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**INDIANA  
STATE DEPARTMENT OF HEALTH**

**TITLE 410 INDIANA ADMINISTRATIVE CODE**

**ARTICLE 15. HOSPITAL LICENSURE RULES**

**Rule 1.1 thru 1.7 and Interpretive Guidelines**

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**10/20/2016**

**TITLE 410, INDIANA ADMINISTRATIVE RULES  
 ARTICLE 15.1 HOSPITAL LICENSURE RULES  
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ARTICLE 15.1 HOSPITAL LICENSURE RULES

Tag Number	Rule 1.1. Definitions	Guidance to Surveyors
	<p>410 IAC 15-1.1-1 Applicability                      Authority: IC 16-21-1-7; IC 16-21-1-8; IC 16-21-1-9                      Affected: IC 16-21-1</p> <p>Sec. 1. The definitions in this rule apply throughout this article. <i>(Indiana State Department of Health; 410 IAC 15-1.1-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	
	<p>410 IAC 15-1.1-2 “Ambulatory outpatient surgical center” defined                      Authority: IC 16-21-1-7                      Affected: IC 16-18-2-14; IC 16-21-1; IC 16-25-1</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 15-1.1-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</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"> <li>(1) Is established, equipped, and operated primarily for the purpose of performing surgical procedures and services;</li> <li>(2) Is operated under the supervision of at least one (1) physician duly licensed in the state of Indiana or the governing board of the hospital if the center is affiliated with a hospital;</li> <li>(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"> <li>(A) Is qualified by education and training to perform the surgical procedure.</li> <li>(B) Is legally authorized to perform the procedure.</li> <li>(C) 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 located.</li> <li>(D) Is admitted to the open staff of the ambulatory outpatient surgical center;</li> </ol> </li> <li>(4) Requires that in all cases other than those requiring only local infiltrate anesthetics, that a physician licensed under IC 25-22.5 who has had specialized training or experience in the administration of an anesthetic supervise the administration of the anesthetic and remain present in the facility during the surgical procedure.</li> <li>(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.</li> <li>(6) Is equipped to perform diagnostic x-ray and laboratory examinations required in connection with any surgery to be performed.</li> <li>(7) Does not provide accommodations for patient stays of longer than twenty-four (24) hours.</li> <li>(8) Provides full-time services of duly registered and licensed nurses for the professional care of the patients in the post-anesthesia recovery room.</li> <li>(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.</li> <li>(10) Maintains a written agreement with at least one (1) hospital for immediate acceptance of patients who develop complications or require postoperative confinement.</li> <li>(11) 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 connection with the center.</li> <li>(12) Maintains adequate medical records for each patient.</li> <li>(13) Meets all additional minimum requirements as established by the State Department for building and equipment</li> </ol>

		requirements. (14) Meets the rules and other requirements established by the State Department for the health, safety, and welfare of the patients.
	<p>410 IAC 15-1.1-2.5 "ASA Class I patient" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 2.5. "ASA Class I patient" means a normal, healthy patient. (<i>Indiana State Department of Health; 410 IAC 15-1.1-2.5</i>)</p>	
	<p>410 IAC 15-1.1-3 "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> <p>(1) a full signature, including first initial, last name, and discipline;</p> <p>(2) written initials if full signature appears on the same page;</p> <p>(3) a unique identifier such as a number or computer key; or</p> <p>(4) a signature stamp.</p> <p>(<i>Indiana State Department of Health; 410 IAC 15-1.1-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	<p>"Authenticate" means the author or responsible individual validates an entry in a record by:</p> <p>(a) A full signature including first initial, last name, and discipline; or</p> <p>(b) Written initials if full signature appears on the same page; or</p> <p>(c) A unique identifier, such as number or computer key; or</p> <p>(d) A signature stamp.</p>
	<p>410 IAC 15-1.1-3.3 "Biologics" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 3.3. "Biologics" means a biological product, such as:</p> <p>(1) a globulin;</p> <p>(2) a serum;</p> <p>(3) a vaccine;</p> <p>(4) an antitoxin;</p> <p>(5) blood; or</p> <p>(6) an antigen;</p> <p>used in the prevention or treatment of disease. (<i>Indiana State Department of Health; 410 IAC 15-1.1-3.3</i>)</p>	

	<p>410 IAC 15-1.1-3.7 "Burn" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 3.7. "Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:</p> <ol style="list-style-type: none"> <li>(1) Fire.</li> <li>(2) Heat.</li> <li>(3) Chemicals.</li> <li>(4) Electricity.</li> <li>(5) Radiation.</li> <li>(6) Gases.</li> </ol> <p><i>(Indiana State Department of Health; 410 IAC 15-1.1-3.7)</i></p>	
	<p>410 IAC 15-1.1-4 "Commissioner" defined  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 4. "Commissioner" means the state health commissioner or the state health commissioner's designee.  <i>(Indiana State Department of Health; 410 IAC 15-1.1-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>"Commissioner" refers to the State Health Commissioner or the designee of the State Health Commissioner.</p>
	<p>410 IAC 15-1.1-5 "Council" defined  Authority: IC 16-21-1-7  Affected: IC 16-18-2-84; IC 16-21-1</p> <p>Sec. 5. "Council" means the body defined in IC 16-18-2-84(1). <i>(Indiana State Department of Health; 410 IAC 15-1.1-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>"Council" refers to the hospital council.</p>
	<p>410 IAC 15-1.1-6 "Department" defined  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 6. "Department" means the Indiana state department of health. <i>(Indiana State Department of Health; 410 IAC 15-1.1-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>"Department" refers to the Indiana State Department of Health.</p>

<p>410 IAC 15-1.1-7 “Division” defined  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 7. “Division” means the division of acute care of the department. (<i>Indiana State Department of Health; 410 IAC 15-1.1-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1261; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	<p>“Division” refers to the Division of Acute Care of the Indiana State Department of Health.</p>
<p>410 IAC 15-1.1-8 “Donor” defined  Authority: IC 16-21-1-7  Affected: IC 16-21-1; IC 29-2-16-1-1</p> <p>Sec. 8. “Donor” means an individual as defined in IC 29-2-16-1-1. (<i>Indiana State Department of Health; 410 IAC 15-1.1-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	<p>“Donor” means an individual who makes a gift of all or part of his body.</p>
<p>410 IAC 15-1.1-8.5 "Elopement" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 8.5. "Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision making capacity, leaves the hospital without staff being aware that the patient has done so. (<i>Indiana State Department of Health; 410 IAC 15-1.1-8.5</i>)</p>	
<p>410 IAC 15-1.1-9 “Executive board” defined  Authority: IC 16-21-1-7  Affected: IC 16-18-2-14; IC 16-18-2-120; IC 16-21-1</p> <p>Sec. 9. “Executive board” means the board as defined in IC 16-18-2-120. (<i>Indiana State Department of Health; 410 IAC 15-1.1-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	<p>“Executive Board” refers to the executive board of the Indiana State Department of Health.</p>
<p>410 IAC 15-1.1-10 “Governing board” defined  Authority: IC 16-21-1-7  Affected: IC 16-18-2-149; IC 16-21-1</p> <p>Sec. 10. “Governing board” means the body defined in IC 16-18-2-149. (<i>Indiana State Department of Health; 410 IAC 15-1.1-10; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	<p>“Governing board” means the board of trustees, governing board, board of directors, or other body responsible for governing a hospital.</p> <p>Responsibilities include, but are not limited to:</p> <ol style="list-style-type: none"> <li>(1) the management, operation, functioning, and control of the hospital;</li> <li>(2) the appointment and reappointment of the members of the medical staff, and the assignment of privileges to members of the medical staff, with the advice and recommendations of the medical staff, consistent with their individual training, experience, and other qualifications; and</li> </ol>

		(3) establishing requirements for initial and subsequent appointments to and continued service on the hospital's medical staff, consistent with the appointee's individual training, experience, and other qualifications.
<p>410 IAC 15-1.1-11 "Health care provider" defined  Authority: IC 16-21-1-7  Affected: IC 16-18-2-163;IC16-21-1-1</p> <p>Sec. 11. "Health care provider" means a provider as defined in IC 16-18-2-163. [IC 27-12 was repealed by P.L.1-1998, SECTION 221, effective July 1, 1998.]. (Indiana State Department of Health; 410 IAC 15-1.1-11; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</p>	<p>"Health Care Provider" means:</p> <ol style="list-style-type: none"> <li>(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 physician, psychiatric hospital, hospital health facility, emergency ambulance service (IC 16-18-2-107), dentist, registered or licensed practical nurse, midwife, optometrist, podiatrist, chiropractor, physical therapist, respiratory care practitioner, occupational therapist, psychologist, paramedic, emergency medical technician, or advanced 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.</li> <li>(2) A college, university, or junior college that provides health care to a student, faculty member, or 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;</li> <li>(3) A blood bank, community mental health center, community mental retardation center, community health center, or migrant health center;</li> <li>(4) A home health agency (as defined in IC 16-27-1-2);</li> <li>(5) A prepaid health care delivery plan (as defined in IC 16-27-8-7-1);</li> <li>(6) A health care organization whose member, shareholders, or partners are health care providers under subdivision (1); and</li> <li>(7) A corporation partnership, or professional corporation not otherwise qualified under this subsection that; <ol style="list-style-type: none"> <li>(A) as one (1) of its functions, provides health care;</li> <li>(B) is organized or registered under state law; and</li> <li>(C) is determined to be eligible for coverage as a health care provider under this chapter for its health care function. 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.</li> </ol> </li> </ol>	
<p>410 IAC 15-1.1-12 "Health care worker" defined  Authority: IC 16-21-1-7  Affected: IC 16-21-1-6</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 hospital. (Indiana State Department of Health; 410 IAC 15-1.1-12; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</p>	<p>"Health care worker" is a person who provides services whether as individual health care providers, volunteers, students or employees of a hospital.</p>	
<p>410 IAC 15-1.1-13 "Hospital" defined  Authority: IC 16-21-1-7  Affected: IC 16-18-2-14; IC 16-18-2-179</p> <p>Sec. 13. "Hospital" means an organization as defined in IC 16-18-2-179. (Indiana State Department of Health; 410 IAC 15-1.1-13; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</p>	<p>"Hospital" (for purposes of IC 16-21) means an institution, a place, a building, or an agency that holds out to the general public accommodations, facilities, and equipment, in connection with the services of a physician, to individuals who may need medical or surgical services. The term does not include the following:</p> <ol style="list-style-type: none"> <li>(1) Freestanding health facilities.</li> <li>(2) Hospitals or institutions specifically intended to diagnose, care, and treat the following: <ol style="list-style-type: none"> <li>(A) Mentally ill individuals (as defined in IC 12-7-2-131).</li> <li>(B) Individuals with developmental disabilities (as defined in IC 12-7-2-61).</li> </ol> </li> <li>(3) Offices of physicians where patients are not regularly kept as bed patients.</li> <li>(4) Convalescent homes, boarding homes, or homes for the aged.</li> </ol>	



	<p>410 IAC 15-1.1-13.1 "Hyperbilirubinemia" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 13.1. "Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dl in a neonate. <i>(Indiana State Department of Health; 410 IAC 15-1.1-13.1)</i></p>	
	<p>410 IAC 15-1.1-13.2 "Hypoglycemia" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 13.2. "Hypoglycemia" means a physiologic state in which:</p> <ul style="list-style-type: none"> <li>(1) the blood sugar falls below sixty (60) mg/dl (forty (40) mg/dl in neonates); and</li> <li>(2) physiological or neurological, or both, dysfunction begins.</li> </ul> <p><i>(Indiana State Department of Health; 410 IAC 15-1.1-13.2)</i></p>	
	<p>410 IAC 15-1.1-13.3 "Immediately postoperative" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 13.3. "Immediately postoperative" means within twenty-four (24) hours after either of the following:</p> <ul style="list-style-type: none"> <li>(1) Administration of anesthesia (if surgery or other invasive procedure is not completed).</li> <li>(2) Completion of surgery or other invasive procedure.</li> </ul> <p><i>(Indiana State Department of Health; 410 IAC 15-1.1-13.3)</i></p>	
	<p>410 IAC 15-1.1-13.4 "Informed consent" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 13.4. "Informed consent" means a patient's authorization or agreement to undergo surgery or other invasive procedure that is based upon communication between a patient and his or her physician regarding the surgery or other invasive procedure. <i>(Indiana State Department of Health; 410 IAC 15-1.1-13.4)</i></p>	

<p>410 IAC 15-1.1-13.6 "Joint movement therapy" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 13.6. "Joint movement therapy" means all types of manual techniques, to include:  (1) mobilization (movement of the spine or a joint within its physiologic range of motion);  (2) manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of motion); or  (3) any other type of manual musculoskeletal therapy; regardless of their precise anatomic and physiologic focus or their discipline of origin. <i>(Indiana State Department of Health; 410 IAC 15-1.1-13.6)</i></p>	
<p>410 IAC 15-1.1-13.7 "Kernicterus" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 13.7. "Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage. <i>(Indiana State Department of Health; 410 IAC 15-1.1-13.7)</i></p>	
<p>410 IAC 15-1.1-14 "Licensed health professional" defined  Authority: IC 16-21-1-7  Affected: IC 16-21-1; IC 25-23-1-27.1</p> <p>Sec. 14. "Licensed health professional" means an individual as defined in IC 25-23-1-27.1. <i>(Indiana State Department of Health; 410 IAC 15-1.1-14; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>"Licensed Health Professional" means:</p> <ol style="list-style-type: none"> <li>(1) a registered nurse;</li> <li>(2) a licensed practical nurse;</li> <li>(3) a physician with an unlimited license to practice medicine or osteopathic medicine;</li> <li>(4) a licensed dentist;</li> <li>(5) a licensed chiropractor</li> <li>(6) a licensed pharmacist;</li> <li>(7) a licensed physical therapist;</li> <li>(8) a certified psychologist;</li> <li>(9) a licensed podiatrist; or</li> <li>(10) a licensed speech-language pathologist or audiologist.</li> </ol>
<p>410 IAC 15-1.1-14.2 "Low-risk pregnancy" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 14.2. "Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) years of age with no previous diagnosis of any of the following:  (1) Essential hypertension.</p>	

	<p>(2) Renal disease.  (3) Collagen-vascular disease.  (4) Liver disease.  (5) Preeclampsia.  (6) Cardiovascular disease.  (7) Placenta previa.  (8) Multiple gestation.  (9) Intrauterine growth retardation.  (10) Smoking.  (11) Pregnancy-induced hypertension.  (12) Premature rupture of membranes.  (13) Other previously documented condition that poses a high risk of pregnancy-related mortality.  <i>(Indiana State Department of Health; 410 IAC 15-1.1-14.2)</i></p>	
	<p><b>410 IAC 15-1.1-15 "Medical staff" defined</b>  Authority: IC 16-21-1-7  Affected: IC 16-18-2-149; IC 16-21-2-7</p> <p>Sec. 15. "Medical staff" means a group as defined in IC 16-21-2-7. <i>(Indiana State Department of Health; 410 IAC 15-1.1-15; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>The medical staff of a hospital is responsible to the governing board for the following:</p> <ol style="list-style-type: none"> <li>(1) The clinical and scientific work of the hospital.</li> <li>(2) Advice regarding professional matters and policies.</li> <li>(3) Review of the professional practices in the hospital for the purpose of reducing morbidity and mortality and for the improvement of the care of patients in the hospital including the following: <ol style="list-style-type: none"> <li>(A) The quality and necessity of care provided.</li> <li>(B) The preventability of complications and deaths occurring in the hospital.</li> </ol> </li> </ol>
	<p><b>410 IAC 15-1.1-15.5 "Neonates" defined</b>  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 15.5. "Neonates" means infants in the first twenty-eight (28) days of life. <i>(Indiana State Department of Health; 410 IAC 15-1.1-15.5)</i></p>	
	<p><b>410 IAC 15-1.1-16 "Pharmacist" defined</b>  Authority: IC 16-21-1-7  Affected: IC 16-21-1; IC 25-26-13</p> <p>Sec. 16. "Pharmacist" means an individual licensed under IC 25-26-13. <i>(Indiana State Department of Health; 410 IAC 15-1.1-16; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>"Pharmacist" means a person licensed under IC 25-26-13-2.</p>
	<p><b>410 IAC 15-1.1-17 "Physician" defined</b>  Authority: IC 16-21-1-7  Affected: IC 16-21-1; IC 25-22.5-5</p> <p>Sec. 17. "Physician" means an individual licensed under IC</p>	<p>"Physician" means any person who holds 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>

	<p>25-22.5-5. (<i>Indiana State Department of Health; 410 IAC 15-1.1-17; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	
	<p>410 IAC 15-1.1-18 "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 15-1.1-18; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	<p>"Practitioner" means an individual who holds:</p> <ol style="list-style-type: none"> <li>(1) An unlimited license, certificate, or registration.</li> <li>(2) A limited or probationary license, certification, or registration.</li> <li>(3) A temporary license, certificate, registration, or permit.</li> <li>(4) An Intern permit.</li> <li>(5) A provisional license.</li> </ol> <p>Issued by the board regulating the profession in question, including a certificate of registration issued under IC 25-20.</p>
	<p>410 IAC 15-1.1-19 "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 15-1.1-19; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	<p>"Registered Nurse" means:</p> <p>(A) Any person who applies to the board for a license to practice as a registered nurse must:</p> <ol style="list-style-type: none"> <li>(1) Not have: <ol style="list-style-type: none"> <li>(a) Been convicted of a crime that has a direct bearing on the person's ability to practice competently.</li> <li>(b) Committed an act that would constitute a ground for a disciplinary sanction under IC 25-1-9.</li> </ol> </li> <li>(2) Have completed: <ol style="list-style-type: none"> <li>(a) The prescribed curriculum and met the graduation requirements of a state accredited program of registered nursing that only accepts students who have a high school diploma or its equivalent as determined by the board.</li> <li>(b) The prescribed curriculum and graduation requirements of a nursing education program in a foreign country that is substantially equivalent to a board approved program as determined by the board. The board may, by rule adopted under IC 4-22-2, require an applicant under this subsection to successfully complete an examination approved by the board to measure the applicant qualifications and background in the practice of nursing and proficiency in the English language.</li> </ol> </li> <li>(3) Be physically and mentally capable of and professionally competent to safely engage in the practice of nursing as determined by the board. The board may not require a person to have baccalaureate degree in nursing as a prerequisite for licensure.</li> </ol>
	<p>410 IAC 15-1.1-20 "Serious disability" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 20. "Serious disability" means either of the following:</p> <ol style="list-style-type: none"> <li>(1) Significant loss of function including sensory, motor, physiologic, or intellectual impairment: <ol style="list-style-type: none"> <li>(A) not present on admission and requiring continued treatment; or</li> <li>(B) for which there is a high probability of long term or permanent lifestyle change at discharge.</li> </ol> </li> <li>(2) Unintended loss of a body part.</li> </ol> <p>(<i>Indiana State Department of Health; 410 IAC 15-1.1-20</i>)</p>	

<p>410 IAC 15-1.1-21 "Sexual assault" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1; IC 35-42-4; IC 35-46-1-3</p> <p>Sec. 21. "Sexual assault" means a crime included under IC 35-42-4 or IC 35-46-1-3. (<i>Indiana State Department of Health; 410 IAC 15-1.1-21</i>)</p>	
<p>410 IAC 15-1.1-22 "Surgery or other invasive procedure" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 22. For purposes of this rule, 410 IAC 15-1.4-2.2, and 410 IAC 15-2.4-2.2, "surgery or other invasive procedure" means surgical or other invasive procedures that involve a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure ends when the surgical incision has been closed or operative devices, such as probes, have been removed. The procedures include, but are not limited to, the following:</p> <ol style="list-style-type: none"> <li>(1) Open or percutaneous surgical procedures.</li> <li>(2) Percutaneous aspiration.</li> <li>(3) Selected injections.</li> <li>(4) Biopsy.</li> <li>(5) Percutaneous cardiac and vascular diagnostic or interventional procedures.</li> <li>(6) Laparoscopies.</li> <li>(7) Endoscopies.</li> <li>(8) Colonoscopies.</li> </ol> <p>The term excludes intravenous therapy, venipuncture for phlebotomy, diagnostic tests without intravenous contrast agents, nasogastric tubes, or indwelling urinary catheters. (<i>Indiana State Department of Health; 410 IAC 15-1.1-22</i>)</p>	

	<p>410 IAC 15-1.1-23 "Toxic substance" defined  Authority: IC 16-19-3-4; IC 16-21-1-7  Affected: IC 16-19-3; IC 16-21-1</p> <p>Sec. 23. "Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health. (<i>Indiana State Department of Health; 410 IAC 15-1.1-23</i>)</p>	
	<b>Rule 1.2. Compliance with Rules</b>	
A0102	<p>410 IAC 15-1.2-1 Compliance with rules  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 1. (a) All hospitals shall be licensed by the department and shall comply with all applicable federal, state, and local laws and rules.</p>	(a) Verify that the hospital has a current license.
A0104	<p>(b) Components required for licensure as a hospital are the following:</p> <ol style="list-style-type: none"> <li>(1) Governing board.</li> <li>(2) Quality assessment and improvement program.</li> <li>(3) Dietary service.</li> <li>(4) Infection control program.</li> <li>(5) Laboratory service.</li> <li>(6) Medical record service.</li> <li>(7) Medical staff.</li> <li>(8) Nursing service.</li> <li>(9) Pharmaceutical service.</li> <li>(10) Physical environment service.</li> <li>(11) Plant maintenance service.</li> <li>(12) Radiologic service.</li> </ol>	(b) Verify that the hospital has or provides under arrangement the services required for licensure. Verify that there are contracts or agreements for those required services the hospital provides under arrangement.
A0116	(c) Optional services, not required for licensure, shall comply with all rules for that service.	(c) List the optional services provided by the hospital or under arrangement.
A0118	<p>(d) The hospital shall have a plan to address the internal review and reporting of unusual occurrences and disasters. This plan shall cover, but not be limited to, the following:</p> <ol style="list-style-type: none"> <li>(1) Patient injuries or marked deterioration of patient condition occurring under unanticipated or unexpected circumstances.</li> <li>(2) Chemical poisoning occurring within the hospital resulting in a negative patient outcome.</li> <li>(3) Unexplained loss of or theft of a controlled substance.</li> </ol>	(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.

	(4) Missing patient whose whereabouts are unknown for over twenty-four (24) hours.	
A0130	<p>(e) The hospital shall report the following incidents to the division:</p> <p>(1) Verbal reports within twenty-four (24) hours of occurrence on:</p> <p>(A) murder, suicide, or kidnapping of patient occurring after admission;</p> <p>(B) reportable infection outbreaks or food poisonings as required by federal, state, and local law; and</p> <p>(C) a disruption, exceeding four (4) hours, in the continued safe operation of the hospital or in the provision of patient care, caused by internal or external disasters, strikes by health care workers, or unscheduled termination of vital services.</p>	(e) Review incidents that have occurred since the last survey. Verify that they have been reported in accordance with the plan and as required by the rules. If reports of incidents have been sent to ISDH or other state agencies, verify that copies have been furnished the Division.
A0138	<p>(2) Written reports on occurrences listed in subdivision (1), if requested, shall be submitted to the division within a reasonable period of time and document all information required by the department, including, but not limited to, the following:</p> <p>(A) An explanation of the circumstances surrounding the incident.</p> <p>(B) Summaries of all findings, conclusions, and recommendations associated with the review of the incident.</p> <p>(C) A summary of actions taken to resolve identified problems, to prevent recurrence of the incident, and to improve overall patient care.</p> <p>(3) This subsection does not replace other reporting requirements. Copies of these required reports will be acceptable in satisfying subdivision (2).</p>	
A0148	<p>(f) In the event of flood, fire, or other disaster, the governing board, or the governing board's designee, or the commissioner shall close all or that part of the hospital as may be necessary to ensure the safety and well-being of patients. The commissioner shall approve reopening. <i>(Indiana State Department of Health; 410 IAC 15-1.2-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	(f) If there have been any events as outlined in the rules verify that action has been taken.

	Rule 1.3. Licensure Requirements	
A0152	<p>410 IAC 15-1.3-1 Issuance of license  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 1. (a) The hospital shall file an application for licensure on a yearly basis with the division, prior to the expiration of the current license.</p>	(a) Verify through file review at the Division that the current application is on file.
A0164	(b) A license is not transferable or assignable and shall be issued only for the premises named in the application.	(b) Verify that the license covers the premises and locations named in the application. Verify that other locations/entities not listed are not considered included by the hospital.
A0166	<p>(c) If multiple buildings are licensed under a single license, the licensee shall operate these buildings as a single integrated system as follows:</p> <p>(1) All buildings or portions of buildings under a single license shall be governed by a single governing body and under administrative control of a single administrator.</p> <p>(2) All hospital facilities operating under a single license shall have a single medical staff.</p>	(c) When any of the buildings or locations are not under the hospital governing board and administrative control of the hospital, then a separate license is required if that entity is covered under another licensing law. View the separate license, if applicable, and document.
A0170	(d) Reapplication shall be filed when a change of fifty percent (50%) or greater ownership occurs.	(d) If there has been a change in ownership, verify that a reapplication has been filed with the Division.
A0172	(e) An application for license from a newly constructed hospital shall be obtained from the division and submitted after the physical plant plans have been approved under 410 IAC 15-1.5-8. Upon receipt of a design release from the state building commissioner, an application shall be submitted to the division on the form provided, along with the documents required by the application form.	(e) Determine that this information is on file in the Division prior to the pre-occupancy survey.
A0174	(f) Any full or partial replacement of the physical plant of a hospital, any addition or renovation to the physical plant of a hospital, or any acquisitions of additional buildings under the current license of an existing hospital, shall meet the provisions of 410 IAC 15-1.5-8. ( <i>Indiana State Department of Health; 410 IAC 15-1.3-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1263; filed Jun 3, 1996, 9:00 a.m.: 19 IR 2876; errata filed Jun 10, 1996, 2:00 p.m.: 19 IR 2884; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i> )	(f) All buildings under the license shall comply with 15-1.5-8 unless a waiver is granted by the department. Verify the waivers before citing variations.



A0178	<p>410 IAC 15-1.3-2 Posting of license  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 2. (a) The license shall be conspicuously posted on the hospital premises in an area open to patients and public. A copy shall be conspicuously posted in an area open to patients and public on the premises of each separate hospital building of a multiple hospital building system. <i>(Indiana State Department of Health; 410 IAC 15-1.3-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1263; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>(a) The hospital has leeway in what area to post the license. Verify that the area where posted is open to the patients and public. Verify the location of the current license in the main building and any locations in separate hospital buildings of a multiple system where in-patients are kept or patient care is administered.</p>
	<p>410 IAC 15-1.3-3 Suspension or revocation of license  Authority: IC 16-21-1-7  Affected: IC 4-21.5; IC 16-21-1</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"> <li>(1) Issue a letter of correction.</li> <li>(2) Issue a probationary license.</li> <li>(3) Conduct a resurvey.</li> <li>(4) Deny renewal of a license.</li> <li>(5) Revoke a license.</li> <li>(6) Impose a civil penalty in an amount not to exceed ten thousand dollars (\$10,000).</li> </ol> <p>(b) The commissioner may take action under subsection (a) on any of the following grounds:</p> <ol style="list-style-type: none"> <li>(1) Violation of any of the provisions of this article.</li> <li>(2) Permitting, aiding, or abetting the commission of any illegal act in an institution.</li> <li>(3) Conduct or practice found by the council to be detrimental to the welfare of the patients of an institution.</li> </ol> <p>(c) IC 4-21.5 applies to an action under this section.  (d) A licensee or an applicant for a license aggrieved by an action under this rule may request review under IC 4-21.5.  (e) The state department shall appoint an appeals panel consisting of three (3) members as follows:</p> <ol style="list-style-type: none"> <li>(1) One (1) member of the executive board.</li> </ol>	<p>No survey requirements.</p>

<p>(2) One (1) attorney admitted to the practice of law in Indiana.</p> <p>(3) One (1) individual with qualifications determined by the state department.</p> <p>(f) An employee of the department may not be a member of the panel.</p> <p>(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 15-1.3-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1264; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i>)</p>	
<p><b>410 IAC 15-1.3-4 Complaint investigation</b>  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 4. (a) The division shall investigate all complaints that come under the department's jurisdiction, regardless of the method of communication.</p> <p>(b) The complaints will be assigned a priority based on the seriousness of the complaint, according to division policy, and the priority will dictate the immediacy of the investigation.</p> <p>(c) The complaint investigations will be unannounced and may:</p> <ul style="list-style-type: none"> <li>(1) occur at the time of the annual licensure inspection; and</li> <li>(2) evolve into a full survey.</li> </ul> <p>(d) The results of the investigation will be given in writing to the hospital.</p> <p>(e) The hospital will have a reasonable period of time to respond in writing with an acceptable plan of correction for noncompliance with state rules noted as a result of the investigation before this information is made available to the public.</p> <p>(f) The results will be reviewed and upon recommendation of the division forwarded to the commissioner for action under section 3 of this rule.</p> <p>(g) The completed complaint and survey results will become part of the hospital's public file. (<i>Indiana State Department of Health; 410 IAC 15-1.3-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1264; errata filed Feb 23, 1995,</i></p>	<p>(a) No survey requirements.</p> <p>(b) No survey requirements.</p> <p>(c) No survey requirements. All complaint investigations are unannounced and are investigated either on site, or by mail, or by phone.</p> <p>(c)(1) If the complaint survey is being conducted during the licensing survey, inform the hospital that the complaint has been filed and that you are looking into it now. Document the outcome for the complaint report, and indicate any non-compliance on the annual survey and the complaint report.</p> <p>(c)(2) Conduct the investigation of the complaint and if any non-compliance is discovered, cite the hospital in accordance with the rules. If a sufficient number of non-compliances are discovered to warrant a full survey, notify the Division for concurrence, then notify the hospital.</p> <p>(d) No survey requirements.</p> <p>(e) No survey requirements. In general, the time lapse would be 13 days from the time that the deficiency report was deposited in the U.S. Mail by the ISDH.</p> <p>(f) No survey requirements.</p> <p>(g) No survey requirements.</p>

	2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)	
	<b>Rule 1.4. Governing Board Responsibilities</b>	
A0252	410 IAC 15-1.4-1 Governing board Authority: IC 16-21-1-7 Affected: IC 16-21-1  Sec. 1. (a) The governing board is legally responsible for the conduct of the hospital as an institution. The governing board shall do the following: (1) Function as the supreme authority of the hospital.	(a) Verify that the hospital has an organized governing board or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.  (a)(1) Review the bylaws to determine the authority of the Governing Board. Determine if all functions are under the board or what particular functions, if any, are reserved for other entities, i.e., corporate boards, systems boards, University boards of trustees etc. Review the relationship between the boards to verify that the actions taken are in accordance with the bylaws. If any functions board are advisory only, review documentation (need not be minutes, could be other appropriate documentation) to verify that action is taken on the advisory function by the corporate/system/other board. Review governing board minutes to insure the action taken by the corporate/system/other board (i.e., approval, disapproval, etc.) is documented in the minutes of the governing board.
A0256	(2) Ensure that the hospital: (A) meets all rules and regulations for licensure and certification, if applicable; and (B) makes available to the commissioner upon request all reports, records, minutes, documentation, information, and files required for licensure.	(a)(2) (A) Conduct the survey to ascertain compliance.  (b) Reports, records, minutes, documentation, information and files must be supplied to the commissioner (or the commissioner's representative, the surveyor) as requested.  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 hospital 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.
A0264	(3) Adopt bylaws and function accordingly.	(a) (3) Review the bylaws and determine if the governing board functions in accordance with the bylaws. Determine if the committees required by the bylaws are established and functioning. Review the minutes of the governing board meetings (since the last survey) to determine if the information required by the bylaws to be reported to the governing board is being reported.
A0266	(4) Review the bylaws at least triennially.	(a)(4) Determine and document the date of adoption of the bylaws and the last date of review. (These dates may not necessarily be on the document itself but could be reflected in the minutes of the governing board meetings.)
A0268	(5) Maintain a liaison with the medical staff.	(a)(5) Review records to verify entries covering medical staff and governing board communication and actions on pertinent issues.
A0270	(6) Review, at least quarterly, reports of management operations, medical staff actions, and quality monitoring, including patient services provided, results attained, recommendations made, actions taken, and follow-up.	(a)(6) Review minutes of governing board meetings (since the last survey) to verify reports on required areas and quarterly review.  Quality monitoring reports are to be submitted quarterly in accordance with the QA plan.
A0272	(7) Ensure that there is a hospital-wide, quality assessment and improvement program to evaluate the provision of patient care.	(a)(7) Verify that the governing board has approved the quality assessment & improvement (QA&I) program by reviewing the entries in the minutes, or other appropriate method.
A0276	(b) The governing board is responsible for the conduct of the medical staff. The governing board shall do the following:	(b) Verify that the bylaws establish the responsibility of the governing board for the conduct of the medical staff.

A0277	(1) Determine, with the advice and recommendation of the medical staff, and in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.	(b)(1) It is the responsibility of the governing board 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.
A0278	(2) Ensure that: (A) the requests of practitioners, for appointment or reappointment to practice in the hospital, are acted upon, with the advice and recommendation of the medical staff; (B) reappointments are acted upon at least biennially; (C) practitioners are granted privileges consistent with their individual training, experience, and other qualifications; and (D) this process occurs within a reasonable period of time, as specified by the medical staff bylaws.	(b)(2) Review the governing board minutes and confirm that the governing board appoints all members to the medical staff in accordance with established policies and based on the practitioners scope of clinical expertise.
A0284	(3) Ensure that the medical staff has approved bylaws and rules and that the bylaws and rules are reviewed and approved at least triennially. Governing board approval of medical staff bylaws and rules shall not be unreasonably withheld.	(b)(3) Verify that the medical staff operates under current bylaws, rules and regulations that have been approved by the governing board. Verify that any revisions or modifications in medical staff bylaws, rules and regulations have been approved by the medical staff and governing board and documented in the minutes.
A0286	(4) Ensure that the medical staff is accountable and responsible to the governing board for the quality of care provided to patients.	(b)(4) Verify that the governing board is periodically apprised concerning medical staff evaluation of patient care services provided by the institution.
A0288	(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 board 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 other criteria such as training, character, competence and judgement. (A hospital is not prohibited from requiring board certification when considering a practitioner for medical staff membership. Rather, the intent is that a hospital may not rely <u>solely</u> on the fact that a practitioner is or is not board certified in making a judgement (on medical staff membership.)
A0290	(6) Ensure that the granting of medical staff membership or professional privileges in the hospital is not solely dependent upon certification, fellowship, or membership in a specialty body or society.	
A0294	(c) The governing board is responsible for managing the hospital. The governing board shall do the following:	(c) Verify that the bylaws establish the responsibility of the governing board for managing the hospital.
A0295	(1) Develop criteria, which include, but are not limited to, defining educational and experience requirements for the chief executive officer. These criteria would apply to all chief executive officers appointed after the effective date of this article.	(c)(1) Verify that the governing board has established criteria defining the experience, education, etc., requirements for CEO and that the CEOs appointed meet the criteria requirements.
A0296	(2) Appoint a qualified chief executive officer who is delegated the authority and responsibility for managing the hospital and report to the division the name of the chief executive officer within ten (10) days after the	(c)(2) Verify that the hospital has a chief executive officer appointed by the governing board.

	appointment.	
A0298	(3) Delineate in writing the responsibility and authority of the chief executive officer.	(c)(3)&(4) Verify the documentation of the CEO's responsibility and authority.
A0300	(4) Require that the chief executive officer or designee attends meetings of the governing board and its committees and act as its representative at medical staff meetings.	
A0302	(5) Require that the chief executive officer has designated in writing an administrative officer to serve during his or her absence.	(c)(5) Verify the designation of administrative authority in the absence of the CEO.
A0306	(6) Require that the chief executive officer develops policies and programs for the following: (A) Ensuring the employment of personnel, in accordance with state and federal rules, whose qualifications are commensurate with anticipated job responsibilities.	(c)(6) Verify that the current policies and programs/procedures cover the requirements listed as required by rule or hospital policy whichever is more restrictive.
A0308	(B) Orientation of all new employees, including contract and agency personnel, to applicable hospital, department, service, and personnel policies.	
A0310	(C) Ensuring that all health care workers, including contract and agency personnel, for whom a license, registration, or certification is required, maintain current license, registration, or certification and keep documentation of same so that it can be made available within a reasonable period of time.	
A0312	(D) Annual performance evaluations, based on a job description, for each employee providing direct patient care or support services, including contract and agency personnel, who are not subject to a clinical privileging process.	
A0314	(E) Establishing criteria for each service manager, department director, or supervisor that includes, but is not limited to, the following: (i) Definition of educational requirements. (ii) Experience requirements. (iii) Professional certification, licensing, or registration, where appropriate.	

A0318	(F) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and hospital policy for all health care workers, including contract and agency personnel, who provide direct patient care.	(F) Verify that policies and procedures provided cover the requirements listed as required by rule or hospital policy, whichever is more restrictive.
A0320	(G) Providing employee health services and a post offer physical examination in consultation with the infection control committee.	
A0322	(H) Requiring all services to have written policies and procedures that are updated as needed and reviewed at least triennially.	(H) Review policies and procedures in each service for update and verify that they are reviewed/revised in accordance with hospital policy or triennially, whichever is less. In accordance with hospital 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/signature and date of review/revision.
A0326	(I) Establishing a policy and procedure for communicating with physicians concerning an inpatient emergency in accordance with 410 IAC 15-1.5-5(b)(3)(L).	(I) Verify that a policy and procedure exists that outlines who contacts the appropriate practitioner on in-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.
A0328	(J) Maintaining a current roster of members of the medical staff and their service categories.	(J) This roster may be hard copy, listing, computer listing, or other methods easily accessible when required.
A0330	(K) Maintaining personnel records for each employee of the hospital which include personal data, education and experience, evidence of participation in job related educational activities, and records of employees which relate to post offer and subsequent physical examinations, immunizations, and tuberculin test or chest x-ray, as applicable.	
A0332	(L) Demonstrating and documenting personnel competency in fulfilling assigned responsibilities and verifying inservicing in special procedures.	
A0334	(M) Coordinating with local, regional, and state health planning groups and other hospital services providers so that effective disaster preparedness, emergency service communication, and transportation systems are established and maintained.	
A0336	(N) Annual implementation of internal and external disaster preparedness plans with documentation of outcome.	
A0338	(O) Development, implementation, and monitoring of a safety management program under the direction of a safety officer, qualified by experience or education.	

A0340	(P) Safe, appropriate, and adequate transport of patients.	
A0344	(d) The governing board is responsible for assuring that quality patient care is provided. In accordance with hospital policy, the governing board shall do the following: (1) Ensure all patients are admitted to the hospital only by a licensed practitioner who has been granted admitting privileges in accordance with the credentialing process of the hospital.	(d) Verify that the bylaws establish the responsibility of the governing board for assuring the provision of quality patient care.  (d)(1) Verify that admitting privileges are limited to those categories of practitioners specified under state law.
A0346	(2) Ensure a qualified licensed physician member of the medical staff is responsible for the care and treatment of each patient with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that does not specifically fall within the scope of practice or the medical staff privileges of the admitting practitioner.	(d)(2) 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 hospital policy.  Verify that patients are under the care of a licensed practitioner member of the medical staff in accordance with that practitioner's privileges.
A0348	(3) Provide the following for any patients requiring emergency care: (A) In hospitals with at least one hundred (100) acute care staffed beds, a licensed physician on the premises at all times who has the responsibility to respond to patients requiring emergency care as defined in 410 IAC 15-1.5-5(b)(3)(L)(i). (B) In hospitals of less than one hundred (100) acute care staffed beds: (i) a licensed physician on the premises as in clause (A); or (ii) a licensed physician who has the responsibility to respond to patients requiring emergency care as defined in 410 IAC 15-1.5-5(b)(3)(L)(i) and who is on call at all times and immediately available by phone and then available on the premises within thirty (30) minutes, if necessary, and in accordance with hospital and medical staff policies.	(d)(3) Verify the governing board has established and monitors the enforcement of policies that ensure a physician is on duty or on call at all times to provide medical care and on-site supervision when necessary.  (A) Verify that the governing board has established policies that ensure a physician is on duty on the premises at all times and that the responsibility to respond to patients requiring emergency care is spelled out and clearly stated.  (B) Verify that the governing board has established a policy that indicates the requirements for the on-call physician to respond to an emergency as defined by medical staff policy.
A0356	(4) Ensure either of the following: (A) If the hospital does provide community emergency services to the public, it shall provide that service in compliance with 410 IAC 15-1.6-2. (B) If the hospital does not provide community emergency services to the public, it shall do the following:	(d)(4)(A) If emergency service is provided, refer to guidelines in Emergency Services.  (B) Determine that the medical staff has policies and procedures to cover appraisal, treatment, and referral. Determine that the policies cover transfer of patient and records.

	<p>(i) Have written medical staff policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.</p> <p>(ii) Provide immediate lifesaving measures within the scope of services available to all persons who appear for emergency care which includes, but is not limited to, the following:</p> <p>(AA) Timely assessment.</p> <p>(BB) Stabilization.</p> <p>(CC) Treatment prior to transfer.</p> <p>(iii) Arrange for transfer of the patient, with copies of records of treatments provided, to another hospital which does provide appropriate clinical services.</p>	
A0358	<p>(5) Ensure policies are established to cover physician limited practice problems that may include, but are not necessarily limited to, the following:</p> <p>(A) Impaired physicians.</p> <p>(B) Criminal checks.</p> <p>(C) Disciplinary action.</p>	(d)(5) Verify that the governing board has adopted a policy on appraisal of physician limited practice problems.
A0362	<p>(6) Ensure that the hospital does the following:</p> <p>(A) Establish written protocols to identify potential organ and tissue donors.</p> <p>(B) Has written policies and procedures for the facilitation of organ and tissue donations, including procurement.</p> <p>(C) Inform families or authorized persons of potential organ and tissue donors of the option of donation on admission or at the time of death of a potential donor.</p> <p>(D) Use discretion and sensitivity in contacts with potential organ donor families.</p> <p>(E) Notify the appropriate procurement organization of potential organ donors.</p> <p>(F) Establish membership in the organ procurement and transplantation network if the hospital performs transplants.</p>	<p>(d)(6)(A,B,C)</p> <p>Verify that the hospital has policies that include:</p> <ol style="list-style-type: none"> <li>1. written criteria to identify potential organ donors;</li> <li>2. protocols regarding which categories of the hospital staff may notify family members of their options;</li> <li>3. a requirement for immediate acceptance of a family's decision to decline the option to donate organs.</li> </ol> <p>(D) Review the protocol to determine if it: covers those staff persons designated by the hospital to notify the family of its options; encourages discretion and sensitivity when notifying the family of its options; stresses acceptance and respect of each individual's circumstances, views and beliefs.</p> <p>(E, F) Verify that the appropriate Organ Procurement Organization is notified as soon as possible of a potential organ donor and that the hospital is a member of the Organ Procurement and Transplantation Network if transplants are performed there.</p>



A0376	<p>(e) The governing board is responsible for the overall institutional plan as follows:</p> <p>(1) The institutional plan shall:</p> <p>(A) be reviewed and updated annually; and</p> <p>(B) be prepared, under the direction of the governing board, by a committee with representatives from:</p> <p>(i) the governing board;</p> <p>(ii) the administration, which includes, but is not limited to:</p> <p>(AA) nursing;</p> <p>(BB) finance; and</p> <p>(CC) medical staff of the hospital.</p>	<p>(e) Verify that the hospital has a plan and budget and that it is reviewed and updated annually. Verify that the committee is established with membership as required and receives direction from the governing board.</p>
A0388	<p>(2) The plan shall include, but not be limited to, the programs and services provided and an annual operating budget prepared according to generally accepted accounting principles.</p>	
A0390	<p>(f) The governing board is responsible for services delivered in the hospital whether or not they are delivered under contracts. The governing board shall ensure the following:</p> <p>(1) That a contractor of any service furnishes those services in such a manner as to permit the hospital to comply with all applicable statutes and rules.</p>	<p>(f) Verify that the bylaws establish the responsibility of the governing board for assuring that hospital services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by hospital employees or indirectly by arrangement.</p> <p>(f)(1) Verify that the contracted services are provided in accordance with current statutes, rules, and regulations. When touring these services observe for compliance.</p>
A0392	<p>(2) That the services performed under a contract are provided in a safe and effective manner and are included in the hospital's quality assessment and improvement program.</p>	<p>(f)(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 hospital-wide quality assurance and improvement program evaluation as other services provided directly by the hospital.</p>
A0394	<p>(3) That the hospital maintains a list of all contracted services, including the scope and nature of the services provided.</p> <p><i>(Indiana State Department of Health; 410 IAC 15-1.4-1; filed Dec 21, 1994, 9:40 a.m.; 18 IR 1264; readopted filed Jul 11, 2001, 2:23 p.m.; 24 IR 4234)</i></p>	<p>(f)(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.</p>
A0406	<p>410 IAC 15-1.4-2 Quality assessment and improvement</p> <p>Authority: IC 16-21-1-7</p> <p>Affected: IC 16-21-1</p> <p>Sec. 2. (a) The hospital shall have an effective, organized, hospital-wide, comprehensive quality assessment and improvement program in which all areas of the hospital participate. The program shall be ongoing and have a</p>	<p>(a) Verify that the hospital has developed a QA&amp;I program to meet its needs. The methods used by each hospital for self-assessment (QA&amp;I) are flexible and a wide variety of techniques are used by hospitals 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 hospital is based on criteria and/or measures generated by the medical and professional/technical staffs and reflects hospital practice patterns, staff performance, and patient outcomes. Review the QA&amp;I plan and verify that it has been reviewed and approved according to hospital policy. Verify that the plan is continuous.</p>

	written plan of implementation that evaluates, but is not limited to, the following: (1) All services, including services furnished by a contractor.	(a)(1) Verify that the QA&I plan covers all the services listed as required and those services the hospital 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 hospital, determine that mechanisms are in place to assure appropriate communication across departments and services.
A0408	(2) All functions, including, but not limited to, the following: (A) Discharge planning. (B) Infection control. (C) Medication therapy. (D) Response to emergencies as defined in 410 IAC 15-1.5-5(b)(3)(L)(i).	(a)(2) Verify that the QA&I plan covers all the services listed as required and those services the hospital 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 hospital, determine that mechanisms are in place to assure appropriate communication across departments and services.
A0416	(3) All medical and surgical services performed in the hospital with regard to appropriateness of diagnosis and treatments related to a standard of care and anticipated or expected outcomes.	(a)(3) Verify that the review of medical and 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.
A0418	(b) The hospital shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows: (1) The action shall be documented. (2) The outcome of the action shall be documented as to its effectiveness, continued follow-up, and impact on patient care. <i>(Indiana State Department of Health; 410 IAC 15-1.4-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i>	(b) Review the documentation of action taken by the hospital 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 patient care outcome is stated and that the outcome was effective and is reported in accordance with the hospital plan.  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 hospital 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.)
A0420	410 IAC 15-1.4-2.2 Reportable events Authority: IC 16-19-3-4; IC 16-21-1-7 Affected: IC 16-19-3; IC 16-21-1; IC 25  Sec. 2.2. (a) The hospital's quality assessment and improvement program under section 2 of this rule shall include the following: (1) A process for determining the occurrence of the following reportable events within the hospital: (A) The following surgical events: (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: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining	

	<p>informed consent;</p> <p>or both.</p> <p>(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.</p> <p>(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. Excluded are emergent situations:</p> <p>(AA) that occur in the course of surgery; or</p> <p>(BB) whose exigency precludes obtaining informed consent;</p> <p>or both.</p> <p>(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:</p> <p>(AA) Objects intentionally implanted as part of a planned intervention.</p> <p>(BB) Objects present before surgery that were intentionally retained.</p> <p>(CC) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.</p> <p>(v) Intraoperative or immediately postoperative 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.</p> <p>(B) The following product or device events:</p> <p>(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the hospital. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p> <p>(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</p>	
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	<p>to, the following:</p> <ul style="list-style-type: none"> <li>(AA) Catheters.</li> <li>(BB) Drains and other specialized tubes.</li> <li>(CC) Infusion pumps.</li> <li>(DD) Ventilators.</li> </ul> <p>(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p> <p>(C) The following patient protection events:</p> <ul style="list-style-type: none"> <li>(i) Infant discharged to the wrong person.</li> <li>(ii) Patient death or serious disability associated with patient elopement.</li> <li>(iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the hospital, defined as events that result from patient actions after admission to the hospital.</li> </ul> <p>Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the hospital.</p> <p>(D) The following care management events:</p> <ul style="list-style-type: none"> <li>(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong: <ul style="list-style-type: none"> <li>(AA) drug;</li> <li>(BB) dose;</li> <li>(CC) patient;</li> <li>(DD) time;</li> <li>(EE) rate;</li> <li>(FF) preparation; or</li> <li>(GG) route of administration.</li> </ul> </li> </ul> <p>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.</p> <ul style="list-style-type: none"> <li>(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</li> </ul>	
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	<p>(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the hospital. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:</p> <ul style="list-style-type: none"> <li>(AA) Pulmonary or amniotic fluid embolism.</li> <li>(BB) Acute fatty liver of pregnancy.</li> <li>(CC) Cardiomyopathy.</li> </ul> <p>(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the hospital.</p> <p>(v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</p> <p>(vi) Stage 3 or Stage 4 pressure ulcers acquired after admission to the hospital. 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.</p> <p>(vii) Patient death or serious disability resulting from joint movement therapy performed in the hospital.</p> <p>(viii) Artificial insemination with the wrong donor sperm or wrong egg.</p> <p>(E) The following environmental events:</p> <ul style="list-style-type: none"> <li>(i) Patient death or serious disability associated with an electric shock while being cared for in the hospital.</li> </ul> <p>Excludes events involving planned treatment, such as electrical countershock or elective cardioversion.</p> <ul style="list-style-type: none"> <li>(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient: <ul style="list-style-type: none"> <li>(AA) contains the wrong gas; or</li> <li>(BB) is contaminated by toxic substances.</li> </ul> </li> <li>(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the hospital.</li> <li>(iv) Patient death or serious disability associated with a fall while being cared for in the hospital.</li> <li>(v) Patient death or serious disability associated</li> </ul>	
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	<p>with the use of restraints or bedrails while being cared for in the hospital.</p> <p>(F) The following criminal events:</p> <ul style="list-style-type: none"> <li>(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</li> <li>(ii) Abduction of a patient of any age.</li> <li>(iii) Sexual assault on a patient within or on the grounds of the hospital.</li> <li>(iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the hospital.</li> </ul>	
A0422	<p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the hospital's quality assessment and improvement program to have occurred within the hospital.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) improvement program shall be designed by the hospital to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the hospital in a timely manner.</p> <p>(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:</p> <p>(1) The report shall:</p> <ul style="list-style-type: none"> <li>(A) be made to the department;</li> <li>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the hospital's quality assessment and improvement program;</li> <li>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and</li> <li>(D) identify the reportable event, the quarter of occurrence, and the hospital, but shall not include any identifying information for any: <ul style="list-style-type: none"> <li>(i) patient;</li> <li>(ii) individual licensed under IC 25; or</li> </ul> </li> </ul>	

	<p>(iii) hospital employee involved; or any other information.</p> <p>(2) A potential reportable event may be identified by a hospital that:</p> <p>(A) receives a patient as a transfer or</p> <p>(B) admits a patient subsequent to discharge from another health care facility subject to a reportable event requirement. In the event that a hospital identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying hospital 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.</p> <p>(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.</p> <p>(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.</p>	
	<p>(d) The hospital'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 such reportable events occurring within each hospital. The department's public report will be issued annually.</p> <p>(e) Any reportable event listed in subsection (a)(1), that:</p> <p>(1) is determined to have occurred within the hospital between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> <p>(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 15-1.4-2.2</i>)</p>	

	Rule 1.5. Required Hospital Services	
A0504	<p>410 IAC 15-1.5-1 Dietetic services            Authority: IC 16-21-1-7            Affected: IC 16-21-1</p> <p>Sec. 1. (a) The hospital shall have organized food and dietary services that are directed and staffed by adequate, qualified personnel, or a contract with an outside food management company that meets the minimum standards specified in this section.</p>	(a) Determine if the service is provided by the hospital or under contract. The same standards apply if the service is provided by the hospital or contracted through an agreement.
A0508	<p>(b) The food and dietetic service shall have the following:</p> <p>(1) A full-time employee who:</p> <p>(A) serves as director of the food and dietetic services; and</p> <p>(B) is responsible for the daily management of the dietary services.</p>	<p>(b) Review the personnel records for the director and dietitian. Include in the review a sampling of other dietary service personnel records.</p> <p>(b)(1) Verify that the director is a full-time employee and has the authority and responsibility for assuring that established policies and procedures are maintained.</p> <p>Verify that the director is qualified by experience or training as established by hospital policy.</p>
A0512	<p>(2) A qualified dietitian, full-time, part-time, or on a consulting basis. If a consultant is used, he or she shall:</p> <p>(A) submit periodic written reports on the dietary services provided; and</p> <p>(B) provide the number of on-site dietitian hours commensurate with:</p> <p>(i) the type of dietary supervision required;</p> <p>(ii) the bed capacity; and</p> <p>(iii) the complexity of the patient care services.</p>	<p>(b)(2) Verify that a qualified dietitian supervises the nutritional aspects of patient care. Qualifications include:</p> <ul style="list-style-type: none"> <li>▪ Registered by the Commission on Dietetic Registration of the American Dietetic Association (ADA).</li> <li>▪ A baccalaureate degree with major studies in food, nutrition, diet therapy, and has completed a dietetic internship approved by the ADA, or</li> <li>▪ Has equivalent training and experience, and is eligible for registration by the Commission of Dietetic Registration, ADA.</li> <li>▪ Verify that the dietitian, when appropriate, makes an assessment of the nutritional status and adequacy of the nutritional regimen, provides for diet instruction, approves menus, is responsible for –patient and family counseling, -documenting nutritional status and adequacy in patient’s medical records, and –liason with other services.</li> </ul> <p>(A) Review the reports as appropriate.</p> <p>(B) Review documentation of hours and the contract for service.</p>
A0520	<p>(3) Administrative and technical personnel competent in their respective duties.</p>	(b)(3) Verify by observation in the kitchen and by checking work schedules that there are adequate levels of staffing and that the personnel assigned are provided with training and are using proper techniques.



A0522	<p>(c) The dietary service shall do the following:</p> <p>(1) Provide for liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.</p> <p>(2) Correlate and integrate dietary care functions with those of other patient care personnel which include, but are not limited to, the following:</p> <p>(A) Patient nutritional assessment and intervention.</p> <p>(B) Recording pertinent information on the patient's chart.</p> <p>(C) Conferring with and sharing specialized knowledge with other members of the patient care team.</p>	<p>(c) Determine the dietary service is represented when appropriate in patient care team activities and participates in patient nutritional assessment and policy development affecting the nutritional aspects of patient care. Verify documentation of pertinent nutritional information by dietary service personnel in the patient record.</p>
A0536	<p>(d) Menus shall meet the needs of the patients as follows:</p> <p>(1) Therapeutic diets shall be prescribed by the practitioner responsible for the care of the patient, <b><u>or by a qualified dietitian as authorized by the medical staff.</u></b></p> <p>(2) Nutritional needs shall be met in accordance with recognized dietary standards of practice and in accordance with the orders of the responsible practitioner.</p> <p>(3) A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing, and food service personnel.</p> <p><i>(Indiana State Department of Health; 410 IAC 15-1.5-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234) ; <b><u>filed Aug 30, 2016, 12:46 p.m.: 20160928-IR-410150386FRA</u></b></i></p>	<p>(d) Review the menus.</p> <p>(d)(1) Determine that therapeutic diets are prescribed by the practitioner responsible for the care of that patient, <b><u>or by a qualified dietitian as authorized by the medical staff.</u></b></p> <p>(d)(2) For nutritional needs, refer to the current Recommended Allowances of the Food and Nutrition Board, National Research Council. (RDA's are revised every 5 years.) Verify that menus provide sufficient variety of foods served in adequate amounts at each meal to satisfy recommended dietary allowance, a different menu is followed each day of the week, and nourishment is provided to ensure adequate nutritional intake, when needed.</p> <p>(d)(3) Verify that the diet manual has been approved by the medical staff, is appropriate for the diets routinely ordered, that the diets are in keeping with the standards for Recommended Dietary Allowances (diets not in compliance are so specified), and that the manual is revised as needed, usually every 5 years.</p>
A0554	<p>410 IAC 15-1.5-2 Infection control</p> <p>Authority: IC 16-21-1-7</p> <p>Affected: IC 16-21-1</p> <p>Sec. 2. (a) The hospital shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors.</p>	<p>(a) Tour the hospital, observing 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 hospital.</p>
A0556	<p>(b) There shall be an active, effective, and written hospital-wide infection control program. Included in this program shall be a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers.</p>	<p>(b) Determine that the hospital policies or other appropriate documents demonstrate that the hospital 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 QA&amp;I in accordance with the hospital plan. Review hospital and department/service policies to determine that the program is both hospital-wide and department/service-specific. Review policies to assure the hospital has addressed immunization and TB screening of Health Care workers in accordance with current standards of practice.</p>

A0558	(c) The infection control program shall have a method for identifying and evaluating trends or clusters of nosocomial infections or communicable diseases.	(c) Verify that there is a method established to identify clusters of nosocomial infections or communicable diseases and that the evaluation is reported or acted upon in accordance with hospital policy.
A0560	(d) A person qualified by training or experience shall be designated as responsible for the ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases.	(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 hospital policies and procedures. Verify that the program is integrated by the CEO, Medical staff, and Nurse Executive into the hospital's QA&I and inservice training programs.
A0566	(e) The chief executive officer, medical staff, and executive nurse shall do the following: (1) Be responsible for the implementation of successful corrective action plans in affected problem areas. (2) Provide for appropriate infection control input into plans for renovation and new construction to ensure awareness of federal, state, and local rules that affect infection control practices as well as plan for appropriate protection of patients and employees during construction or renovation.	(e)(1) Verify that corrective action has been implemented in problem areas and that documentation concerning corrective actions and outcomes is maintained.  (e)(2) Verify that there is documentation of involvement by infection control in plans for construction and renovation and protection of patients/staff during construction and renovation if construction or renovation has/is/ or will be taking place.
A0570	(f) The hospital shall establish an infection control committee to monitor and guide the infection control program in the facility as follows: (1) The infection control committee shall be a hospital or medical staff committee that meets at least quarterly, with membership that includes, but is not limited to, the following: (A) The person directly responsible for management of the infection surveillance, prevention, and control program.	(f) 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.  (f)(1) Verify the composition of the committee and the meeting schedule by reviewing the minutes.  (A) Verify that the IC officer/practitioner(s) is a member of the committee.
	(B) A representative from the medical staff. (C) A representative from nursing service. (D) A representative from administration. (E) Consultants from other appropriate services within the hospital, as needed.	(B)(C)(D) Verify that there are provisions for representation from Medical Staff, Nursing & Administration. Determine that they participate.  (E) Verify that there are provisions for participation of other department/service representatives when necessary.
A0582	(2) The chairman should be a person with interest or experience in infection control.	(f)(2) Verify that the chairman participates by attending meetings, signing documents, and reviewing incident/occurrence reports in accordance with program policy.
A0584	(3) The infection control committee responsibilities shall include, but not be limited to, the following: (A) Establishing techniques and systems for identifying, reviewing, and reporting infections in the hospital.	(f)(3)(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 feed-back and intervention.

A0588	(B) Recommending corrective action plans on identified problems, reviewing outcomes, and assuring resolution.	(B) Review the minutes for committee input and action.
A0590	(C) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.	(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.
A0592	(D) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following: (i) Sanitation.	(D)(i) Observe the hospital environment for general cleanliness as opposed to litter: crevices as opposed to spills.
A0594	(ii) Universal precautions, including infectious waste management.	(D)(ii) Review the program for compliance with current CDC guidelines and 410 IAC 1-4 (new rules for universal precautions).
A0596	(iii) Cleaning, disinfection, and sterilization.	(D)(iii) Review the program for compliance with hospital policy. Determine that periodic biological monitoring is used to check sterilization processes. Verify that the results of bacteriological tests are evaluated and any necessary corrective action taken.
A0598	(iv) Aseptic technique, invasive procedures, and equipment usage.	(D)(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.
A0600	(v) Reuse of disposables.	(D)(v) Verify that the hospital policy address the use and re-use of disposables in accordance with the product manufacturer's recommendations on allowing re-use.
A0602	(vi) An isolation system.	(D)(vi) Verify that there is a hospital 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 hospital staff in accordance with hospital policy on isolation.
A0604	(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.	(D)(vii) Verify written protocol to determine appropriate employee post exposure management to minimize the risk of secondary spread of infection.
A0606	(viii) An employee health program to determine the communicable disease history of new personnel as required by state and federal agencies.	(D)(viii) Review the documentation of history of or immunity to Rubella, Rubeola, and Chicken Pox.
A0608	(ix) Requirements for personal hygiene and attire appropriate for work settings.	(D)(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.
A0610	(x) A program of food preparation and storage for all personnel involved in food handling which includes, but is not limited to, the following: (AA) Storage of employee food in patient refrigerators. (BB) Medications in nutrition refrigerators. (CC) Refrigerator and freezer temperature	(D)(x) Verify that the hospital follows rules in ISDH Retail Food Establishment Sanitation Requirements, 410 IAC 7-24 or current addition.

	monitoring.	
A0612	(xi) A program of linen management for personnel involved in linen handling. <i>(Indiana State Department of Health; 410 IAC 15-1.5-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1267; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i>	(D)(xi) Review the procedures and linen handling program to verify compliance with hospital 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 hospital policy.
A0656	410 IAC 15-1.5-3 Laboratory services Authority: IC 16-21-1-7 Affected: IC 16-21-1 Sec. 3. (a) The hospital shall have, or make available, those pathology and medical laboratory services and consultation to meet the needs of patients served as determined by the medical staff which include the following:	(a) Determine which services are provided directly by the hospital and which are provided through a contractual agreement.
A0657	(1) Emergency laboratory services shall be available twenty-four (24) hours a day as determined by the medical staff.	(a)(1) Review the policy on stat lab service and determine by reviewing records that those services are provided when required.
A0658	(2) The laboratory performs tests and examines specimens on the written request of individuals and practitioners allowed to order such evaluations and receive the results of the evaluations to the extent permitted by law and authorized by the governing body.	(a)(2) Review the policy on who can order tests and examinations and review a sampling of orders to determine that the hospital policy is being observed.
A0660	(3) A written description of available laboratory services, reference values, critical values, and expected turnaround time shall be available to the medical and nursing staff.	(a)(3) 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.
A0662	(4) Frozen section shall be provided where surgical procedures are performed which require immediate pathological examination.	(a)(4) Determine if there is a requirement for and a policy on frozen section service. Verify that this service is provided as required.
A0664	(b) The hospital shall assure that all laboratory services provided to its inpatients and outpatients are performed in a facility possessing a valid certificate, in accordance with 42 CFR 493 (excluding Subparts F, R, Q, and T) authorizing the performance of testing in the specialty or subspecialty of service for level of complexity in which the test is categorized.	(b) Verify current CLIA certificate and expiration date. Verify that deficiencies cited on the last CLIA survey have been addressed and that proficiency testing records reflect satisfactory results.
A0668	(c) The medical staff and a pathologist shall determine which tissue specimens require a macroscopic examination only and which require both macroscopic and microscopic examinations. Categories of specimens removed during surgical procedures which are determined to require only macroscopic examination shall be specified in the	(c) Verify that the requirements concerning which tissue specimens removed during surgical procedures require macroscopic and/or microscopic examinations is covered in the medical staff rules and regulations and that the requirements are being carried out.

	laboratory policies and the medical staff rules. The medical staff and a pathologist shall determine the qualified licensed health professional responsible for macroscopic examination.	
A0670	(d) Laboratory supervisory and testing personnel qualifications shall be consistent with the work assignments and in compliance with 42 CFR 493.	(d) Review the personnel records of the director and a sample of laboratory personnel records to assure they are in compliance with 42 CFR Part 493 for complexity of testing performed.
A0672	(e) All nursing and other hospital personnel performing out-of-laboratory testing shall have annually updated performance certification maintained in the employee file for the procedures being performed.	(e) 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.
A0674	(f) If sufficient or suitable outside facilities are not provided by undertakers or others, the hospital shall have a morgue or a low temperature body holding room. Policies covering appropriate refrigeration requirements and length of holding bodies shall be approved by the medical staff. If autopsies are performed in the hospital, there shall be a refrigerated storage unit designed for holding bodies, along with hand washing facilities and other necessary personal hygiene facilities available.	(f) Verify that policies, approved by the medical staff, cover body holding, autopsies, and body pick-up and transfer. If the hospital policy allows autopsies, tour the autopsy area and verify that there is a refrigerated storage unit and that personal hygiene facilities are available nearby.
A0676	(g) The hospital shall maintain a minimum supply of blood and blood products or have an agreement with licensed blood sources which are in compliance with state law to obtain blood and blood products as quickly as needed.	(g) Verify that the hospital has an agreement with a licensed blood source or that it is currently licensed by the state as a blood center. Verify that there is a hospital procedure for reporting transfusion reactions.
A0678	(h) If donor blood is drawn in the hospital, the blood center shall be: (1) in compliance with state law; (2) appropriately licensed or registered by the Food and Drug Administration (FDA); and (3) in compliance with 21 CFR 640 and 21 CFR 606. <i>(Indiana State Department of Health; 410 IAC 15-1.5-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1268; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i>	(h) If donor blood, including autologous units, are drawn routinely in the facility, verify that the hospital is licensed as a Blood Center in accordance with 410 IAC 25 and is licensed or registered by the FDA.
A0704	410 IAC 15-1.5-4 Medical record services Authority: IC 16-21-1-7 Affected: IC 16-18-2-149  Sec. 4. (a) The medical record service has administrative responsibility for the medical records that shall be maintained for every individual evaluated or treated within those services that come under the hospital's license.	(a) Verify that the medical records service is structured appropriately to meet the needs of the hospital and the patients.
A0708	(b) The organization of the medical record service shall be	(b) Verify that there is an established system which addresses at least the following activities of the medical records

	<p>appropriate to the scope and complexity of the services provided as follows:</p> <p>(1) The service shall be directed by a registered health information administrator (RHIA) or a registered health information technician (RHIT). If a full-time or part-time RHIA or RHIT is not employed, then a consultant RHIA or RHIT shall be provided to assist the person in charge. Documentation of the findings and recommendations of the consultant shall be maintained.</p> <p>(2) The medical record service shall be provided with the necessary direction, staffing, and facilities to perform all required functions in order to ensure prompt completion, filing, and retrieval of records.</p>	<p>services:</p> <ul style="list-style-type: none"> <li>▪ Timely processing, coding/indexing, and retrieval of records;</li> <li>▪ Protecting the confidentiality of medical information; and</li> <li>▪ Compiling and retrieval of data for quality assurance activities.</li> </ul> <p>(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 consultant. Determine if the recommendations and outcomes are recorded.</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>
A0712	<p>(c) An adequate medical record shall be maintained with documentation of service rendered for each individual who is evaluated or treated as follows:</p> <p>(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> <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 the information can be retrieved promptly and in accordance with hospital policy.</p>
A0714	<p>(2) A unit record system of filing should be utilized. When this is not possible, a system shall be established by the hospital to retrieve when necessary all divergently located record components.</p>	<p>(c)(2) If the hospital 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 hospital does not utilize the unit record system, verify that there is a system to retrieve all patient informational elements in a timely manner from different locations.</p>
A0718	<p>(3) The hospital shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry shall be authenticated promptly in accordance with the hospital and medical staff policies.</p>	<p>(c)(3) Verify that the hospital 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 hospital and medical staff policies (“In accordance with the hospital and medical staff policies” addresses method and not timeframes. Time frame for authentication is promptly, which in most cases will be when the entry is made. In cases of dictated entries, if not electronically signed at time of dictation, then as soon as report is available.)</p> <ul style="list-style-type: none"> <li>▪ Verify that the policy includes authenticated signatures, written initials, codes, mechanical signatures and signature stamps. If used, verify that computer code signatures, mechanical signatures and signature stamps are authorized by the governing board, that the codes and stamps are maintained under adequate safeguards, that the policies cover review by the author of the transcribed reports prior to authentication, and that policies and procedures provide for appropriate sanctions for unauthorized or improper use of computer codes mechanical signatures, or signature stamps and that there is a signed statement that 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 that there is no delegation of the use of such code or stamp to another individual.</li> <li>▪ Verify that there is a system established for author identification, i.e., signature sheets, lists, signature in personnel files, signature cards, etc.</li> </ul>
A0720	<p>(4) Medical records shall be retained in their original or legally reproduced form as required by federal and state law.</p>	<p>(c)(4) Verify that medical records are retained in their original or legally reproduced form in hard copy, microfilm, or computer memory banks. Current state law requires health records be kept a minimum of 7 years.</p>
A0722	<p>(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if</p>	<p>(c)(5) Determine if hospital policy allows facsimile orders, reports, and documents and if so that plain paper is required.</p>

	allowed by the hospital policies.	
A0724	(6) The hospital shall have a system of coding and indexing medical records which allows for timely retrieval of records by diagnosis and procedure in order to support continuous quality assessment and improvement activities.	(c)(6) Verify that the hospital uses a coding and indexing system that permits timely retrieval of patient records by diagnosis and procedure.
A0726	(7) The hospital shall ensure the confidentiality of patient records which includes, but is not limited to, the following: (A) A procedure for releasing information from or copies of records only to authorized individuals in accordance with federal and state laws. (B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.	(c)(7) Verify that only authorized persons are permitted access to records maintained by the service. Verify that the hospital 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. <ul style="list-style-type: none"><li>▪ Verify that medical records are released only for patient care evaluation, utilization review, treatment, quality assurance and improvement programs, in-house educational purposes, or as dictated by hospital policy.</li><li>▪ Other than the above, verify that copies of medical records are released outside the hospital 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.</li></ul>
A0732	(d) The medical record shall contain sufficient information to: (1) identify the patient; (2) support the diagnosis; (3) justify the treatment; and (4) document accurately the course of treatment and results.	(d) Review a sample of active and closed patient records for completeness and accuracy in accordance with hospital policy. The sample should be at least 10% of the census, but not fewer than 30 records.
A0744	(e) All entries in the medical record shall be:  (1) legible and complete;	(e) Review a sampling of medical record entries. If there are isolated instances of non-compliance bring them to the attention of the hospital. 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.  (e)(1) Determine if there is a procedure for verifying entries with questionable legibility/readability.
A0746	(2) made only by individuals given this right as specified in hospital and medical staff policies; and	(e)(2) Review the policies to verify that they specify which individuals/categories of staff/professionals are allowed to make medical record entries.
A0748	(3) authenticated and dated promptly, in accordance with subsection (c)(3).	(e)(3) Verify that all entries in the medical record have been authenticated by the individual who is responsible for ordering, providing, or evaluating the services furnished or by a responsible individual as designated in the hospital and medical staff policies. Authentication may include written signatures, written initials, signature stamps, codes, mechanical or computer entry in accordance with Federal guidelines, hospital and medical staff policy.
A0750	(f) All inpatient records, except those in subsection (g), shall document and contain, but not be limited to, the following: (1) Identification data.	(f) Review a sampling of the current and closed in-patient records from the various units. Verify that the required items are included where appropriate.
A0751	(2) The medical history and physical examination of the patient done within the time frames as prescribed by the medical staff rules and section 5(b)(3)(M) of this rule.	
A0752	(3) A statement of the diagnosis or impressions drawn from the admission history and physical examination.	

A0753	(4) Diagnostic and therapeutic orders.	
A0754	(5) Evidence of appropriate informed consent for procedures and treatments for which it is required as specified by the informed consent policy developed by the medical staff and governing board, and consistent with federal and state law.	
A0755	(6) Clinical observations, including results of therapy, documented in a timely manner.	
A0756	(7) Progress notes.	
A0757	(8) Operative note in accordance with 410 IAC 15-1.6-9(c)(7).	
A0758	(9) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.	
A0759	(10) Nursing notes, nursing plan of care, and entries by other health care providers that contain pertinent, meaningful observations and information.	
A0760	(11) Reports of pathology and clinical laboratory examinations, radiology and nuclear medicine examinations or treatment, anesthesia records, and any other diagnostic or therapeutic procedures and their results.	
A0761	(12) Documentation of complications and unfavorable reactions to drugs and anesthesia.	
A0762	(13) A discharge summary authenticated by the physician. A final progress note may be substituted for the discharge summary in the case of a normal newborn infant and uncomplicated obstetric delivery. The final progress note should include any instruction given to the patient and family.	
A0763	(14) Final diagnosis	
A0765	(g) A short stay record form used for inpatients hospitalized for less than forty-eight (48) hours, observation patients, ambulatory care patients, and ambulatory surgery patients shall document and contain, but not be limited to, the following: (1) Identification data.	(g) Review a sampling of the current and closed short stay, ambulatory care, ambulatory surgery, and observation records. Verify that the required items are included where appropriate.
A0766	(2) Medical history and description of the patient's condition and pertinent physical findings.	
A0767	(3) Diagnostic and therapeutic orders.	
A0768	(4) Care based on identified standard of care and standard of practice.	



A0769	(5) Data necessary to support the diagnosis and the treatment given, with reports of procedures and tests, and their results, clinical observations, including the results of therapy, and anesthesia given, if applicable.	
A0770	(6) Operative note in accordance with 410 IAC 15-1.6-9(c)(7), if applicable.	
A0771	(7) Final progress note, including instructions to the patient and family with dismissal diagnosis and disposition of patient.	
A0772	(8) Authentication by the physician and other responsible personnel in attendance.	
A0774	(h) Outpatient records shall document and contain, but not be limited to, the following: (1) Identification data.	(h) Review a sampling of the current and closed out-patient records. Verify that the required items are included where appropriate.
A0775	(2) Diagnostic and therapeutic orders.	
A0776	(3) Description of treatment given, procedures performed, and documentation of patient response to intervention, if applicable.	
A0777	(4) Results of diagnostic tests and examinations done, if applicable.	
A0780	(i) Emergency service records shall document and contain, but not be limited to, the following: (1) Identification data.	(i) Review a sampling of the current and closed emergency service records. Verify that the required items are included where appropriate.
A0781	(2) Time of arrival, means of arrival, time treatment is initiated, and time examined by the physician, if applicable.	(i)(2) If the patient arrived by ambulance, verify the presence of a copy of the EMS "Report of Ambulance Run", in accordance with hospital policy.
A0782	(3) Pertinent history of illness or injury, description of the illness or injury, and examination, including vital signs.	
A0783	(4) Diagnostic and therapeutic orders.	
A0784	(5) Description of treatment given or prescribed, clinical observations, including the results of treatment, and the reports of procedures and test results, if applicable.	
A0785	(6) Authentication by the practitioner or licensed health professional who rendered treatment or prescribed for the patient in accordance with hospital policy.	
A0786	(7) Instruction given to patient on release, prescribed follow-up care, signature of patient or responsible other, and name of person giving instructions.	
A0787	(8) Diagnostic impression and condition on discharge documented by the practitioner, and disposition of the	

	patient and time of dismissal.	
A0788	<p>(9) Copy of transfer form, if patient is referred to the inpatient service of another hospital. If care is not furnished to a patient or if the patient is referred elsewhere, the reasons for such action shall be recorded.</p> <p><i>(Indiana State Department of Health; 410 IAC 15-1.5-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1269; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	
A0804	<p>410 IAC 15-1.5-5 Medical staff  Authority: IC 16-21-1-7  Affected: IC 16-21-1; IC 25-22.5</p> <p>Sec. 5. (a) The hospital shall have an organized medical staff that operates under bylaws approved by the governing board and is responsible to the governing board for the quality of medical care provided to patients. The medical staff shall be composed of two (2) or more physicians and other practitioners as appointed by the governing board and do the following:</p> <p>(1) Conduct outcome oriented performance evaluations of its members at least biennially.</p>	<p>(a) Review the bylaws of the medical staff to insure it is established in accordance with the governing board bylaws.</p> <p>(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&amp;I program. Verify the member's adherence to medical staff bylaws and rules and regulations.</p>
A0808	<p>(2) Examine credentials of candidates for appointment and reappointment to the medical staff by using sources in accordance with hospital policy and applicable state and federal law.</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"> <li>▪ a request for clinical privileges;</li> <li>▪ current licensure;</li> <li>▪ training and professional education;</li> <li>▪ documented experience; and</li> <li>▪ supporting references of competence.</li> </ul>
A0810	<p>(3) Make recommendations to the governing board 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 board for new members and re-appointments that are specific to type of appointment and extent of clinical privileges, and that the governing board takes final appropriate action.</p>

A0812	<p>(4) Maintain a 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 copy of their current Indiana license showing date of licensure and current number or an available certified list provided by the health professions bureau. A copy of practice restrictions, if any, shall be attached to the license issued by the health professions bureau through the medical licensing board.</p> <p>(D) A copy of their current Indiana controlled substance registration showing number, as applicable.</p> <p>(E) A copy of their current Drug Enforcement Agency registration showing number, as applicable.</p> <p>(F) Documentation of experience in the practice of medicine.</p> <p>(G) Documentation of specialty board certification, as applicable.</p> <p>(H) Category of medical staff appointment and delineation of privileges approved.</p> <p>(I) A signed statement to abide by the rules of the hospital.</p> <p>(J) Documentation of current health status as established by hospital and medical staff policy and procedure and federal and state requirements.</p> <p>(K) Other items specified by the hospital and medical staff.</p>	<p>(a)(4) Verify that a separate file is maintained for each member of the medical staff and applicant. Review the file of the chairperson of each department/service and at least one other member of that service. Include in the review a sample of the files of special categories of staff members, i.e., Dentists, Podiatrists, Optometrists, Allied Health Professionals, CRNA's, etc.</p> <p>(A &amp; B) Review the application for required information.</p> <p>(B) 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>(D &amp; E) View the copies or acceptable list.</p> <p>(F &amp; G) Review the application for required information.</p> <p>(H) Verify that the request for appointment and privileges is addressed in the appointment and that documentation explains the differences, if any.</p> <p>(I) This statement may be found on the medical staff application.</p> <p>(J) Verify that Infection Control policy or medical staff rule address practitioner health status.</p> <p>(K) Review the record for required information.</p> <p><b>Interpretive Guidelines Recommendations for Tag A0812, 410 IAC 15-1.5-5(a)(4)(C)(D)(E)</b>  Due to the use of electronic verification and use of contracted organizations to verify practitioners' current Indiana License, Indiana Control Substance Registration &amp; Drug Enforcement Agency Registration, the information provided to facilities may not look like the original documents from the primary source websites. Verify that the contract indicates the document verifying organization will use primary source verification.  If the facility does its own electronic verification of practitioners' current Indiana License, Indiana Control Substance Registration &amp; Drug Enforcement Agency Registration, verify the facility is using primary source verification.</p>
A0838	<p>(b) The medical staff shall adopt and enforce bylaws and rules to carry out its responsibilities. These bylaws and rules shall:</p> <p>(1) be approved by the governing board;</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 board approval by citing a signed, dated copy of the bylaws, rules and regulations, or documentation in the minutes of a governing board meeting that the bylaws, rules and regulations were presented and approved. Verify adherence to rules and regulation (see (I) above).</p>

A0840	(2) be reviewed at least triennially; and	(b)(2) Verify review at least every three years by dated, signed copy or documentation of review and approval in medical staff and governing board meeting minutes.
A0842	<p>(3) include, but not be limited to, the following:</p> <p>(A) A description of the medical staff organizational structure. If the organization calls for an executive committee, a majority of the members shall be physicians on the active medical staff.</p> <p>(B) Meeting requirements of the staff.</p> <p>(C) A provision for maintaining records of all meetings of the medical staff and its committees.</p> <p>(D) A procedure for designating an individual physician with current privileges as chief, president, or chairperson of the staff.</p> <p>(E) A statement of duties and privileges for each category of the medical staff.</p> <p>(F) A description of the medical staff applicant qualifications.</p> <p>(G) Criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.</p> <p>(H) A process for review of applications for staff membership, delineation of privileges in accordance with the competence of each practitioner, and recommendations on appointments to the governing board.</p> <p>(I) A process for appeals of decisions regarding medical staff membership and privileges.</p> <p>(J) A process for medical staff performance evaluations based on clinical performances indicated in part by the results of quality assessment and improvement activities.</p> <p>(K) A process for reporting practitioners who fail to comply with state professional licensing law requirements as found in IC 25-22.5, and for documenting appropriate enforcement actions against practitioners who fail to comply with the hospital and medical staff bylaws and rules.</p>	<p>(b)(3)(A) Verify that the bylaws describe the organizational structure of the medical staff, delineate accountability to the governing board, 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 diagnostic, medical, surgical and rehabilitative services.</p> <p>(B, C) Verify the schedule of meetings and that the meetings are held at least as required. Review a sample of the minutes. (Since the last survey)</p> <p>(D) Verify the existence of a procedure for appointment or election for president, etc.</p> <p>(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>(F) Verify that the bylaws describe the qualification such as licensure, specific training, experience, current competence and health status to be met by a candidate for appointment to the medical staff.</p> <p>(G) Verify that 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> <p>(H, I, J, K) Verify that the bylaws cover these requirements.</p>

A0866	<p>(L) A provision for physician coverage of emergency care that addresses at least:</p> <ul style="list-style-type: none"> <li>(i) a definition of emergency care to include, but not be limited to: <ul style="list-style-type: none"> <li>(AA) inpatient emergencies; and</li> <li>(BB) emergency services emergencies; and</li> </ul> </li> <li>(ii) a timely response.</li> </ul>	<p>(L) Verify that the medical staff has adopted a definition of emergency care. Verify that the medical staff has addressed emergencies for both in-patient and out-patient situations at least and that there is a plan for coverage.</p> <p>Verify that 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.</p>
A0868	<p>(M) A requirement that a complete physical examination and medical history be performed:</p> <ul style="list-style-type: none"> <li>(i) on each patient admitted by a practitioner who has been granted such privileges by the medical staff;</li> <li>(ii) within seven (7) days prior to date of admission and documented in the record with a durable, legible copy of the report and changes noted in the record on admission; or</li> <li>(iii) within forty-eight (48) hours after an admission.</li> </ul>	<p>(M) Verify that the bylaws require an H &amp; 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 physician may delegate all or part of the H &amp; P to other practitioners, as allowed by medical staff policy, but verify that the physician signs for and assumes full responsibility for these activities.) <u>If the H &amp; P is done prior to the 7 day requirement (i.e., 30 days in JCAHO/AOA hospitals)</u> look for an updating entry or progress note made on admission or within 48 hours after admission that covers the vital signs, documents the systems stability or change, and other pertinent information.</p>
A0870	<p>(N) A requirement that all physician orders shall be:</p> <ul style="list-style-type: none"> <li>(i) in writing or acceptable computerized form; and</li> <li>(ii) shall be authenticated by the responsible individual in accordance with hospital and medical staff policies.</li> </ul>	<p>(N) Verify that there is a policy on written and verbal orders. Verify that the policy covers what categories of professionals may receive verbal orders and the procedures for entering and authenticating those orders.</p>
A871	<p>(O) A requirement that all verbal orders must be authenticated by the responsible individual in accordance with hospital and medical staff policies. The individual receiving a verbal order shall date, time, and sign the verbal order in accordance with hospital policy. Authentication of a verbal order must occur within forty-eight (48) hours unless a read back and verify process described under items (i) and (ii) is utilized. If a patient is discharged within forty-eight (48) hours of the time that the verbal order was given, authentication shall occur within thirty (30) days after the patient's discharge.</p>	
A0872	<p>(P) A requirement that the final diagnosis be documented along with completion of the medical record within thirty (30) days following discharge.</p>	<p>(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 hospital, i.e., coroner's report, autopsy report, or CDC report.</p>

A0874	<p>(c) The medical staff should attempt to secure autopsies in all cases of unusual deaths and educational interest. There shall be the following:</p> <p>(1) A mechanism for documenting in writing the following:</p> <p>(A) That permission to perform an autopsy was obtained.</p> <p>(B) The source of the permission.</p>	<p>(c) Verify that the medical staff has policies requiring practitioners to attempt to secure permission to perform meaningful autopsies, that the mechanism for documenting permission to perform an autopsy is defined, and that there is a system for notifying the medical staff, specifically the attending practitioner, when an autopsy is performed.</p>
A0882	<p>(2) A system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.</p> <p><i>(Indiana State Department of Health; 410 IAC 15-1.5-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1271; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	
A0904	<p>410 IAC 15-1.5-6 Nursing service  Authority: IC 16-21-1-7  Affected: IC 16-21-1; IC 25-23-1-11</p> <p>Sec. 6. (a) The hospital shall have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse. The service shall have the following:</p> <p>(1) An organizational plan which delineates the responsibilities for patient care.</p>	<p>(a) Verify, through review of the organizational chart, job descriptions, and nursing policies and procedures, that the responsibility of the Nurse Executive (NE) is clearly defined, that the NE is delegated the specific responsibility for operation of the service, that the lines of authority that delegate responsibilities within the department are outlined, and that the NE is currently licensed. Verify that the in-service requirements for nursing staff have been fulfilled and are appropriately documented. Verify through review of the staffing schedules that a RN is on duty at all times and immediately available.</p>
A0908	<p>(2) A nurse executive who is:</p> <p>(A) licensed under IC 25-23-1-11; and</p>	
A0912	<p>(B) responsible for the following:</p> <p>(i) The operation of the services, including, but not limited to, determining the types and numbers of nursing personnel and staff necessary to provide care for all patient care areas of the hospital.</p> <p>(ii) Maintaining a current nursing service organization chart.</p> <p>(iii) Maintaining current job descriptions with reporting responsibilities for all nursing staff positions.</p>	

A0912 CONTD	(iv) Ensuring that all nursing personnel meet annual in-service requirements as established by hospital and medical staff policy and procedure, and federal and state requirements. (v) Establishing the standards of nursing care and practice in all settings in which nursing care is provided in the hospital.	
A0926	(b) The nursing service shall have the following: (1) Adequate numbers of licensed registered nurses, licensed practical nurses, and other ancillary personnel necessary for the provision of appropriate care to all patients, as needed, to include the immediate availability of a registered nurse.	(b) Review the staffing schedules and a sampling of nursing service personnel records.  (b)(1) Determine by reviewing the written staffing schedules for the two week period covering the survey that there are sufficient personnel to respond to the appropriate medical needs and care of the patients being served. (Take into consideration the physical layout and size of the units, number of patients, intensity of illness and nursing needs, availability of nurses aides, orderlies, and support staff, and the training and experience of personnel.)
A0928	(2) The service shall have a procedure to ensure that hospital nursing personnel, including nurse registry personnel for whom licensure is required, have valid and current licensure.	(b)(2) Review the hospital personnel records or the records or recording system kept by nursing to determine that RN's, LPN's, and other nursing personnel for whom licensure is required have current valid licenses.
A0930	(3) A registered nurse shall supervise and evaluate the care planned for and provided to each patient.	(b)(3) Verify that an RN is assigned to supervise and evaluate the nursing care furnished to each patient.
A0932	(4) The nursing staff shall develop and utilize an ongoing individualized plan of care based on standards of care for each patient.	(b)(4) Review approximately 6 to 12 care plans. Determine that they are authenticated as soon as possible after admission for each patient. Determine that they describe patient goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. Determine that each plan is in consonance with the attending practitioners plan for medical care. Determine that the plans are revised as the needs of the patient change. Determine that the plans are implemented.
A0934	(5) A registered nurse shall assign the care of each patient to nursing personnel in accordance with the patient's need and the specialized qualifications and competence of the nursing staff available.	(b)(5) Verify that the assignments were made by an RN and determine that the assignments take into consideration the complexity of patients' needs and the competence and specialized qualifications of the nursing staff.
A0936	(6) All nursing personnel shall demonstrate and document competency in fulfilling assigned responsibilities.	(b)(6) Review a sample of nursing personnel files or nursing records to verify documentation of current competence in accordance with recognized standards and hospital requirements to ensure personnel are being utilized consistent with their abilities. Verify orientation and in-service training in the sample of files. Include in the review, a sampling of agency/contract personnel records.
A0940	(c) Drugs and biologicals shall be prepared for administration and administered as follows: (1) By, or under the supervision of, a registered nurse or other qualified personnel.	(c) Review the policies on preparation of drugs and biologicals. (c)(1) Verify that nursing or other personnel authorized by medical staff policy to prepare and administer drugs have the required training. Determine the method of providing supervision and verify that the supervision is provided.
A0942	(2) In accordance with current federal and state laws.	(c)(2)(3) Review the drug administration policies and procedures to ascertain that they are in compliance with federal and state laws, medical staff rules and regulations, and that they are approved by the medical staff. Verify that the policies and procedures cover who is authorized to accept telephone or verbal orders and who is authorized to administer medication.
A0944	(3) In accordance with medical staff rules.	
A0946	(4) In accordance with the signed written orders of the practitioner or practitioners responsible for the patient's	(c)(4) Determine that all drug orders are written in the patient record and signed by the practitioner responsible for the patient or in accordance with Medical Staff Policy.

	care. When verbal or telephone orders are used, they shall be accepted only by personnel that are authorized to do so by the medical staff rules.	Review a sample of medication administration records to verify that they conform with the practitioner's order, that the order is current, and that drug dosages are correct and administered as ordered and within 60 minutes of the scheduled time. Cite a non-compliance if a <u>pattern</u> of late or early administration occurs on the part of one nurse or in general by the nurses. Verify by chart review that the telephone/verbal orders are taken by authorized personnel and are correctly reviewed and authenticated in accordance with hospital and medical staff policy.
A0948	(5) In accordance with currently acceptable standards of practice.	(c)(5) Note any variance with current standards of practice and if they are allowed by hospital policy and medical staff rule and regulation.
A0950	(6) As specified under section 7 of this rule.	(c)(6) See the pharmaceutical services section 7 of this rule.
A0952	(d) Blood transfusions and intravenous medications shall be administered in accordance with state law and approved medical staff policies and procedures. If the blood transfusions and intravenous medications are administered by personnel other than physicians, the personnel shall have special training for these procedures in accordance with subsection (b)(6).	(d) Verify that the nursing or other non-physician personnel administering blood transfusions and intravenous medications are appropriately trained in accordance with nursing policies and other pertinent hospital policies.
A0954	(e) Emergency equipment and emergency drugs shall be available for use on all nursing units. ( <i>Indiana State Department of Health; 410 IAC 15-1.5-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1272; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i> )	(e) Verify that emergency equipment and drugs are available for use on patient care units in accordance with hospital policy and acceptable standards.
A1004	410 IAC 15-1.5-7 Pharmaceutical services Authority: IC 16-21-1-7 Affected: IC 16-21-1 Sec. 7. (a) The hospital shall have a pharmaceutical service that meets the needs of the patient and complies with requirements set forth by the Indiana board of pharmacy.	(a) Verify that the pharmacy is currently licensed by the State Board of Pharmacy and a pharmacist is designated as director.
A1008	(b) The hospital shall have a pharmacy service directed by a pharmacist, as follows: (1) A full-time, part-time, or consulting pharmacist shall be responsible for developing, supervising, coordinating, and implementing the written policies and procedures to ensure appropriate distribution, control, therapeutic monitoring, and accountability of all drugs used in the hospital.	(b) Verify that the director is a pharmacist currently licensed in the state. (b)(1) Direction of pharmaceutical services may not require on premises supervision but may be accomplished through regularly scheduled visits. Document the status of the director and verify that the director's responsibilities are clearly defined and include development, supervision and coordination of all the activities of the pharmacy services.
A1010	(2) The pharmacy service shall be administered in accordance with accepted professional standards and federal and state laws.	(b)(2) Verify that standards of practice as defined by state law are followed regarding the provision of the service. The hospital may utilize a unit dose system, individual prescription, floor stock system, either automated or electronic, or any combination of these systems.
A1012	(3) The pharmacy service shall have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.	(b)(3) Review a sampling of pharmaceutical service personnel records. Determine that the pharmacy service staff is sufficient in number and training to provide quality services, including 24 hour, 7 day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients served as specified by hospital policy and approved by the medical staff.



A1014	(c) In order to provide patient safety, the director of pharmacy shall develop and implement written policies and procedures for the appropriate selection, control, labeling, storage, use, monitoring, and quality assurance of all drugs and biologicals.	(c) Review the policies and procedures to verify that the director, in order to provide for patient safety, has developed the required policies and procedures and that they are being implemented accordingly.
A1016	(d) Written policies and procedures shall be developed and implemented that include the following: (1) Establish a formulary system with specifications for the selection and procurement of all drugs and biologicals at reasonable costs and as approved by the medical staff.	(d) Review the policies and procedures to verify inclusion of those required by the regulations as well as hospital policies. (d)(1) Verify the formulary has been approved by the medical staff either by signature or appropriate documentation in medical staff meeting minutes. Interview the pharmacist to determine that the medical staff has established a formulary that lists drugs that actually are available in the hospital.
A1020	(2) Ensure the monthly inspection of all areas where drugs and biologicals are stored and which address, but are not limited to, the following: (A) Separation of drugs designed for external use from drugs intended for internal use.	(d)(2) Verify the policies cover the monthly inspection and documentation of inspections. Determine that the inspections are carried out by the health care workers assigned that duty by the policy and that the reports are reviewed by the pharmacist. (A) Verify that the policies cover the requirements, and that inspections and documentation are in accordance with the policies.
A1022	(B) Appropriate storage conditions.	(B) Verify that the policies cover the requirements, and that inspections and documentation are in accordance with the policies.
A1024	(C) Detection and quarantine of outdated or otherwise unusable drugs and biologicals from general inventory pursuant to their return to the manufacturer, distributor, or destruction.	(C) Verify that the policies cover the requirements, and that inspections and documentation are in accordance with the policies.
A1026	(D) Documentation and accountability for an accurate accounting of controlled substances from the time of receipt in the institution through the administration to the patient or subsequent removal from general stock and reporting of all abuses and losses of controlled substances.	(D) Verify that a system has been developed for the counting and verification of scheduled drugs in accordance with Federal and State requirements and hospital policy and procedure. Verify that the system allows for documentation of all transactions including withdrawals, returns, wastage and verification of wastage. <ul style="list-style-type: none"><li>▪ The system could be a secure and reliable automated distribution system that perpetually maintains and monitors for accountability and usage, all transactions including withdrawals, returns, wastage and verifications of wastage.</li><li>▪ The system could electronically document all drug transactions including withdrawals, returns, wastage and verification of wastage and have on-line availability of transaction histories.</li></ul>
A1028	(E) Security of and authorized access to all drug storage areas within the hospital, as approved by the medical staff, when the pharmacist is absent.	(E) Determine that there is a policy for the safeguarding, transferring, and availability of keys to the locked storage area is designated and approved by the medical staff.
A1030	(F) Availability of information relating to drug interactions and information on the following: (i) Drug therapy. (ii) Side effects. (iii) Toxicology. (iv) Dosage. (v) Indications for use. (vi) Routes of administration.	(F) Determine that inspections cover availability of the required information.

A1038	<p>(3) Review the use of medications with the standards developed by the medical staff, which include stop orders for scheduled drugs and biologicals not specifically prescribed as to time or number of doses.</p> <p>(4) Allow for adequate drug therapy monitoring procedures to exist.</p> <p>(5) Minimize medication errors and document, monitor, evaluate, and report adverse drug reactions and medication errors.</p> <p>(6) Provide for the maintenance of drug and poison information materials.</p> <p><i>(Indiana State Department of Health; 410 IAC 15-1.5-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1272; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>(d)(3) Review the policies for medication standards as established by the medical staff, to include stop order requirements. In your record review determine that automatic stop orders are being followed.</p> <p>(d)(4) Review the policies for requirements on drug therapy monitoring procedures.</p> <p>(d)(5) Determine that there is a system for reporting immediately to the responsible practitioner any medication error or adverse response to therapy and also for reporting to the hospital quality assessment and improvement program.</p> <p>(d)(6) Review the policy and determine the extent of information and/or procedures for finding the information on drugs and poisons. Determine that the information is available as the policy requires.</p>
A1104	<p>410 IAC 15-1.5-8 Physical plant, maintenance, and environmental services</p> <p>Authority: IC 16-21-1-7 Affected: IC 16-21-1</p> <p>Sec. 8. (a) The hospital shall be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for services authorized under the hospital license as follows:</p> <p>(1) The plant operations and maintenance service, equipment maintenance, and environmental service shall be:</p> <p>(A) staffed to meet the scope of the services provided; and</p> <p>(B) under the direction of a person or persons qualified by education, training, or experience.</p>	<p>(a) Verify through observation that the hospital has adequate facilities for diagnostic and therapeutic 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.</p> <p>(a)(1) Review a sampling of the plant operations and maintenance, equipment maintenance, and environmental service personnel records. Verify that service personnel have received orientation and follow-up training, including training in principles of asepsis, infection control, and safe practices.</p>
A1110	<p>(2) There shall be a safety officer designated to assume responsibility for the safety program.</p>	<p>(a)(2) Verify the appointment of the safety officer and determine the scope of his/her responsibility.</p>
A1112	<p>(3) The hospital shall provide a physical plant and equipment that meet the statutory requirements and regulatory provisions of the state department of fire and building services, including 675 IAC 22, Indiana fire prevention codes, and 675 IAC 13, Indiana building codes.</p>	<p>(a)(3) Determine that the hospital has been inspected by the Local / State Fire Authority and note date of last inspection.</p>

A1114	<p>(b) The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:</p> <p>(1) No condition in the facility or on the grounds shall be maintained that may be conducive to the harborage or breeding of insects, rodents, or other vermin.</p>	<p>(b) Tour the hospital and grounds.</p> <ul style="list-style-type: none"> <li>▪ If the hospital is non-accredited, it comes under the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association that apply to hospitals. JCAHO accredited hospitals meet the applicable sections of the 2000 edition of the Life Safety Code of the National Fire Protection Association.</li> </ul> <p>(b)(1) Determine compliance with this requirement. Determine that problem areas have been reported to the safety committee and addressed in the QA&amp;I program, if appropriate. Verify that plans of action have been implemented and the outcomes documented.</p>
A1118	<p>(2) No condition shall be created or maintained that may result in a hazard to patients, public, or employees.</p>	<p>(b)(2) There shall be proper ventilation, light and temperature controls in pharmaceutical, food preparation, 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 product manufacturer.</p> <p>Determine that ceiling finishes in operating rooms, delivery rooms for cesarean section, isolation rooms, and sterile processing rooms are provided with ceilings with a minimum number of fissures, open joints, or crevices and minimize retention or passage of dirt particles.</p>
A1120	<p>(3) There shall be emergency power and lighting in accordance with National Fire Protection Association (NFPA) 99.</p>	<p>(b)(3) The hospital shall comply with the applicable provisions of the Life Safety code, NFPA 101, for emergency lighting, and with appropriate provisions of NFPA 99, Health Care Facilities, (section 3-4.2.2.2), Emergency System.</p>
A1122	<p>(4) There shall be a plan for emergency fuel and water supply.</p>	<p>(b)(4) Verify that arrangements have been made with utility companies or others for the provision of emergency sources of critical utilities such as water and gas or other fuels, or that the hospital has back-up utility resources stockpiled for use in emergencies.</p>
A1124	<p>(5) Provision shall 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 shall be available, along with training or instruction of the appropriate personnel, in the maintenance and operation of the fixed and movable equipment.</p>	<p>(b)(5) 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>(A) Determine that there are training schedules and documentation on personnel training. Check for the availability of manuals.</p>
A1125	<p>(B) Operational and maintenance control records shall be established and analyzed periodically. These records shall be readily available on the premises.</p>	<p>(B) Review the operational and maintenance control records. (They shall be available for review on the premises.)</p>
A1126	<p>(C) Maintenance and repairs shall be carried out in accordance with applicable codes, rules, standards, and requirements of local jurisdictions, the administrative building council, the state fire marshal, and the department.</p>	<p>(C) Determine if there have been any code violations on maintenance and repairs. Review the reports from the various jurisdictions. Verify that violations have been or are being corrected and that the corrections are ongoing.</p>

A1128	(c) In new construction, renovations, and additions, the hospital site and facilities, or nonlicensed facilities acquired for the purpose of providing hospital services, shall meet the following: (1) The 2001 edition of the national “Guideline for Construction and Equipment of Hospital and Medical Facilities” (Guidelines).	(c) Note any construction activity or plans for renovation, construction, addition, etc. for verification of plan review by the division and information on future activity.  (c)(1) No survey requirements.
A1132	(2) All building, fire safety, and handicapped accessibility codes and rules adopted and administered by the state building commissioner shall apply to all facilities covered by this rule and take precedence over any building, fire safety, or handicapped accessibility requirements of the Guidelines.	(c)(2) No survey requirements.
A1134	(3) When renovation or replacement work is done within an existing facility, all new work or addition, or both, shall comply, insofar as practical, with applicable sections of the Guidelines and for certification with appropriate parts of National Fire Protection Association (NFPA) 101 (2000 Edition).	(c)(3) No survey requirements.
A1136	(4) Proposed sites shall be located away from detrimental nuisances, well drained, and not subject to flooding. A site survey and recommendations shall be obtained from the department prior to site development.	(c)(4) No survey requirements.
A1138	(5) Water supply and sewage disposal services shall be obtained from municipal or community services. Outpatient facilities caring for patients less than twenty-four (24) hours that do not provide surgery, laboratory, or renal dialysis services may be served by approved private on-site septic tank absorption field systems.	(c)(5) No survey requirements.
A1140	(6) Site utility installations for water, sprinkler, sanitary, and storm sewer systems, and wells for potable emergency water supplies shall comply with applicable sections of Bulletin S.E. 13, “On-Site Water Supply and Waste-water Disposal for Public and Commercial Establishments”, 1988 edition.	(c)(6) No survey requirements.
A1142	(7) As early in the construction, addition, or renovation project as possible, the functional and operational description shall be submitted to the division. This submission shall consist of, but not be limited to, the following: (A) Functional program narrative as established in	(c)(7) No survey requirements.  (A) No survey requirements.

	<p>the Guidelines.</p> <p>(B) Schematics, based upon the functional program, consisting of drawings (as single-line plans), outline specifications, and other documents illustrating the scale and relationship of project components.</p>	(B) No survey requirements.
A1146	<p>(8) Prior to the start of construction, addition, or renovation projects, detailed architectural and operational plans for construction shall be submitted to the plan review division of the department of fire and building services and to the division of sanitary engineering of the department, as follows:</p> <p>(A) Working drawings, project manual, and specifications shall be included.</p> <p>(B) Prior to submission of final plans and specifications, recognized standards and codes, including infection control standards, shall be reviewed as required in section 2(f)(2) of this rule.</p> <p>(C) All required approvals shall be obtained from the state building commissioner and final approval from the division of sanitary engineering of the department prior to issuance of the occupancy letter by the division.</p>	<p>(c)(8) No survey requirements.</p> <p>(A)(B)(C) No survey requirements.</p>
A1150	<p>(9) All back flow prevention devices shall be installed as required by 327 IAC 8-10 and the current edition of the Indiana plumbing code. Such devices shall be listed as approved by the department.</p>	<p>(c)(9) During the tour, determine that back flow preventers (vacuum breakers) are installed on hose bibs, laboratory sinks, janitors' sinks, bedpan flushing attachments, autopsy tables, and other fixtures to which hoses and tubing can be/are attached.</p> <p>(For information on approved list contact ISDH Sanitary Engineering.)</p>
A1152	<p>(10) Upon receipt of a design release from the state building commissioner and documentation of a completed plan review by the division of sanitary engineering of the department, a licensure application shall be submitted to the division on the form approved and provided by the department.</p>	(c)(10) No survey requirements.
A1154	<p>(11) Documentation from the state building commissioner that the hospital is in compliance with the fire safety rules of the fire prevention and building safety commission shall be furnished to the division with the licensure application.</p>	(c)(11) No survey requirements.
A1156	<p>(12) Plans for constructing, expanding, or remodeling x-ray or gamma ray facilities shall be accompanied by an evaluation of the radiation protection features by a radiation qualified expert as required by 410 IAC 5.</p>	(c)(12) No survey requirements.

	After completion of the x-ray or gamma ray installation and prior to use, a radiation safety survey shall be performed by a radiation qualified expert to insure that the facility meets all applicable requirements of 410 IAC 5 and National Council on Radiation Protection and Measurements (NCRP) Reports Number 49 and 102.	
A1158	(13) Outpatient facilities, rehabilitation facilities, psychiatric facilities, and mobile, transportable, and relocatable units that are included under the hospital license may comply with appropriate sections of the Guidelines. If not, they shall comply with the hospital section of the Guidelines.	(c)(13) No survey requirements.
A1160	(d) The equipment requirements are as follows: (1) All equipment shall be in good working order and regularly serviced and maintained.	(d) Review the preventive maintenance policies and procedures.  (d)(1) Determine the schedule for maintenance and service of various types of equipment and verify compliance with hospital policy and manufacturers recommendations.
A1162	(2) There shall be sufficient equipment and space to assure the safe, effective, and timely provision of the available services to patients, as follows: (A) All mechanical equipment (pneumatic, electric, or other) shall be on a documented maintenance schedule of appropriate frequency and with the manufacturer's recommended maintenance schedule.	(d)(2) Tour areas where the equipment is located.  (A) Determine that the equipment is on a maintenance schedule and verify that the maintenance is being done in accordance with policy/schedule.
A1164	(B) There shall be evidence of preventive maintenance on all equipment.	(B) Observe the system used for delivering preventative maintenance for the equipment to determine if it is in accordance with policy.
A1166	(C) Appropriate records shall be kept pertaining to equipment maintenance, repairs, and current leakage checks.	(C) Determine from a record check that the hospital required maintenance activities are being done.
A1168	(3) Defibrillators shall be discharged at least in accordance with manufacturers recommendations and a discharge log with initialed entries shall be maintained.	(d)(3) Review the hospital policy on defibrillator discharging and verify compliance and documentation of discharge.
A1170	(4) Electrical safety shall be practiced in all areas.	(d)(4) During tour of areas observe electrical safety practices. Determine that grounded (3-prong) plugs are on all electrical medical equipment. Determine if appropriate actions are being/have been taken on electrical problems.

A1172	<p>(e) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, shall be kept clean and orderly in accordance with current standards of practice as follows:</p> <p>(1) Environmental services shall be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:</p> <p>(A) asepsis;  (B) cross-infection; and  (C) safe practice.</p>	<p>(e) Tour the hospital and observe cleanliness of walls, painted surfaces, ceilings, floors, equipment and the procedures being utilized for cleaning them.</p> <p>(e)(1) 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>
A1178	<p>(2) Refuse and garbage shall be collected, transported, sorted, and disposed of by methods that will minimize nuisances or hazards.</p>	<p>(e)(2) Verify that there are policies on collection, transportation, sorting, storage and disposal of trash. Determine through observation that these policies are followed.</p>
A1180	<p>(f) The safety management program shall include, but not be limited to, the following:</p> <p>(1) An ongoing hospital-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the safety committee.</p>	<p>(f) Review the safety management program and interview the safety officer.</p> <p>(f)(1) Determine that the safety program is an established, functioning, hospital wide program that evaluates safety issues and problems. Determine review by the safety committee is documented and timely, and that actions are taken to correct and improve hospital safety and provide a safe environment for patients, workers, and public.</p>
A1184	<p>(2) A safety committee appointed by the chief executive officer that includes representatives from administration, patient services, and support services.</p>	<p>(f)(2) Determine that a safety committee has been appointed and that it meets in accordance with program requirements. Review the minutes of the committee to establish participation of committee members.</p>
A1186	<p>(3) The safety program that includes, but is not limited to, the following:</p> <p>(A) Patient safety.  (B) Health care worker safety.  (C) Public and visitor safety.  (D) Hazardous materials and wastes management in accordance with federal and state rules.  (E) A written fire control plan that contains provisions for the following:</p> <p>(i) Prompt reporting of fires.  (ii) Extinguishing of fires.  (iii) Protection of patients, personnel, and guests.  (iv) Evacuation.  (v) Cooperation with firefighting authorities.</p>	<p>(f)(3) Review the safety program.</p> <p>(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 hospital policy.</p> <p>(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 hospital policy. Determine that there is a system to evaluate employee complaints of environment related illnesses and product allergy.</p> <p>(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 hospital policy.</p> <p>(D) Determine that the program addresses hazardous materials and waste management. Review documentation of action taken.</p> <p>(E) Review the hospital's written fire control plans to verify they contain the required provisions of the Life Safety Code or State Law.</p>
A1197	<p>(F) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies.</p>	<p>(F) 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>
A1198	<p>(G) Emergency and disaster preparedness coordinated with appropriate community, state,</p>	<p>(G) Review the emergency and disaster plans and determine that the hospital is participating on a regular basis and that there is documentation of drills and practices in accordance with the hospital policy and program requirements.</p>

	<p>and federal agencies.  <i>(Indiana State Department of Health; 410 IAC 15-1.5-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1273; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	See also 410 IAC 15-1.4-1(c)(6)(N).
A1204	<p><b>410 IAC 15-1.5-9 Radiologic services</b>  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 9. (a) The hospital shall have on-site, or available by arrangement, the diagnostic imaging services required by the needs of the patients served and within the scope of the service provided, that are in compliance with federal and state rules, as follows:</p> <p>(1) If radiation emitting or nonionizing services, either diagnostic or therapeutic, are provided, the applicable requirements of this section apply. The services may include, but not be limited to the following:</p>	<p>(a) If the hospital does not provide diagnostic imaging and therapeutic radiologic services or nuclear medicine services directly, but under arrangement, review the contract for the scope of the service and verify that the service is being provided.</p> <p>(a)(1) Review the service for compliance with appropriate regulations.</p>
	<p>(A) Mammography.  (B) Computerized tomography.  (C) Magnetic resonance imaging.  (D) Ultrasound.  (E) Catheterization lab.  (F) Interventional radiology.</p>	
A1214	<p>(2) If therapeutic or diagnostic nuclear medicine services are provided, they shall comply with the applicable requirements of this section and with 410 IAC 15-1.6-4.</p>	<p>(a)(2) Review the service for compliance with appropriate sections of the rule and Nuclear Medicine Section 410 IAC 15-1.6-4.</p>
A1216	<p>(b) The services that use ionizing radiation shall not compromise the health, safety, and welfare of patients or personnel in accordance with federal and state rules, as follows:</p> <p>(1) Proper safety precautions shall be maintained against radiation hazards in accordance with the hospital's radiation and safety program as developed by the radiation safety officer. This includes, but is not limited to, the following:</p>	



A1216	<p>(A) Adequate shielding for patients, personnel, and facilities.</p> <p>(B) Procedures for monitoring:</p> <ul style="list-style-type: none"> <li>(i) skin dosage;</li> <li>(ii) radionuclide contamination;</li> <li>(iii) quality control;</li> <li>(iv) technique charts, where applicable; and</li> <li>(v) handling of hazardous materials.</li> </ul> <p>(C) Appropriate storage, use, and disposal of radioactive materials.</p>	<p>(b) Review the policies and programs for ionizing radiation and verify that health, safety, and welfare of patient and personnel are addressed and actions documented.</p> <p>(b)(1) Review the policies and procedures or other readily available sources, and verify that a Radiation Safety Officer has been appointed and the program is documented. Review the policies and verify that the program covers the items required. Verify that there is a policy for periodic radiation exposure checks on radiation workers.</p>
A1226	<p>(2) Equipment shall be inspected, tested, and calibrated at least annually by qualified personnel with appropriate documentation reasonably available.</p>	<p>(b)(2) Check for ionizing survey reports from a qualified physicist.</p>
A1228	<p>(3) Hazards and faulty equipment identified shall be promptly corrected in accordance with current standards of practice and applicable federal and state rules to include, but not be limited to, collimation and filtration, and evaluation of equipment performance.</p>	<p>(b) (3) Verify that policies cover hazards and maintenance requirements and that policies are followed.</p>
A1230	<p>(4) Written preventive maintenance policies and procedures, in accordance with manufacturer's recommendations and hospital policy, shall be maintained and compliance shall be documented.</p>	<p>(b) (4) Verify that policies cover hazards and maintenance requirements and that policies are followed.</p>
A1232	<p>(c) Procedures and treatments are performed on the written request of individuals and practitioners allowed to order such procedures and treatments and receive the results of the evaluations to the extent permitted by law and authorized by the governing body.</p>	<p>(c) Verify that the hospital has policies that radiologic services are provided on the order of practitioners with clinical privileges or on the orders of individuals or practitioners outside the hospital as authorized by the governing body.</p>
A1234	<p>(d) A full-time, part-time, or consulting radiologist or physician qualified by education and experience in the service provided as determined by the medical staff shall do the following:</p> <ul style="list-style-type: none"> <li>(1) Supervise the service provided.</li> </ul>	<p>(d) Verify through examination of the records that a qualified physician with staff privileges has been designated by the medical staff to supervise the service.</p> <p>(d)(1) Determine through observation of the service and interviews with the staff, that supervision of the radiologic services is restricted to a radiologist or a physician qualified by education and training who is a member of the medical staff.</p>
A1238	<p>(2) Ensure that only personnel use the equipment and administer procedures who:</p> <ul style="list-style-type: none"> <li>(A) have been designated as qualified by the medical staff; and</li> <li>(B) are allowed to do so in accordance with current standards of practice and state rules.</li> </ul>	<p>(d)(2) Examine hospital policies and review a sampling of service personnel folders to verify that radiologic personnel meet the qualifications established by the medical staff and state regulations.</p>
A1242	<p>(3) Interpret those tests that are determined by the medical staff to require a radiologist's or appropriately credentialed physician's specialized knowledge.</p>	<p>(d)(3) Verify that a qualified radiologist interprets the tests designated by the medical staff to require a radiologist's knowledge. If other practitioners are allowed by the medical staff to interpret diagnostic images, determine that they are credentialed to do so.</p>

A1244	(4) Be available for consultation for the quality and necessity of diagnostic imaging, nuclear medicine, and therapeutic procedures, if applicable.	(d)(4) Verify that a policy exists that covers consultation as required.
A1246	(e) Records shall be maintained as follows: (1) The radiologist or other practitioner shall authenticate reports of his or her interpretations.	(e) Review the policy on record maintenance and verify compliance. (e)(1) Verify that reports are authenticated by the practitioner who interprets and evaluates the film, scan, or procedure.
A1250	(2) The hospital shall maintain the following for at least five (5) years: (A) Copies of reports and printouts. (B) Films, scans, and other image records. (C) If clauses (A) and (B) are maintained in the medical record, these items shall be maintained in accordance with state and federal law. <i>(Indiana State Department of Health; 410 IAC 15-1.5-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1275; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i>	(e)(2) Verify that the records are retained as required. Current state law and federal regulation require that x-rays and mammogram images are 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 department.
A1304	410 IAC 15-1.5-10 Utilization review and discharge planning services Authority: IC 16-21-1-7 Affected: IC 16-21-1  Sec. 10. (a) The hospital shall have and implement a written plan, approved by the medical staff and governing body, that describes the utilization review program and governs its operation.	(a) Determine that the plan includes a delineation of the responsibilities and authority for those involved in the performance of utilization review activities.
A1306	(b) The utilization review program shall address appropriate utilization of patient care resources.	(b) Determine that the plan provides for review of the medical necessity of admissions, the appropriateness of the setting, the medical necessity of extended stays, and the medical necessity of professional services.
A1308	(c) Concurrent review shall focus on those diagnoses problems, procedures, or practitioners with identified or suspected utilization-related problems.	(c) Determine that concurrent review is being conducted as required and documented appropriately.
A1310	(d) The hospital's utilization review program shall be reviewed and evaluated at least annually and be revised, as appropriate, to reflect the findings of the hospital's utilization review activities.	(d) Determine that the program is reviewed and verify this through documentation of program review and evaluation.
A1312	(e) To facilitate discharge as soon as an acute level of care is no longer required, the hospital shall have effective, ongoing discharge planning that: (1) facilitates the provision of follow-up care;	(e) Verify that the hospital does discharge planning. Determine that the medical staff has approved the discharge plan and is involved in its implementation. Determine that the medical staff participates in the evaluation of the program.  (e)(1) Verify a policy covering facilitation of the provision of follow-up care.
A1316	(2) is initiated in a timely manner as established by written hospital policy;	(e)(2) Verify that the policies require timely initiation of discharge planning and that time frames are established and adhered to. Review a sample of medical records.

A1318	<p>(3) transfers or refers patients, along with necessary medical information and records, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care. The information shall include, but not be limited to, the following:</p> <ul style="list-style-type: none"> <li>(A) medical history;</li> <li>(B) current medications;</li> <li>(C) activities status;</li> <li>(D) nutritional needs;</li> <li>(E) outpatient service needs;</li> <li>(F) follow-up care needs; and</li> </ul>	(e)(3) Verify that policies cover the requirements for transfers and referrals and includes the required information. Verify that arrangements have been made, in accordance with hospital policy, with the receiving entity.
A1326	(4) utilizes available community and hospital resource to provide appropriate referrals or make available social, psychological, and educational services to meet the needs of the patient.	(e)(4) Determine that there is resource information available and that the hospital and agency services are utilized as appropriate.
A1328	(f) If required by Medicare, the hospital has a current memorandum of understanding covering binding review that complies with federal peer review rules. ( <i>Indiana State Department of Health; 410 IAC 15-1.5-10; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1276; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i> )	(f) If the hospital has a current Memorandum of Understanding with the state Peer Review Organization, the hospital is in compliance with (a), (b), (c), and (d) of this Section.
<b>Rule 1.6. Optional Hospital Services</b>		
A1404	<p><b>410 IAC 15-1.6-1 Anesthesia services</b>  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 1. (a) If the hospital furnishes anesthesia services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and be under the direction of a qualified physician. The service is responsible for all anesthesia administered in the hospital.</p>	(a) 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 throughout the hospital, i.e., in-patient and out-patient O.R. suites, obstetrical suites, radiology department, clinics, out-patient surgery areas,, etc. The director is responsible for planning, directing, supervising all activities of the service, and monitoring of the QA&I of anesthesia patient care.
A1406	<p>(b) Anesthesia shall only be administered by those privileged by the medical staff who are:</p> <ul style="list-style-type: none"> <li>(1) an anesthesiologist;</li> <li>(2) a qualified physician with appropriate training, experience, and privileges;</li> <li>(3) a dentist, oral surgeon, or a podiatrist who is qualified to administer anesthesia under state law; or</li> </ul>	<p>(b) Review a sampling of records of practitioners and others privileged to administer anesthesia to determine compliance with the requirements.</p> <p>(b)(1) A qualified anesthesiologist is a physician who has completed an approved residency training program in anesthesia. "Qualified to administer anesthesia" requires specialized training or equivalent experience in the delivery of anesthesia.</p> <p>(b)(2) A doctor of medicine or osteopathy qualified and privileged to administer anesthesia in accordance with medical staff policy.</p> <p>(b)(3) A doctor of dental surgery or medicine, or doctor of podiatric medicine qualified under state law and privileged to administer anesthesia in accordance with medical staff policy.</p>

	(4) a certified registered nurse anesthetist (CRNA) who is under the direction of the operating practitioner or of a qualified physician who is immediately available if needed.	(b)(4) Verify that the CRNA's are currently certified by the Council on Certification of Nurse Anesthetists and that they, in accordance with medical staff policy, administer anesthesia under the supervision of the operating practitioner or qualified physician who is immediately available.
A1414	(c) Anesthesia services shall be consistent with needs and resources, as follows: (1) There shall be written policies and procedures on monitored anesthesia care (MAC), general anesthesia, and regional anesthesia which include, but are not limited to, the following: (A) The delineation of preanesthesia and postanesthesia responsibilities.	(c) Review the anesthesia service program to determine if it provides the services outlined and consistent with patient needs and hospital resources. (c)(1) Review the policies and procedures to determine if the service incorporates the minimum policies required. (A) Determine that the policies designate who is responsible for the pre and post anesthesia requirements.
	(B) The completion, within forty-eight (48) hours prior to surgery, of a preanesthesia evaluation for each patient by an individual(s) qualified to administer anesthesia. (C) The requirement of an intra-operative anesthesia record on each patient.	(B) Determine that the pre-operative 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. (C) 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, any complications or problems occurring during anesthesia including time and description of systems, vital signs, treatment rendered, and patient's response to treatment and is in accordance with medical staff policy.
A1420	(D) The completion, within forty-eight (48) hours after surgery, of a postanesthesia follow-up report on each inpatient by the individual who administered the anesthesia.	(D) Determine that the post-anesthesia follow up report documents: cardiopulmonary status; level of consciousness; complication or problems occurring during post-anesthesia recovery; and any follow up care and/or observations.
A1422	(E) The completion of a postanesthetic evaluation for proper anesthesia recovery of each outpatient in accordance with written policies and procedures approved by the medical staff.	(E) Determine that the post-anesthesia recovery record contains information in accordance with hospital policies and procedures, and depending on the type of anesthesia and length of surgery, determine that the post operative check includes the items listed in (D) above.
A1424	(F) The requirement that all postoperative patients shall be discharged from the postanesthetic care unit by the practitioner in subsection (b) responsible for the patient's care in accordance with hospital policy.	(F) Verify that each patient is discharged from the PACU as required and in accordance with hospital/medical staff policy.
A1426	(2) There shall be written policies and procedures on local anesthesia.	(c)(2) Review the policies and procedures on the administration and documentation of use of local anesthetics.
A1428	(3) There shall be intra-operative monitoring in accordance with current acceptable standards of practice.	(c)(3) Determine that there is monitoring and documentation of monitoring intra-operatively in accordance with current acceptable standards of practice and medical staff policies.
A1430	(4) Anesthesia equipment shall be checked for operational readiness and safety prior to patient administration. Documentation to that effect shall be	(c)(4) Determine through documentation in the patient record that required checks were performed on the anesthesia equipment prior to each administration of anesthesia.

	included in the patient's medical record. (Indiana State Department of Health; 410 IAC 15-1.6-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1276; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)	
A1504	410 IAC 15-1.6-2 Emergency services Authority: IC 16-21-1-7 Affected: IC 16-21-1  Sec. 2. (a) If a hospital provides a community emergency service, the service shall meet the emergency needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and be under the direction of a physician qualified by education or experience.	(a) Hospitals that provide emergency services to all patients with emergency conditions shall do so in accordance with Federal, State, and Local laws, and acceptable standards of practice. If the hospital does not provide an emergency service, it shall provide immediate lifesaving measures to persons with emergency conditions, and arrange for their transfer to another hospital that provides emergency services. (Determine that OBRA '87 signage is prominently displayed in the Emergency Department.) Verify that emergency services are organized under the direction and supervision of a qualified member of the medical staff.
A1506	(b) The emergency service shall have the following: (1) A scope of service that is clearly defined.	(b) Review the emergency service program for compliance with requirements. (b)(1) Determine that the emergency service provided is in accordance with hospital policies and procedures and medical staff requirements.
A1510	(2) Written policies and procedures governing medical care provided in the emergency service are established by and are a continuing responsibility of the medical staff. The policies shall include, but not be limited to, the following: (A) Provision for the care of the disturbed patient.  (B) Provision for immediate assessment of all patients presenting for emergency and obstetrical care.  (C) Provision for transfer of patients when care is needed which cannot be provided.	(b)(2) Verify that procedures and policies for emergency medical services (including triage of patients) are established, evaluated, and updated on an ongoing basis by the medical staff.  (A) Verify a policy for the provision of care and appropriate treatment of the disturbed patient, admission, or subsequent transfer if the hospital does not provide psychiatric services. (B) Verify that a procedure for assessment on all patients presenting for emergency care and obstetrical care is appropriate to the scope of the emergency care provided by the hospital. (The hospital may have a protocol/policy on what is to be done for those patients presenting to the emergency room who are not classified as emergencies in accordance with hospital definition.) (C) Determine that there is a transfer procedure for those patients that require treatment that the hospital does not provide. Verify that the procedure includes notification requirements to the receiving hospital, and medical record/test result transfer requirements, as specified by federal law.
A1518	(3) Integration with other hospital services.	(b)(3) Verify that there are established procedures to assure integration with other hospital services to provide continuity of care.
A1520	(4) Laboratory and x-ray services available at all times.	(b)(4) Verify that these services are available in accordance with hospital policy and as required by the medical staff.
A1522	(5) Adequate qualified medical and nursing personnel available to meet the needs anticipated by the facility in accordance with 410 IAC 15-1.4-1 and 410 IAC 15-1.5-6, which includes, but is not limited to, the following: (A) A registered nurse on duty and available to patients presenting with an emergency condition, on a twenty-four (24) hours per day, seven (7) day per week basis.	(b)(5) Verify that there are sufficient medical and nursing personnel qualified in emergency care to meet written emergency procedures and needs anticipated by the facility and that there are specific assigned duties for emergency care personnel and a clear chain of command.  (A) Verify that there is an RN on duty in the hospital at all times who is available to the patients presenting with an emergency condition.  (B) Verify that there is a physician available to treat the patients who present with emergency conditions as outlined in the medical staff policies.

	(B) A physician available at all times in accordance with 410 IAC 15-1.4-1(d)(3) and attending to patients with an emergency condition.	
A1528	(6) A physician on-call roster available in the emergency service department which lists medical specialists in addition to scheduled medical staff.	(b)(6) Verify that there is a current physician on-call and duty roster, that it is available to the ER personnel and medical staff, and that it contains information necessary to contact the physicians listed.
A1530	(7) A patient control register. <i>(Indiana State Department of Health; 410 IAC 15-1.6-2; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1277; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i>	(b)(7) View the patient control register to determine that it is current and kept according to policy.
A1604	410 IAC 15-1.6-3 Nuclear medicine services Authority: IC 16-21-1-7 Affected: IC 16-21-1  Sec. 3. (a) If the hospital provides nuclear medicine services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice, and comply with applicable requirements of 410 IAC 15-1.5-9.	(a) Verify through review of policies, procedures, other documentation and interview of nuclear medicine personnel that the organization of the service reflects the extent and complexity of services provided, as specified by the medical staff. Verify that the service has complied with the appropriate Federal requirements by reviewing the hospital's permit. <ul style="list-style-type: none"> <li>▪ Determine that there is a director who is a physician qualified in nuclear medicine.</li> <li>▪ Verify that the qualifications, training, functions, and responsibilities of nuclear medicine personnel are specified by the service director and approved by the medical staff.</li> <li>▪ Verify that nuclear medicine services are ordered by a practitioner whose scope of Federal or State licensure allow such referrals.</li> <li>▪ Verify that the reports of nuclear medicine interpretations are authenticated and dated by practitioners authorized by the medical staff to perform these interpretations.</li> </ul>
A1608	(b) Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice, and federal and state law, as follows: (1) In-house preparation of radio-pharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or physician.	(b) Review the policies and other records to determine that standards are established. (b)(1) Verify that the preparation of radio-pharmaceuticals is performed or directly supervised by an appropriately trained pharmacist or physician.
A1610	(2) There is proper storage and disposal of radioactive material.	(b)(2) Verify through inspection and records that radioactive materials are properly disposed of or properly stored.
A1612	(3) If clinical laboratory tests are performed in the nuclear medicine service, the service shall meet the requirements for laboratory services, in this article, with respect to the following: (A) Management. (B) Adequacy of facilities. (C) Proficiency testing. (D) Quality control.	(b)(3) Verify that nuclear medicine clinical lab testing is certified for CLIA either under the hospital lab certification or has a separate CLIA certificate. [To be under the hospital certificate, testing must be performed on the same campus (i.e., a few miles) and be under the same director as the hospital lab.] Determine that any deficiencies cited at the last CLIA survey have been addressed appropriately.
A1618	(c) Equipment and supplies shall: (1) be appropriate for the types of nuclear medicine services offered;	(c) Observe the equipment and supplies for compliance with requirements. (c)(1) Verify that reagents are labeled to assure proper identification, use, storage and safe handling and date of preparation and assay.
A1620	(2) be maintained in safe operating condition; and	(c)(2) Verify that the service has a preventive maintenance schedule which is followed to assure proper and safe

		equipment performance.
A1622	(3) be inspected, tested, and calibrated at least annually by qualified personnel.	(c)(3) Verify that records of calibration and accuracy of test equipment are reviewed to assure patient safety and adequate test performance. Determine that all safety survey equipment is calibrated annually. Verify that equipment for radionuclide measurements are assured to be in proper operating condition to assure accurate results and patient safety each day of use.
A1624	(d) The hospital shall maintain the following: (1) Signed and dated reports of nuclear medicine interpretations, consultation, and procedures in accordance with applicable requirements of 410 IAC 15-1.5-9(e).	(d) Determine that the policies cover the maintenance of reports and records as required.  (d)(1) Verify that the hospital has policies for maintaining authenticated and dated nuclear medicine reports.
A1628	(2) Records of the receipt and disposition of radio-pharmaceuticals in accordance with federal and state rules.  <i>(Indiana State Department of Health; 410 IAC 15-1.6-3; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1277; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i>	(d)(2) Verify that there are accurate records maintained regarding the receipt and disposition of radio-pharmaceuticals.
A1704	410 IAC 15-1.6-4 Outpatient care services Authority: IC 16-21-1-7 Affected: IC 16-21-1 Sec. 4. (a) If the hospital provides outpatient care services, the service shall meet the needs of the patients, within the scope of the service offered, in accordance with acceptable standards of practice. The service shall be under the direction of a qualified person or persons.	(a) Tour the facilities and determine that they are adequate to provide examinations, diagnostic tests and treatment regimens that meet acceptable standards of practice.
A1706	(b) Outpatient care services shall be appropriately organized and integrated with inpatient services, as follows: (1) Assign a qualified registered nurse to supervise the nursing care in outpatient care services. (2) Have appropriate personnel available. (3) Ensure a record is maintained in accordance with 410 IAC 15-1.5-4 and hospital policy.	(b) Verify that the outpatient services are organized to provide the type of care needed by the patients presenting themselves for care. Verify that there are established methods of communication as well as established procedures to assure integration with inpatient services that provide continuity of care. (b)(1) Determine that there is an RN designated to supervise the nursing care. (b)(2) Determine by comparing duty rosters to patient log that sufficient practitioners, nurses and other staff are available to provide appropriate care. (b)(3) Verify that the information required by regulation and hospital policy is contained in the out-patient care record. In addition, during your review of medical records determine that the in-patient records of out-patients who were admitted contain pertinent information from the out-patient care record.

A1714	<p>(c) Outpatient care services may include, but are not limited to, the following:</p> <ol style="list-style-type: none"> <li>(1) Observation care.</li> <li>(2) Ambulatory care.</li> <li>(3) Other care programs designated by the hospital.</li> </ol> <p><i>(Indiana State Department of Health; 410 IAC 15-1.6-4; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>(c) Review the scope of service to determine the following:</p> <p>(c)(1) Determine if observation care is provided. (“Observation” is the periodic monitoring of a patient, on hospital premises, by a hospital’s nursing or other staff under the supervision of an RN, to evaluate an out-patient’s condition and need for admission.) Determine that records are maintained in accordance with 410 IAC 15-1.5-4(g).</p> <p>(c)(2) When ambulatory care is provided verify that it complies with the appropriate in-patient regulations for that service.</p> <ul style="list-style-type: none"> <li>▪ If the out-patient ambulatory surgical service is provided verify that it complies with the appropriate in-patient regulations for that service.</li> <li>▪ If the ambulatory care service provided is a “clinic”, i.e., Arthritis Clinic, Eating Disorder Clinic, etc., determine that the clinic complies with the appropriate requirements of these rules, the hospital policies, and acceptable standards of practice.</li> <li>▪ If the ambulatory care service provided is testing only, determine that: <ul style="list-style-type: none"> <li>▪ the test is ordered in accordance with the hospital policy;</li> <li>▪ the test report is made available in a timely manner to the ordering practitioner or authorized individual per medical staff/hospital policy; and</li> <li>▪ the documentation is maintained in accordance with hospital policy.</li> </ul> </li> </ul> <p>(c)(3) Review the other provided services for compliance with regulations and hospital policies.</p>
A1804	<p><b>410 IAC 15-1.6-5 Psychiatric services</b>  Authority: IC 16-21-1-7  Affected: IC 12-22-2-3; IC 16-21-1</p> <p>Sec. 5. (a) If the hospital provides psychiatric services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice.</p>	<p>(a) Review the policies to determine that the service is organized, staffed and equipped to ensure the health and safety of the patients who are presented for treatment within the scope of the service offered.</p> <ul style="list-style-type: none"> <li>▪ If the services are provided under contract, determine that they are provided in accordance with the terms of the contract and state rules and regulations.</li> </ul>
A1806	<p>(b) The service shall be under the direction of a physician qualified by training or experience.</p>	<p>(b) Determine that the physician has the qualifications as specified by the medical staff or federal regulations if the service is an excluded unit.</p>
A1808	<p>(c) The service shall be staffed in accordance with hospital policies and with applicable state and federal rules.</p>	<p>(c) Review the staffing to determine if there are sufficient trained staff to meet the needs of the patients based on severity and scope of care. If the service is an excluded unit verify that the staffing is in accordance with federal regulations.</p>
A1810	<p>(d) If the service provided includes a psychiatric unit exempt from the Medicare prospective payment system, it shall comply with 42 CFR Part 412, Subpart B, section 412.25 and CFR Part 412, Subpart B, section 412.27 for the purposes of licensure.</p>	<p>(d) If the service is a Medicare/Medicaid excluded unit, determine that the unit complies with the appropriate Medicare/Medicaid regulations and guidelines.</p>
A1812	<p>(e) If the service provided includes a subacute short term stabilization program provided in a group home setting as provided for in IC 12-22-2-3, this article will apply with the exception of 410 IAC 15-1.5-8. <i>(Indiana State Department of Health; 410 IAC 15-1.6-5; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>(e) Review the policies for the group home program. Survey the site and determine compliance.</p>



A1904	<p>410 IAC 15-1.6-6 Rehabilitation services  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 6. (a) If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, speech pathology, or other therapy services, the service shall meet the needs of the patients served, within the scope of the service offered, in accordance with acceptable standards of practice.</p>	<p>(a) Review the policies for the service(s) provided and determine that the service(s) is organized, staffed and equipped to ensure the health and safety of the patients who are presented for treatment within the scope of the service offered.</p> <ul style="list-style-type: none"> <li>▪ Verify that the service(s) has the equipment and facilities required to provide the range of services necessary in the treatment of the types of physical disabilities, speech-language and hearing disorders accepted for the service.</li> <li>▪ Determine that services are provided through the use of appropriate modalities and techniques;</li> <li>▪ If the services are provided under contract, determine that they are provided in accordance with the terms of the contract and state rules and regulations.</li> </ul>
A1906	<p>(b) The services shall be under the direction of a physician qualified by training or experience and supervised by a qualified person or persons.</p>	<p>(b) Verify that the service(s) is under the direction of a qualified physician approved by the medical staff who has the knowledge and experience and is supervised by a person qualified to supervise and administer the services.</p>
A1908	<p>(c) Available services shall be provided on the written request of individuals and practitioners allowed by law to order such services and as authorized by the governing body, and furnished in accordance with a written plan of treatment, if appropriate.</p>	<p>(c) Determine that treatments are provided in accordance with the written orders of practitioners or individuals in accordance with hospital policy. Determine that there is a policy for patient assessment and provision of treatment based on a written plan of treatment, if appropriate.</p>
A1910	<p>(d) The services shall have appropriate personnel available.</p>	<p>(d) Determine that the service is staffed with currently licensed, certified, or registered therapists, and assistants, and supportive personnel in sufficient numbers to provide for the needs of the patients.</p>
A1912	<p>(e) If the services provided include an inpatient rehabilitation unit or the hospital itself is exempt from the Medicare prospective payment system, it shall comply with 42 CFR Part 412, Subpart B, section 412.25, 42 CFR Part 412, Subpart B, section 412.29, and 42 CFR Part 412, Subpart B, section 412.30 for purposes of licensure. <i>(Indiana State Department of Health; 410 IAC 15-1.6-6; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	<p>(e) If the in-patient unit is a Medicare/Medicaid excluded unit or the hospital is Medicare/Medicaid DRG exempt, review in accordance with current federal Medicare/Medicaid certification regulations.</p>
A2004	<p>410 IAC 15-1.6-7 Respiratory care services  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 7. (a) If the hospital provides respiratory care services, the service shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.</p>	<p>(a) Review the policies and the scope of the diagnostic and therapeutic service offered and determine that they are appropriate to meet the needs of the patients and in accordance with acceptable standards of practice.</p>
A2006	<p>(b) The service shall be under the direction of a physician who is a pulmonologist or a physician qualified by training or experience, and supervised by a qualified person.</p>	<p>(b) Review the records to verify compliance. Verify that the medical director is a physician qualified in accordance with regulations and approved by the medical staff. Verify that the chief Therapist/Director is currently certified or licensed in accordance with statute or qualified as required by hospital and medical staff.</p>

A2012	(c) The respiratory care service shall meet the following requirements: (1) Have certified respiratory care practitioners or other personnel who meet the qualifications specified by the medical staff.	(c) Review the policies and documentation.  (c)(1) Determine that the service is staffed with currently licensed, certified, or registered therapists, and assistants, and supportive personnel in sufficient numbers to provide for the needs of the patients.
A2016	(2) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.	(c)(2) Verify that specific procedures are performed by personnel with documented qualifications to perform those procedures and that they are supervised in accordance with hospital policies.
A2018	(d) Respiratory care services shall be: (1) delivered in accordance with medical staff directives;	(d) Examine a sampling of the records of patients for whom respiratory care has been ordered. (d)(1) Review the policies. As appropriate to the service provided, determine that these services are delivered in accordance with current standards of practice.
A2022	(2) documented in the medical record; and	(d)(2) Verify that the medical record contains the documentation required.
A2024	(3) provided only on the orders of a physician or appropriately credentialed practitioner.	(d)(3) Verify that services are provided only on the orders of a practitioner with appropriate credentials and that services are provided in accordance with those orders.
A2026	(e) If blood gases or other clinical laboratory tests are performed by the respiratory care service, 410 IAC 15-1.5-3 applies. ( <i>Indiana State Department of Health; 410 IAC 15-1.6-7; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1278; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234</i> )	(e) Determine that the service complies with the requirement of Laboratory services with respect to management, adequacy of facilities, proficiency testing, quality control and other applicable requirements.
A2104	410 IAC 15-1.6-8 Surgical services Authority: IC 16-21-1-7 Affected: IC 16-21-1  Sec. 8. (a) If the hospital provides inpatient or ambulatory surgical services, the services shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice and safety.	(a) Tour the in-patient and out-patient operative suites. Verify that the surgical suite is a segregated unit with safeguards against unrelated traffic. Determine: <ul style="list-style-type: none"> <li>▪ That access to the operative and recovery area is limited to authorized personnel.</li> <li>▪ The conformance to aseptic technique by all individuals in the surgical area.</li> <li>▪ That there is appropriate cleaning between surgical cases.</li> <li>▪ 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 hospital policy.</li> <li>▪ That equipment is available for rapid and routine sterilization of operating room materials.</li> <li>▪ 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 facility has adopted Event Related Sterility. (Event Related Sterility involves unlimited shelf time, so long as there are no “event related” incidents which could compromise the integrity of the package. This program must be reflected in the policies and procedures.)</li> <li>▪ That if out-patient or ambulatory surgical services are offered, the services shall be consistent in quality with the in-patient surgical care, in accordance with hospital policy and the complexity of the services offered.</li> </ul>
A2106	(b) The organization of the surgical services shall be appropriate, according to the scope of the services offered, as follows: (1) The surgical service shall be under the direction of a physician qualified by experience and training.	(b) Review the hospital’s organizational chart displaying the relationship of the surgical service to other services. Confirm that the chart indicates lines of authority and delegation of responsibility within the service.  (b)(1) Verify that a physician is assigned the responsibility of the surgical service.

A2110	<p>(2) An experienced registered nurse shall supervise all nursing personnel in surgical services and post-anesthesia care units (PACU), as follows:</p> <p>(A) Licensed practical nurses, operating room technicians (ORTs), obstetrical technicians (OB Techs), and surgical technologists may serve as scrub personnel under the supervision of a qualified registered nurse.</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 written medical staff policies and procedures.</p>	<p>(b)(2) Verify that an RN is assigned responsibility for supervision of the nursing personnel in the surgical and post anesthesia care units and that he/she is experienced in the management of surgical services.</p> <p>(A) Determine that an RN is available for supervision in the service. Verify qualifications of surgical personnel (random sample).</p> <p>(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 LPNs 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, Laser operation, Lithotripsy, etc., is maintained and available.</p>
A2116	<p>(c) Surgical services shall have policies governing surgical care designed to assure the achievement and maintenance of standards of medical practice and patient care, as follows:</p> <p>(1) A mechanism shall be maintained which specifies the delineated surgical privileges of each practitioner.</p>	<p>(c) 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"> <li>▪ aseptic surveillance and practice, including scrub techniques;</li> <li>▪ identification of infected and non-infected cases;</li> <li>▪ housekeeping requirements/procedures;</li> <li>▪ explosive/flammable anesthetic agent use;</li> <li>▪ patient care requirements, i.e., pre-operative work-up, patient consents and releases, clinical procedures, safety practices, patient identification procedures;</li> <li>▪ duties of scrub and circulating nurse;</li> <li>▪ safety practices;</li> <li>▪ personnel policies unique to the O.R.;</li> <li>▪ resuscitative techniques;</li> <li>▪ care of surgical specimens;</li> <li>▪ tissue review, including macro &amp; micro requirements;</li> <li>▪ sterilization and disinfection procedures;</li> <li>▪ acceptable operating room attire;</li> <li>▪ 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).</li> </ul> <p>(c)(1) 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, file, electronic or other system as long as it is readily available and current.</p>
A2120	<p>(2) There shall be a history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there shall be a statement to that effect and an admission note in the chart by the admitting physician, which includes vital signs,</p>	<p>(c)(2) Review a minimum of six random surgical patient records to determine that a complete history and physical examination by a physician is completed, in accordance with policy, prior to surgery, except in an emergency.</p>

	allergies, and appropriate data.	
A2122	(3) A properly executed informed consent form for the operation shall be in the patient's chart before surgery, except in extreme emergencies.	(c)(3) Review a minimum of six random surgical patient records to verify that they contain consent forms. Determine that a complete consent form contains at least the following information: Name of patient; hospital and patient identification number; name of procedure(s) or operation; name of practitioner(s); signature of patient or or legal guardian; date and time consent is obtained; signature and professional designation or person witnessing consent.
A2124	(4) The following equipment shall be available to the operating room suites and PACU: (A) Cardiac monitor. (B) Resuscitation equipment. (C) Defibrillator. (D) Aspirator. (E) Oximeter. (F) Tracheotomy set.	(c)(4) Determine that the required equipment is available.
A2132	(5) There shall be adequate provision for immediate postoperative care.	(c)(5) Verify that the hospital has provisions for post-operative care. The post-operative care unit (PACU) or recovery room is a separate area of the hospital. Access is limited to authorized personnel. Determine if an emergency cart and defibrillator are immediately available to the PACU. Determine that there are policies and procedures which govern the PACU that include but are not limited to: (1) specifying the transfer requirements to and from the PACU; (2) depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the PACU should include some of the following; level of activity; respirations; blood pressure; level of consciousness; patient color. If patients are not transferred to the PACU, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation in the patient's room.
A2134	(6) The operating room register shall be complete and up-to-date.	(c)(6) Review the register to see that it includes at least: the patient's name; the patient's hospital identification number; date of operation; inclusive or total time of the operation; name of the surgeon and any assistant(s); name of nursing personnel (scrub and circulating); type of anesthesia used and name of person administering it; and the operation performed.
A2136	(7) An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and authenticated by the surgeon.	(c)(7) Review a minimum of six random medical records and verify that the operative report is dated and authenticated and includes: name and hospital 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; complications, if any; a description of techniques, findings, and the tissues removed or altered; and prosthetic devices or implants used, if any.
A2138	(8) A list of tissues excluded from microscopic examination, if applicable, shall be maintained in surgery services.	(c)(8) 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.
A2140	(9) There shall be no explosive anesthetic agents, flammable, or potentially flammable, liquids or agents stored or used in the surgical services area. <i>(Indiana State Department of Health; 410 IAC 15-1.6-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1279; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i>	(c)(9) Verify that there are no flammable, explosive or potentially flammable liquids or agents stored or used.

A2204	<p>410 IAC 15-1.6-9 Other services  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 9. (a) If the hospital provides other services not covered in specific sections of this article, the service shall meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.</p>	<p>(a) Any service that the hospital provides that is not included by the hospital under a specific section of these rules would fall under this section. These services could include but are not limited to the following:</p> <ol style="list-style-type: none"> <li>(1) angioplasty and cardiac catheterization laboratory;</li> <li>(2) eating disorder clinic;</li> <li>(3) endoscopy;</li> <li>(4) lithotripsy;</li> <li>(5) oncology clinic;</li> <li>(6) stress testing;</li> <li>(7) wellness clinic;</li> </ol> <p>If the service provided is testing only, determine:</p> <ol style="list-style-type: none"> <li>(A) That the tests are ordered in accordance with the hospital policy;</li> <li>(B) That the test report is made available in a timely manner to the ordering practitioner; and</li> <li>(C) That the documentation is in accordance with hospital policy.</li> </ol>
A2206	(b) The services shall be under the direction of a qualified person or persons.	(b) Determine that the director is qualified as specified by hospital policy and Medical staff rules. If a physician director, verify the Medical staff appointment.
A2208	(c) The services shall be staffed in accordance with written hospital policies and comply with the applicable state and federal rules. <i>(Indiana State Department of Health; 410 IAC 15-1.6-9; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1279; errata filed Feb 23, 1995, 2:00 p.m.: 18 IR 1837; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i>	(c) Determine that there is enough staff to provide the service. Verify that the staff is qualified in accordance with hospital policy.
<b>Rule 1.7. Incorporation by Reference</b>		
	<p>410 IAC 15-1.7-1 Incorporation by reference  Authority: IC 16-21-1-7  Affected: IC 16-21-1</p> <p>Sec. 1. (a) When used in this article, references to the following publications shall mean the version of that publication listed below. The following publications are hereby incorporated by reference:</p> <ol style="list-style-type: none"> <li>(1) Guidelines for Construction and Equipment of Hospital and Medical Facilities (2001 Edition). Copies are available from the American Institute of Architects, 1735 New York Ave. Northwest, Washington, D.C. 20006.</li> <li>(2) Bulletin S.E. 13, "On-site Water Supply and Waste-water Disposal for Public and Commercial Establishments" (1988 Edition). Copies are available from the Indiana State Department of Health, 1330 West Michigan Street, P.O. Box 1964, Indianapolis, IN 46206-1964.</li> <li>(3) National Fire Protection Association (NFPA) 99, Health Care Facilities (1993 Edition). Copies may be</li> </ol>	<p>Correct Address:  Indiana State Department of Health  2 N. Meridian Street  Indianapolis, IN 46204</p>

<p>obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9904.</p> <p>(4) National Fire Protection Association (NFPA) 101, Life Safety Code Handbook (2000 Edition). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9904.</p> <p>(5) National Committee on Radiation Protection (NCRP) Reports, Number 49, “Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up to 10 MeV”, (September 15, 1976 Edition). Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.</p> <p>(6) National Committee on Radiation Protection (NCRP) Reports, Number 102, “Medical X-ray, Electron Beam and Gamma Ray Protection for Energies Up to 50 MeV (Equipment Design, Performance and Use)”, (June 30, 1989 Edition). Copies may be obtained from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Washington, D.C. 20014.</p> <p>(7) 42 CFR Part 412, Subpart B, section 412.25, 42 CFR Part 412, Subpart B, section 412.27, 42 CFR Part 412, Subpart B, section 412.29, 42 CFR Part 412, Subpart B, section 412.30 (October 1, 1993 Edition).</p> <p>(8) 42 CFR Part 493 (October 1, 1993 Edition).</p> <p>(9) 21 CFR Part 606 (April 1, 1994 Edition).</p> <p>(10) 21 CFR Part 640 (April 1, 1994 Edition).</p> <p>(b) Federal rules which have been incorporated by reference do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. All incorporated material is available for public review at the Indiana State Department of Health. <i>(Indiana State Department of Health; 410 IAC 15-1.7-1; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1280; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)</i></p>	
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