures, and depending on the type of anesthesia and length of surgery, determine that the post operative checks include: cardiopulmonary status; level of consciousness; complication or problems occurring during anesthesia, including time and description of systems, vital signs, treatment rendered, and patients response to treatment; and any follow up care and/or observations.</p>
Q0836	<p>(iv) The requirement that all postoperative patients shall be discharged from the post-anesthetic care unit by the practitioner described in clause (C) as responsible for the patient's care in accordance with center policy.</p>	<p>(c)(1)(F)(iv) Verify that each patient is discharged from the PACU as required and in accordance with the center/medical staff policy.</p>
Q0840	<p>(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.</p>	<p>(c)(2) Determine from documentation in the patient record that the required checks were performed on the anesthesia equipment prior to each administration of anesthesia.</p>
Q0842	<p>(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.</p>	<p>(c)(3) Review to determine that the policy covers the requirements.</p>
Q0850	<p>(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:</p>	<p>(d) Tour the operative/procedure suites. Verify that the surgical suite is a segregated unit with safeguards against unrelated traffic.</p> <p>Determine:</p> <ul style="list-style-type: none"> ▪ That access to the operative and recovery area is limited to authorized personnel. ▪ The conformance to aseptic technique by all individuals in the surgical area. ▪ That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite wear only clean surgical costumes, that surgical costumes are designed for appropriate skin and hair coverage as required by center policy. ▪ That there is appropriate cleaning between surgical cases. ▪ That equipment is available for rapid and routine sterilization of operating room materials if necessary. <p>That sterilized materials are packaged, labeled and stored in a manner that ensures sterility, e.g. in a moisture and dust controlled environment, and that each item is marked with an expiration date except when the center had adopted Event Related Sterility.</p>
Q0852	<p>(1) Surgical services are under the direction of a</p>	<p>(d)(1) Verify that an appropriate practitioner is assigned the responsibility of the surgical service.</p>

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Q0854	<p>physician, dentist, or podiatrist qualified by experience and training.</p> <p>(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:</p>	<p>(d)(2) Review the policies of the service. Determine that policies governing surgical care contain, at a minimum, policies for:</p> <ul style="list-style-type: none"> ▪ Aseptic surveillance and practice, including scrub techniques; ▪ Identification of infected and non-infected cases; ▪ Housekeeping requirements/procedures; ▪ Explosive/flammable anesthetic agent use; ▪ Patient care requirements, i.e. preoperative work-up, patient consents and releases, clinical procedure, safety practices, patient identification procedures; ▪ safety practices; ▪ personnel policies unique to O.R. if any; ▪ resuscitative techniques; ▪ care of surgical specimens; ▪ tissue review, including macro & micro requirements; ▪ sterilization and disinfecting procedures; ▪ acceptable operating room attire <p>appropriate protocols for all surgical procedures performed (these may be procedure specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments.)</p>
Q0856	<p>(A) A mechanism must be maintained which specifies the delineated surgical privileges of each practitioner.</p>	<p>(d)(2)(A) Review the mechanism for maintaining the roster of practitioners specifying the surgical privileges of each practitioner. Determine that the roster is current and updated in accordance with the medical staff reappointment schedule. The roster can be a list, a file, electronic or other system as long as it is readily available and current.</p>
Q0860	<p>(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.</p>	<p>(d)(2)(B) Review a minimum of 30 (except on initial surveys) random patient records to determine that a history and physical examination by the admitting practitioner is completed, in accordance with policy, prior to surgery, except in an emergency.</p>
Q0862	<p>(C) A provision for the following equipment and supplies to be available to the surgical and recovery areas:</p> <ul style="list-style-type: none"> (i) Emergency call system. (ii) Oxygen. (iii) Resuscitation equipment. (iv) Defibrillator. (v) Cardiac monitors. (vi) Tracheostomy set. (vii) Oximeter. 	<p>(d)(2)(C) Determine that the required equipment is available and operable.</p>

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Q0882	<p>(viii) Suction equipment. (ix) Other supplies and equipment specified by the medical staff.</p> <p>(D) A requirement for adequate provision of immediate postoperative care.</p>	<p>(d)(2)(D) Verify that the center has provisions for postoperative care. The post-operative care unit (PACU) or recovery room is a separate area. Access is limited to authorized personnel. Determine if an emergency cart and defibrillator are immediately available to the area. Determine that there are policies and procedures which govern the recovery area that include but are not limited to:</p> <ul style="list-style-type: none"> • specifying the transfer requirements to and from the recovery area; • depending on the type of anesthesia and length of surgery, the postoperative check before transferring the patient from the recovery area should include some of the following: level of activity; respiration; blood pressures; level of consciousness; patient color.
Q0884	<p>(E) A requirement that the patient register is complete and up to date.</p>	<p>(d)(2)(E) Verify by checking the register.</p>
Q0888	<p>(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.</p>	<p>(d)(2)(F) Review a minimum of 30 (except on initial surveys) random medical records and verify that the operative report is dated and authenticated and includes; name and center identification number of the patient; date of surgery, name of surgeon and assistant(s); pre-operative and post-operative diagnoses; name of the specific surgical procedure(s) performed; type of anesthesia administered; complication, if any; a description of techniques, findings, and the tissues removed or altered; and prosthetic devices or implants used, if any.</p>
Q0890	<p>(G) A requirement that a list of tissues excluded from microscopic examination, if applicable, be maintained in surgical services. <i>(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)</i></p>	<p>(d)(2)(G) If applicable, review the list of tissues, approved by the pathologist and medical staff, that is excluded from micro examination. Review several records to verify that tissues are being sent to the lab for micro examination as required. If frozen sections are performed on site, the center needs CLIA Certificate of Compliance or accreditation.</p>
Q0900	<p>410 IAC 15-2-5-5 Patient care services Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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:</p>	<p>(a) Tour the operative areas. Determine that the organizational chart displays the relationship of the patient care service to other services and that the chart indicates lines of authority and delegation of responsibility within the service.</p>
Q0904	<p>(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.</p>	<p>(a)(1) Review the QA&I program for patient care services. Verify from review of meeting minutes that regular review and evaluation of quality of the service is accomplished.</p>
Q0906	<p>(2) That personnel with appropriate training are available at all times to handle possible emergencies involving patients of the center.</p>	<p>(a)(2) Review the staffing schedules and a sampling of the patient care service personnel records to insure adequate qualified staff.</p>
Q0908	<p>(3) That a registered nurse serves as head nurse</p>	<p>(a)(3) Verify the license and training of the nurse that acts as head nurse supervising patient care</p>

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Q0910	<p>supervising patient care services personnel.</p> <p>(4) That all registered nurses and licensed practical nurses must be currently licensed in Indiana.</p>	<p>services nursing personnel.</p> <p>(a)(4) Review the center personnel records and/or other record system kept to determine that RN's, LPN's, and other nursing personnel for whom licensure is required have current valid licenses.</p>
Q0912	<p>(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:</p> <p>(A) Licensed practical nurses and surgical technologists may serve as scrub personnel under the supervision of a qualified registered nurse.</p> <p>(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.</p>	<p>(a)(5) Verify that a RN is assigned responsibility for supervision of the nursing personnel in the surgical and post anesthesia care unit and that he/she is experienced in the management of surgical services.</p> <p>(a)(5)(A) Determine that a RN is available for supervision in the surgical area. Verify the qualifications of surgical personnel (random sample).</p> <p>(a)(5)(B) If LPN's and surgical technologists (STs) are performing circulation duties, verify that they do so in accordance with approved medical staff policies and procedures. Verify in situations where LPN's and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies. Determine that verification of competency and special procedure in-servicing in, but not limited to, Lasers operation, Lithotripsy, etc. is maintained and available.</p>
Q0918	<p>(6) A registered nurse must be in attendance in the postanesthesia recovery room during its operational period when patients are present.</p>	<p>(a)(6) Review the staffing schedule and a sampling of records to insure the presence of a RN as required.</p>
Q0920	<p>(b) Written patient care policies and procedures shall be available to personnel and shall include, but not be limited to, the following:</p>	<p>(b) Review the policies and procedures and verify that the required areas are covered.</p>
Q0922	<p>(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.</p>	<p>(b)(1) Determine that each patient is positively identified and that the means of identification is reliable and in accordance with center policy.</p>
Q0924	<p>(2) A requirement that side rails be provided on recovery carts and kept in the upright position when occupied by sedated patients.</p>	<p>(b)(2) Verify that the policy exists and observe its enforcement if sedated patients are present during survey.</p>
Q0926	<p>(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.</p>	<p>(b)(3) Verify the policy on discharge instructions to determine if all requirements are covered. Note in the patient record that these instructions, in accordance with center policy, were given and to whom.</p>
Q0928	<p>(4) A provision that facilities, reusable equipment, and supplies shall be thoroughly cleaned and/or sterilized following use according to center policies and procedures.</p>	<p>(b)(4) Verify the policy and observe conditions of all patient care areas. Note cleaning schedules and documentation.</p>
Q0930	<p>(5) A provision that all nursing personnel meet annual inservice requirements as established by center and</p>	<p>(b)(5) Verify that the in-service requirements for nursing personnel have been fulfilled and are appropriately documented.</p>

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Q0932	<p>federal and state requirements.</p> <p>(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.</p> <p><i>(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)</i></p>
Q1000	<p>410 IAC 15-2.5-6 Pharmaceutical services Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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:</p>
Q1004	<p>(1) A designated professional person with prescriptive authority, or a pharmacist, who is responsible for the control of drug stocks in the center.</p>
Q1006	<p>(2) Records of stock supplies of all scheduled substances, including an accounting for all items purchased and dispensed.</p>
Q1008	<p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p>
Q1010	<p>(A) Drug handling, storing, labeling, and dispensing.</p>
Q1012	<p>(B) Drug administration according to established center policies and acceptable standards of practice.</p>
Q1014	<p>(C) Intravenous medications administration as it relates to sedation.</p>
Q1020	<p>(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.</p>
Q1024	<p>(E) Drugs must be accurately and clearly labeled and stored in specially-designated, well-illuminated cabinets, closets, or storerooms and the following:</p>
Q1026	<p>(i) Drug cabinets must be accessible only to</p>
	<p>(b)(6) Verify that the assignments were made by a RN and determine that the assignments take into consideration the complexity of patient's needs and the competence and specialized qualification of the nursing staff.</p> <p>(1) Verify that a professional person as required by this rule is designated as the person responsible for the control of drug stocks in the center. Verify that the person holds a current license.</p> <p>(2) Verify that a record system exists and that the accounting of scheduled substances meets current state requirements.</p> <p>(3) Verify that the policies cover the requirements.</p> <p>(3)(A) Verify that the policies cover the requirements.</p> <p>(3)(B) Verify that the policies cover the requirements.</p> <p>(3)(C) Verify that the policies cover the requirements.</p> <p>(3)(D) Verify that the policies cover the requirements. Review incident reports and patient records for documentation of reporting.</p> <p>(3)(E) Verify that the policies cover the requirements. Observe drug storage and labeling.</p> <p>(3)(E)(i) Verify that the policies cover the requirements. Observe security and control of access.</p>

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Q1028	<p>authorized personnel.</p> <p>(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.</p>	(3)(E)(ii) Verify that the policies cover the requirements. Observe security and control of access.
Q1030	(iii) Drug carts with controlled drugs as designated in item (ii) must be securely affixed when not in use.	(3)(E)(iii) Verify that the policies cover the requirements. Observe security and control of access. Note particularly the security system for carts when not in use.
Q1040	(F) Instructions to the patient on the use of take home medication is the responsibility of the prescribing practitioner.	(3)(F) Verify that the policies cover the requirements. Verify by documentation that the policies are carried out.
Q1042	(4) A formulary.	(4) Verify the medical staff has approved the formulary either by signature or appropriate documentation in medical staff meeting minutes. Interview the designated professional person to determine that the medical staff has established a formulary that lists drugs that actually are available.
Q1044	(5) A list of available emergency drugs. <i>(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)</i>	(5) Verify the list and availability of the drugs.
Q1100	<p>410 IAC 15-2.5-7 Physical plant, equipment maintenance, and environmental services Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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:</p> <p>(1) The plant operations and maintenance service, equipment maintenance, and environmental services must be as follows:</p> <p>(A) Staffed to meet the scope of the services provided.</p> <p>(B) Under the direction of a person or persons qualified by education, training, or experience according to center policy, approved by the governing body.</p>	(a) Verify through observation the center has adequate facilities for diagnostic and surgical services and that they are located for the safety of the patients. Determine that the extent and complexity of the facilities are adequate for the services offered, i.e., large enough and properly equipped for the scope of service and the number of patients served.
Q1112	(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	(a)(2) Determine that the center has been inspected by the Fire Marshal's office or local fire authority and note date of last inspection and documentation of compliance with appropriate codes.

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Q1114	<p>codes.</p> <p>(3) There must be emergency power and lighting in accordance with National Fire Protection Association (NFPA) 99.</p>	(a)(3) The center shall comply with applicable NFPA codes as required.
Q1116	<p>(4) In new construction, renovations, and additions, the center site and facilities, or non licensed facilities acquired for the purpose of providing center services shall meet the following:</p> <p>(A) The 2001 edition of the national "Guidelines for Design and Construction of Hospital and Health Care Facilities" (Guidelines).</p>	(a)(4) Note any construction activity or plans for renovation, construction, addition, etc. for verification of plan review by the division and information on future activity. (a)(4)(A) No survey requirements.
Q1118	<p>(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.</p>	(a)(4)(B) No survey requirements.
Q1120	<p>(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.</p>	(a)(4)(C) No survey requirements.
Q1122	<p>(D) Water supply and sewage disposal services shall be obtained from municipal or community services.</p>	(a)(4)(D) No survey requirements.
Q1124	<p>(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:</p> <p>(i) Functional program narrative as established in the Guidelines.</p> <p>(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.</p>	(a)(4)(E)(i & ii) No survey requirements.
Q1130	<p>(F) Prior to the start of construction, addition, and/or renovation projects, detailed architectural and operational plans for construction shall be</p>	(a)(4)(F) No survey requirements.

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	<p>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:</p> <ul style="list-style-type: none"> (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. 	
Q1138	<p>(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.</p>	(a)(4)(G) No survey requirements.
Q1140	<p>(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.</p>	(a)(4)(H) No survey requirements.
Q1142	<p>(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:</p> <ul style="list-style-type: none"> (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. 	<p>(b) Tour the center and other licensed areas.</p> <p>(b)(1) Determine compliance with this requirement. Determine that problem areas have been reported to the safety management function/committee and QA&I program, if appropriate. Verify that plans of action have been implemented and the outcomes documented.</p>
Q1146		<p>(b)(2) There shall be proper ventilation, light and temperature controls in pharmaceutical, food preparation & storage areas if applicable and other appropriate areas. Determine that all food and medication preparation areas are well lighted. Determine that an appropriate number of refrigerators and/or heating devices are provided to ensure that food and medicine do not spoil. Verify through observation that pharmaceuticals are stored at temperatures recommended by the manufacturer.</p>

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Q1148	<p>(3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:</p> <p>(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.</p> <p>(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.</p> <p>(C) Operational and maintenance control records must be established and analyzed at least triennially. These records must be readily available on the premises.</p> <p>(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.</p>	<p>(b)(3) Determine that there is a documented maintenance schedule of appropriate frequency, usually at least annually, and within the manufacturer's recommended maintenance schedule.</p> <p>(b)(3)(A) Determine that there are training schedules and documentation on personnel training. Check for the availability of manuals.</p>
Q1152	<p>(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.</p>	<p>(b)(3)(B) Determine that the equipment is on a maintenance schedule and verify that the maintenance is being done in accordance with policy/schedule. (Policies/schedules must meet acceptable standards of practice or the manufacturer's recommended maintenance schedule.)</p>
Q1154	<p>(C) Operational and maintenance control records must be established and analyzed at least triennially. These records must be readily available on the premises.</p>	<p>(b)(3)(C) Review the operational and maintenance control records. (They shall be available for review on the premises.)</p>
Q1156	<p>(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.</p>	<p>(b)(3)(D) Determine if there have been any code violations on maintenance and repairs. Review the report from the various jurisdictions. Verify that violations have been or are being corrected and that the corrections are ongoing.</p>
Q1158	<p>(4) The patient care equipment requirements are as follows:</p> <p>(A) There must be sufficient patient care equipment and space to assure the safe, effective, and timely provision of the available services to patients.</p>	<p>(b)(4) Review the preventative maintenance policies and procedures.</p> <p>(b)(4)(A) Tour the area where the equipment is located.</p>
Q1162	<p>(B) All patient care equipment must be in good working order and regularly serviced and maintained as follows:</p>	<p>(b)(4)(B) Determine the schedule for maintenance and service of various types of equipment and verify compliance with center policy and manufacturer's recommendations.</p>
Q1164	<p>(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.</p>	<p>(b)(4)(B)(i) Determine that the equipment is on a maintenance schedule and verify that the maintenance is being done in accordance with policy/schedule. (Policies/schedules must meet acceptable standards of practice or the manufacturer's recommended maintenance schedule.)</p>
Q1166	<p>(ii) There must be evidence of preventive maintenance on all patient care equipment.</p>	<p>(b)(4)(B)(ii) Observe the system used for "tagging" the equipment to determine if it is in accordance with the policy.</p>
Q1168	<p>(iii) Appropriate records must be kept pertaining to equipment maintenance,</p>	<p>(b)(4)(B)(iii) Determine from a record check that the center required maintenance activities are being done.</p>

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	<p>repairs, and electrical current leakage checks and analyzed at least triennially.</p>	
Q1170	<p>(iv) Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.</p>	<p>(b)(4)(B)(iv) Review the center policy on defibrillator discharging and verify compliance and documentation of discharge.</p>
Q1172	<p>(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:</p>	<p>(b)(5) Tour the center and observe cleanliness of walls, painted surfaces, ceilings, floors, equipment and the procedures being utilized for cleaning them.</p>
Q1174	<p>(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:</p> <ul style="list-style-type: none"> (i) Asepsis. (ii) Cross-contamination prevention. (iii) Safe practice. 	<p>(b)(5)(A) Verify that personnel engaged in housekeeping activities have received orientation and follow-up training in effective housekeeping procedures and in the principles of asepsis and infection control/safe practices.</p>
Q1178	<p>(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.</p>	<p>(b)(5)(B) Verify that there are policies on collection, transportation, sorting, storage and disposal of trash. Determine through observation that these policies are followed.</p>
Q1180	<p>(c) A safety management program must include, but not be limited to, the following:</p> <ul style="list-style-type: none"> (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. 	<p>(c) Review the safety management program and interview the person assigned responsibility for the safety program.</p> <p>(c)(1) Determine that the safety function is reviewed by a committee and that the committee meets regularly in accordance with program requirements. Review the minutes of the committee assigned the responsibility to review the safety program and establish participation of the committee members required.</p>
Q1182	<p>(3) The safety program includes, but is not limited to, the following:</p> <ul style="list-style-type: none"> (A) Patient safety. (B) Health care worker safety. (C) Public and visitor safety. 	<p>(c)(2) Determine that the safety program is an established, functioning, center wide program that evaluates safety issues and problems. Determine that review by the committee assigned the safety responsibilities is documented and timely, and that actions are taken to correct and improve center safety and provide a safe environment for patients, workers, and public.</p> <p>(c)(3) Review the safety program.</p>
Q1184	<p>(A) Patient safety.</p> <p>(B) Health care worker safety.</p> <p>(C) Public and visitor safety.</p>	<p>(c)(3)(A) Determine that the program addresses patient safety, that there are policies and procedures covering patient safety, and that problems are reported and corrected in accordance with center policy.</p> <p>(c)(3)(B) Determine that the program addresses health care worker safety, that there are policies and procedures covering health care worker safety and that problems are reported and corrected in accordance with center policy. Determine that there is a system to evaluate employee complaints of environment-related illnesses and product allergy.</p>

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Q1188	<p>(4) A written fire control plan that contains provisions for the following:</p> <ul style="list-style-type: none"> (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. 	<p>(c)(3)(C) Determine that the program addresses public and visitor safety, that there are policies and procedures covering public and visitor safety and that problems are reported and corrected in accordance with center policy.</p> <p>(c)(4) Review the center's written fire control plans to verify they contain the required provision of State Law.</p>
Q1196	<p>(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.</p>	<p>(c)(5) Examine copies of the inspection and approval reports from State and local fire control agencies. Determine if problems reported have been addressed and corrected.</p>
Q1198	<p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies. <i>(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)</i></p>	<p>(c)(6) Review the emergency and disaster plans and determine that the center is participating on a regular basis and that there is documentation of drills and practices in accordance with the center policy and program requirements.</p>
Q1204	<p>410 IAC 15-2.5-8 Radiology services Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>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.</p>	<p>(a) Determine if diagnostic radiology service and reports are required and if so that they meet the needs of the patients, as determined by the medical staff.</p>
Q1206	<p>(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.</p>	<p>(b) If the center does not provide the diagnostic radiology services directly, but under arrangement, review the contract for the scope of the service and verify that the service is being provided.</p>
Q1208	<p>(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:</p>	
Q1210	<p>(1) Radiology services must be supervised by a radiologist or radiation oncologist.</p>	<p>(c)(1) Verify that the appropriately trained and licensed physician supervises the service.</p>
Q1212	<p>(2) All radiation therapy treatments, including all</p>	<p>(c)(2) Verify by checking the physician personnel record, that a radiation oncologist is directly</p>

	aspects of radium treatments, must be under the direct supervision of a radiation oncologist.	supervising all radiation therapy and is present during treatment.
Q1214	(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.	
Q1216	(4) All diagnostic radiographic procedures must be conducted by an individual meeting the requirements of 410 IAC 5-11.	(c)(4) Verify current licenses of the radiological technicians/technologists.
Q1220	(d) Written policies and procedures must be developed, implemented, and maintained and made available to personnel.	(d) Review the policies and procedures. Verify that they cover the requirements and are readily available to the employees.
Q1222	(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.	(d) Review the policies for safeguards. (e)(1) Review the policies and procedures or other readily available sources, and verify that a radiation safety program is documented. (e)(2) Verify that policies cover hazards and maintenance requirements and that policies are followed.
Q1230	(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.	(f) Verify that the center has policies that radiological services are provided on the orders of practitioners with clinical privileges or on the orders of individuals or practitioners outside the center as authorized by the governing body.
Q1232	(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.	(g) Verify the current registration and documented inspection reports on all radiological equipment.
Q1234	(h) All radioactive materials must be registered and/or licensed under all applicable state and federal statutes and rules.	(h) Verify the policies concerning registration/licensure.
Q1236	(i) The use of fluoroscopes must be limited to physicians or others authorized to operate in accordance with 410 IAC 5.	(i) Examine center policies and review a sampling of service personnel folders to verify that radiological personnel meet the qualifications established by the medical staff and state regulations.
Q1240	(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.	(j) Verify that the records are retained as required. Current state law and federal regulation require that x-ray and mammogram images be maintained for 5 years. If the reports are kept in the medical record, the state requirement is 7 years. Duplicate reports are not required to be kept in the originating radiology department.

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	<p>(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. <i>(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)</i></p>	
	<p>Rule 2.6. Optional Ambulatory Surgical Center Services</p>	
	<p>410 IAC 15-2.6-1 Dietary services Authority: IC 16-21-1-7 Affected: IC 16-21-1</p>	
Q1300	<p>Sec. 1. (a) If nourishment and other dietary needs of the patients are provided in the center, the center shall comply with 410 IAC 7-24.</p>	(a) Determine from policy review the extent of the dietary service provided.
Q1310	<p>(b) If nourishments are to be prepared, a nourishment area with hand washing lavatory and refrigeration must be provided.</p>	(b) Tour the nourishment area and verify requirements.
Q1314	<p>(c) If prepackaged single service nourishments are provided, refrigeration storage must be provided in the clean area. <i>(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)</i></p>	(c) Verify required refrigeration and location.
	<p>410 IAC 15-2.6-2 Other services Authority: IC 16-21-1-7 Affected: IC 16-21-1</p>	
Q1400	<p>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.</p>	(a) Any service that the center provides that is not included under a specific section of these rules would fall under this section.
Q1410	<p>(b) The services shall be under the direction of a qualified person or persons.</p>	(b) Determine that the director is qualified as specified by center policy and medical staff rules. If the director is a physician, verify the medical staff appointment.
Q1420	<p>(c) The services shall be staffed in accordance with written center policies and comply with the applicable state and federal rules. <i>(Indiana State Department of Health; 410 IAC 15-2.6-2; filed Dec 1, 1999, 3:44 p.m.; 23 IR 795)</i></p>	(c) Determine that there is enough staff to provide the service. Verify that the staff is qualified in accordance with center policy.

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 non-accredited 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 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*)

