

SUBCHAPTER 13C – LICENSING OF AMBULATORY SURGICAL FACILITIES

SECTION .0100 – GENERAL

10A NCAC 13C .0101 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13C .0102 RESERVED FOR FUTURE CODIFICATION

10A NCAC 13C .0103 DEFINITIONS

In addition to the terms defined in G.S. 131E-214.13, the following terms shall apply throughout this Subchapter, unless the context clearly requires otherwise:

- (1) "Adequate" means, when applied to various areas of services, that the services are satisfactory in meeting a referred to need when measured against professional standards of practice.
- (2) "AAAASF" means American Association for Accreditation of Ambulatory Surgery Facilities.
- (3) "AAAHHC" means Accreditation Association for Ambulatory Health Care.
- (4) "Ancillary nursing personnel" means persons employed to assist registered nurses or licensed practical nurses in the care of patients.
- (5) "Anesthesiologist" means a physician whose specialized training and experience qualify him or her to administer anesthetic agents and to monitor the patient under the influence of these agents. For the purpose of this Subchapter, the term "anesthesiologist" shall not include podiatrists.
- (6) "Anesthetist" means a physician or dentist qualified, as defined in Items (10) and (24) of this Rule, to administer anesthetic agents or a registered nurse qualified, as defined in Items (25) and (27) of this Rule, to administer anesthesia.
- (7) "Authority having jurisdiction" means the Division of Health Service Regulation.
- (8) "Chief executive officer" or "administrator" means a qualified person appointed by the governing authority to act in its behalf in the overall management of the facility and whose office is located in the facility.
- (9) "Current Procedural Terminology (CPT)" means a medical code set developed by the American Medical Association.
- (10) "Dentist" means a person who holds a valid license issued by the North Carolina Board of Dental Examiners to practice dentistry.
- (11) "Department" means the North Carolina Department of Health and Human Services.
- (12) "Director of nursing" means a registered nurse who is responsible to the chief executive officer or administrator and has the authority and direct responsibility for all nursing services and nursing care for the entire facility at all times.
- (13) "Financial assistance" means a policy, including charity care, describing how the organization will provide assistance at its facility. Financial assistance includes free or discounted health services provided to persons who meet the organization's criteria for financial assistance and are unable to pay for all or a portion of the services. Financial assistance does not include:
 - (a) bad debt;
 - (b) uncollectable charges that the organization recorded as revenue but wrote off due to a patient's failure to pay;
 - (c) the cost of providing such care to the patients in Sub-Item (13)(b) of this Rule; or
 - (d) the difference between the cost of care provided under Medicare or other government programs, and the revenue derived therefrom.
- (14) "Governing authority" means the individual, agency, group, or corporation appointed, elected, or otherwise designated, in which the ultimate responsibility and authority for the conduct of the ambulatory surgical facility is vested.
- (15) "Healthcare Common Procedure Coding System (HCPCS)" means a three tiered medical code set consisting of Level I, II and III services and contains the CPT code set in Level I.
- (16) "JCAHO" or "Joint Commission" means Joint Commission on Accreditation of Healthcare Organizations.
- (17) "Licensing agency" means the Department of Health and Human Services, Division of Health Service Regulation.
- (18) "Licensed practical nurse (L.P.N.)" means any person licensed as such under the provisions of G.S. 90-171.20(8).
- (19) "Nursing personnel" means registered nurses, licensed practical nurses, and ancillary nursing personnel.
- (20) "Operating room" means a room in which surgical procedures are performed.

- (21) "Patient" means a person admitted to and receiving care in a facility.
- (22) "Person" means an individual, a trust or estate, a partnership or corporation, including associations, joint stock companies and insurance companies; the State, or a political subdivision or instrumentality of the state.
- (23) "Pharmacist" means a person who holds a valid license issued by the North Carolina Board of Pharmacy to practice pharmacy in accordance with G.S. 90-85.3A.
- (24) "Physician" means a person who holds a valid license issued by the North Carolina Medical Board to practice medicine. For the purpose of carrying out these Rules, a "physician" may also mean a person holding a valid license issued by the North Carolina Board of Podiatry Examiners to practice podiatry.
- (25) "Qualified person," when used in connection with an occupation or position, means a person:
 - (a) who has demonstrated through experience the ability to perform the required functions; or
 - (b) who has certification, registration, or other professional recognition.
- (26) "Recovery area" means a room used for the post-anesthesia recovery of surgical patients.
- (27) "Registered nurse" means a person who holds a valid license issued by the North Carolina Board of Nursing to practice nursing as defined in G.S. 90-171.20(7).
- (28) "Surgical suite" means an area that includes one or more operating rooms and one or more recovery rooms.

*History Note: Authority G.S. 131E-149; 131E-214.13;
 Eff. October 14, 1978;
 Amended Eff. April 1, 2003; November 1, 1989;
 Temporary Amendment Eff. December 31, 2014;
 Amended Eff. September 30, 2015.*

SECTION .0200 - LICENSING PROCEDURES

10A NCAC 13C .0201 APPLICATION

(a) A person shall submit an application for a license to establish or maintain an ambulatory surgical facility to the Department in writing on the form provided by the Department. Each application shall contain all necessary and reasonable information that the Department may by rule require, including the following and other pertinent information the Department may deem appropriate to carry out its responsibilities for statistical data collection and long range health planning:

- (1) name of facility,
- (2) address of facility,
- (3) telephone number of facility,
- (4) names of owners,
- (5) names of operator and governing authority,
- (6) name of chief executive officer,
- (7) composition of medical and paramedical staff,
- (8) name of chief of staff,
- (9) director of nursing service,
- (10) number of operating rooms and recovery beds,
- (11) list of surgical procedures to be performed in facility,
- (12) qualification of persons responsible for anesthesia services,
- (13) information regarding use and storage of flammable anesthesia,
- (14) description of laboratory and pathology services,
- (15) name of hospital(s) with which transfer agreement has been made,
- (16) description of arrangements for emergency transportation of patients from the facility,
- (17) description of arrangements for food service, and
- (18) information regarding sanitation inspection and fire inspection.

(b) The person shall make application for a license for a new facility or for the renewal of a license for an existing facility. Applications for licensure for a new facility shall be submitted at least 120 days prior to opening.

(c) Any ambulatory surgical facility desiring licensure which is in operation at the time of promulgation of any applicable rules or regulations shall be given a reasonable time, not to exceed one year from the date of such promulgation, within which to comply with such rules and regulations.

History Note: Authority G.S. 131E-147; 131E-149;

Eff. October 14, 1978;
Amended Eff. November 1, 1989.

10A NCAC 13C .0202 REQUIREMENTS FOR ISSUANCE OF LICENSE

(a) Upon application for a license from a facility never before licensed, a representative of the Department shall make an inspection of that facility. Every building, institution, or establishment for which a license has been issued shall be inspected for compliance with the rules found in this Subchapter. An ambulatory surgery facility shall be deemed to meet licensure requirements if the ambulatory surgery facility is accredited by The Joint Commission (formerly known as "JCAHO"), AAAHC or AAAASF. Accreditation does not exempt a facility from statutory or rule requirements for licensure nor does it prohibit the Department from conducting inspections as provided in this Rule to determine compliance with all requirements.

(b) If the applicant has been issued a Certificate of Need and is found to be in compliance with the Rules found in this Subchapter, then the Department shall issue a license to expire on December 31 of each year.

(c) The Department shall be notified at the time of:

- (1) any change of the owner or operator;
- (2) any change of location;
- (3) any change as to a lease; and
- (4) any transfer, assignment, or other disposition or change of ownership or control of 20 percent or more of the capital stock or voting rights thereunder of a corporation that is the operator or owner of an ambulatory surgical facility, or any transfer, assignment, or other disposition of the stock or voting rights thereunder of such corporation that results in the ownership or control of more than 20 percent of the stock or voting rights thereunder of such corporation by any person.

A new application shall be submitted to the Department in the event of such a change or changes.

(d) The Department shall not grant a license until the plans and specifications that are stated in Section .1400 of this Subchapter, covering the construction of new buildings, additions, or material alterations to existing buildings are approved by the Department.

(e) The facility design and construction shall be in accordance with the licensure rules for ambulatory surgical facilities found in this Subchapter, the North Carolina State Building Code, and local municipal codes.

(f) Submission of Plans.

- (1) Before construction is begun, schematic plans and specifications and final plans and specifications covering construction of the new buildings, alterations, renovations, or additions to existing buildings shall be submitted to the Division for approval.
- (2) The Division shall review the plans and notify the licensee that said buildings, alterations, additions, or changes are approved or disapproved. If plans are disapproved the Division shall give the applicant notice of deficiencies identified by the Division.
- (3) The plans shall include a plot plan showing the size and shape of the entire site and the location of all existing and proposed facilities.
- (4) Plans shall be submitted in duplicate. The Division shall distribute a copy to the Department of Insurance for review of the North Carolina State Building Code requirements if required by the North Carolina State Building Code which is hereby incorporated by reference, including all subsequent amendments. Copies of the Code may be accessed electronically free of charge at http://www.ecodes.biz/ecodes_support/Free_Resources/2012NorthCarolina/12NorthCarolina_main.html.

(g) To qualify for licensure or license renewal, each facility shall provide to the Division, with its application, an attestation statement in a form provided by the Division verifying compliance with the requirements defined in Rule .0301(d) of this Subchapter.

History Note: Authority G.S. 131E-91; 131E-147; 131E-149; S.L. 2013-382, s. 13.1;
Eff. October 14, 1978;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014.

10A NCAC 13C .0203 SUSPENSION OR REVOCATION: AMBULATORY SURGICAL FACILITY

(a) The license may be suspended or revoked at any time for noncompliance with the regulations of the Department.

(b) Suspension or revocation of the license shall be covered by the rules regarding contested cases as found in 10 NCAC 3B .0200.

(c) Notwithstanding Subsection (a) and (b) of this Rule, the Department may summarily suspend the license pursuant to General Statute 150B-3(c).

*History Note: Authority G.S. 131E-148; 131E-149; 143B-165; 150B-3(c);
Eff. October 14, 1978;
Amended Eff. November 1, 1989.*

10A NCAC 13C .0204 TYPE OF FACILITY DEEMED TO BE LICENSED

An ambulatory surgical facility shall be deemed a suitable facility for the performance of abortions pursuant to G.S. 14-45.1(a).

*History Note: Authority G.S. 14-45.1; 131E-147; 131E-149;
Eff. June 30, 1980;
Amended Eff. November 1, 1989.*

10A NCAC 13C .0205 ITEMIZED CHARGES

(a) The facility shall either present an itemized list of charges to all discharged patients or include on patients' bills that are not itemized notification of the right to request an itemized bill within three years of receipt of the non-itemized bill or so long as the facility, collections agency, or other assignee asserts the patient has an obligation to pay the bill.

(b) If requested, the facility shall present an itemized list of charges to each patient or his or her representative. This list shall detail in language comprehensible to an ordinary layperson the specific nature of the charges or expenses incurred by the patient.

(c) The listing shall include each specific chargeable item or service in the following service areas:

- (1) Surgery (facility fee);
- (2) Anesthesiology;
- (3) Pharmacy;
- (4) Laboratory;
- (5) Radiology;
- (6) Prosthetic and Orthopedic appliances; and
- (7) Other professional services.

(d) The facility shall indicate on the initial or renewal license application that patient bills are itemized, or that each patient or his or her representative is formally advised of the patient's right to request an itemized listing within three years of receipt of a non-itemized bill.

*History Note: Authority G.S. 131E-91; 131E-147.1; S.L. 2013-382, s. 13.1;
Eff. December 1, 1991;
Temporary Amendment Eff. May 1, 2014;
Amended Eff. November 1, 2014.*

10A NCAC 13C .0206 REPORTING REQUIREMENTS

(a) The Department shall establish the lists of the statewide 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures performed in the ambulatory surgical facility setting to be used for reporting the data required in Paragraphs (c) and (d) of this Rule. The lists shall be determined annually based upon data provided by the certified statewide data processor. The Department shall make the lists available on its website. The methodology to be used by the certified statewide data processor for determining the lists shall be based on the data collected from all licensed facilities in the State in accordance with G.S. 131E-214.2 as follows:

- (1) the 20 most common imaging procedures shall be based upon all outpatient data for ambulatory surgical facilities and represent all occurrences of the diagnostic radiology imaging codes section of the CPT codes, then selecting the top 20 to be provided to the Department; and
- (2) the 20 most common outpatient surgical procedures shall be based upon the primary procedure code from the ambulatory surgical facilities and represent all occurrences of the surgical codes section of the CPT codes, then selecting the top 20 to be provided to the Department.

(b) All information required by this Rule shall be posted on the Department's website at: <http://www.ncdhhs.gov/dhsr/ahc> and may be accessed at no cost.

(c) In accordance with G.S. 131E-214.13, all licensed ambulatory surgical facilities shall report the data required in Paragraph (d) of this Rule related to the statewide 20 most common outpatient imaging procedures and the statewide 20 most common outpatient surgical procedures to the certified statewide data processor in a format provided by the certified statewide processor. This report shall include the related primary CPT and HCPCS codes. Commencing with the reporting period ending September 30, 2015, an annual data report shall be submitted. Each annual report shall be submitted by January 1.

(d) The report as described in Paragraph (c) of this Rule shall be specific to each reporting ambulatory surgical facility and shall include:

- (1) the average gross charge for each CPT code or procedure without a public or private third party payer source;
- (2) the average negotiated settlement on the amount that will be charged for each CPT code or procedure as required for patients defined in Subparagraph (d)(1) of this Rule. The average negotiated settlement shall be calculated using the average amount charged all patients eligible for the facility's financial assistance policy, including self-pay patients;
- (3) the amount of Medicaid reimbursement for each CPT code or procedure, including all supplemental payments to and from the ambulatory surgical facility;
- (4) the amount of Medicare reimbursement for each CPT code or procedure; and
- (5) on behalf of patients who are covered by a Department of Insurance licensed third-party and teachers and State employees, the lowest, average, and highest amount of payments made for each CPT code or procedure by each of the facility's top five largest health insurers.
 - (A) each ambulatory surgical facility shall determine its five largest health insurers based on the dollar volume of payments received from those insurers;
 - (B) the lowest amount of payment shall be reported as the lowest payment from each of the five insurers on the CPT code or procedure;
 - (C) the average amount of payment shall be reported as the arithmetic average of each of the five health insurers payment amounts;
 - (D) the highest amount of payment shall be reported as the highest payment from each of the five insurers on the CPT code or procedure; and
 - (E) the identity of the top five largest health insurers shall be redacted prior to submission.

(e) The data reported, as defined in Paragraphs (c) and (d) of this Rule, shall reflect the payments received from patients and health insurers for all closed accounts. For the purpose of this Rule, "closed accounts" are patient accounts with a zero balance at the end of the data reporting period.

(f) A minimum of three data elements shall be required for reporting under Paragraph (c) of this Rule.

(g) The information submitted in the report shall be in compliance with the federal Health Insurance Portability and Accountability Act of 45 CFR Part 164.

(h) The Department shall provide all specific ambulatory surgical facility data reported pursuant to this Rule on its website.

*History Note: Authority G.S. 131E-147.1; 131E-214.4; 131E-214.13;
Temporary Adoption Eff. December 31, 2014;
Eff. September 30, 2015;
Temporary Amendment Eff. March 31, 2016;
Amended Eff. January 31, 2017.*

SECTION .0300 – GOVERNING AUTHORITY MANAGEMENT

10A NCAC 13C .0301 GOVERNING AUTHORITY

(a) The facility's governing authority shall adopt bylaws or other operating policies and procedures to assure that:

- (1) a named individual is identified who is responsible for the overall operation and maintenance of the facility. The governing authority shall have methods in place for the oversight of the individual's performance;
- (2) at least annual meetings of the governing authority are conducted if the governing authority consists of two or more individuals. Minutes shall be maintained of such meetings;
- (3) a policy and procedure manual is created that is designed to ensure professional and safe care for the patients. The manual shall be reviewed annually and revised when necessary. The manual shall include provisions for administration and use of the facility, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies and services offered; and

- (4) annual reviews and evaluations of the facility's policies, management, and operation are conducted.
- (b) When services such as dietary, laundry, or therapy services are purchased from others, the governing authority shall be responsible to assure the supplier meets the same local and state standards the facility would have to meet if it were providing those services itself using its own staff.
- (c) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.
- (d) The governing authority shall establish written policies and procedures to assure billing and collection practices in accordance with G.S. 131E-91. These policies and procedures shall include:
- (1) a financial assistance policy as defined in G.S. 131E-214.14(b)(3);
 - (2) how a patient may obtain an estimate of the charges for the statewide 20 most common outpatient imaging procedures and 20 most common outpatient surgical procedures based on the primary Current Procedure Code (CPT). The policy shall require that the information be provided to the patient in writing, either electronically or by mail, within three business days;
 - (3) how a patient or patient's representative may dispute a bill;
 - (4) issuance of a refund within 45 days of the patient receiving notice of the overpayment when a patient has overpaid the amount due to the facility;
 - (5) providing written notification to the patient or patient's representative, at least 30 days prior to submitting a delinquent bill to a collections agency;
 - (6) providing the patient or patient's representative with the facility's charity care and financial assistance policies, if the facility is required to file a Schedule H, federal form 990;
 - (7) the requirement that a collections agency, entity, or other assignee obtain written consent from the facility prior to initiating litigation against the patient or patient's representative;
 - (8) a policy for handling debts arising from the provision of care by the ambulatory surgical facility involving the doctrine of necessities, in accordance with G.S. 131E-91(d)(5); and
 - (9) a policy for handling debts arising from the provision of care by the ambulatory surgical facility to a minor, in accordance with G.S. 131E-91(d)(6).

History Note: Authority G.S. 131E-91; 131E-147.1; 131E-149; 131E-214.13(f); 131E-214.14; S.L. 2013-382, s. 10.1; S.L. 2013-382, s. 13.1;
 Eff. October 14, 1978;
 Amended Eff. November 1, 1989; November 1, 1985; December 24, 1979;
 Temporary Amendment Eff. May 1, 2014;
 Amended Eff. November 1, 2014.

10A NCAC 13C .0302 CHIEF EXECUTIVE OFFICER OR ADMINISTRATOR

- (a) The governing authority shall appoint a qualified person as chief executive officer of the facility to represent the governing authority and shall define his authority and duties in writing. He shall be responsible for the management of the facility, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these regulations.
- (b) The chief executive officer shall designate, in writing, a qualified person to act in his behalf during his absence. In the absence of the chief executive officer, the person on the grounds of the facility who is designated by the chief executive officer to be in charge of the facility shall have reasonable access to all areas in the facility related to patient care and to the operation of the physical plant.
- (c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the facility shall notify the Department.

History Note: Authority G.S. 131E-149;
 Eff. October 14, 1978.

10A NCAC 13C .0303 ADMINISTRATIVE RECORDS

- (a) The following essential documents and references shall be on file in the administrative office of the facility:
- (1) appropriate documents evidencing control and ownerships, such as deeds, leases, or corporation or partnership papers;
 - (2) bylaws of policies and procedures of the governing authority;
 - (3) minutes of the governing authority meetings if applicable;

- (4) minutes of the facility's professional and administrative staff meetings;
 - (5) a current copy of these regulations;
 - (6) reports of inspections, reviews, and corrective actions taken related to licensure; and
 - (7) contracts and agreements related to licensure to which the facility is a party.
- (b) All operating licenses, permits and certificates shall be appropriately displayed on the licensed premises.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .0304 SURGICAL PROCEDURES PERFORMED

A current listing of all types of surgical procedures offered by the facility shall be available.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .0305 PERSONNEL

(a) Personnel Records

- (1) A record of each employee shall be maintained which includes the following:
 - (A) employee's identification;
 - (B) resume of education and work experience;
 - (C) verification of valid license (if required), education, training, and prior employment experience; and
 - (D) verification of references.
- (2) Personnel records shall be confidential.
- (3) Notwithstanding the requirement found in Subparagraph (a)(2) of this Rule, representatives of the Department conducting an inspection of the facility shall have the right to inspect personnel records.

(b) Job Descriptions

- (1) Every position shall have a written description which adequately describes the duties of the position.
- (2) Each job description shall include position title, authority, specific responsibilities and minimum qualifications. Qualifications shall include education, training, experience, special abilities and license or certification required.
- (3) Job descriptions shall be reviewed annually, kept current and given to each employee when assigned to the position and whenever the job description is changed.

- (c) Orientation shall be provided to familiarize each new employee with the facility, its policies, and job responsibilities.
- (d) All persons having direct responsibility for patient care shall be at least 18 years of age. All other employees working in the facility shall be not less than 16 years of age.
- (e) The governing authority shall be responsible for insuring health standards for employees which are consistent with recognized professional practices for the prevention and transmission of communicable diseases.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. November 1, 1989; December 24, 1979.*

10A NCAC 13C .0306 QUALITY ASSURANCE

- (a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the facility. The program shall include the establishment of a committee which shall evaluate:
 - (1) appropriateness and necessity of surgical procedures performed, and
 - (2) compliance with facility procedure and policies.

The committee shall determine corrective action if indicated.

- (b) The committee shall consist of at least one physician or dentist (who is not an owner), the chief executive officer (or his designee), and other health professionals as indicated. There shall be at least one meeting of the committee quarterly.
- (c) The functions of the committee shall include development of policies for selection of patients, review of credentials for staff privileges, peer review, tissue review, establishment of infection control procedures, and approval of additional surgical procedures to be performed in the facility.
- (d) Records shall be kept of the activities of the committee. These records shall include as a minimum:

- (1) reports made to the governing authority;
 - (2) minutes of committee meetings including date, time, persons attending, description and results of cases reviewed, and recommendations made by the committee; and
 - (3) information on any corrective action taken.
- (e) Appropriate orientation, training or education programs shall be conducted as necessary to correct deficiencies which are uncovered as a result of the quality assurance program.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .0400 - MEDICAL AND SURGICAL SERVICES

10A NCAC 13C .0401 MEDICAL SERVICES

- (a) All patients admitted to the facility shall be under the direct care of a physician or dentist.
- (b) The facility shall have available an anesthetist and he or she shall be available to administer regional or general anesthesia.
- (c) Any patient undergoing general or regional anesthesia shall, prior to surgery, have a history and physical examination, relative to the intended procedure, performed by a licensed physician or a dentist who has successfully completed a postgraduate program in oral and maxillofacial surgery accredited by the American Dental Association. Results of the examination and the preoperative diagnosis shall be recorded in the patient's chart prior to surgery.
- (d) The attending physician and dentist, prior to surgery, shall obtain written, informed consent of the patient or legal guardian for surgery and shall record this in the patient's medical record.
- (e) The facility shall have the capability of obtaining blood and blood products to meet emergency situations.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. November 1, 1985.*

10A NCAC 13C .0402 SURGICAL SERVICES

- (a) The governing authority shall delineate surgical privileges for each physician and dentist performing surgery in accordance with criteria which it has established provided, however, that no physician or dentist may be given privileges to perform surgical procedures for which he or she does not have privileges to perform at the hospital with which the facility has a transfer agreement as provided in Paragraph (a) in Rule .0403 of this Section.
- (b) A roster of medical personnel having surgical and anesthesia privileges at the facility specifying the privileges and limitations of each, shall be readily obtainable by the person in charge of the surgical suite.
- (c) The administrator or his designee shall maintain a chronological register of all surgical procedures performed. This shall include type of procedure performed, type of anesthesia used, personnel participating, post operative diagnosis and any unusual or untoward occurrence.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. April 1, 2003.*

10A NCAC 13C .0403 EMERGENCY CASES

- (a) Each facility shall have a written plan for the transfer of emergency cases to a nearby hospital when hospitalization becomes necessary.
- (b) There shall be procedures, personnel and suitable equipment to handle medical emergencies which may arise in connection with services provided by the facility.
- (c) There shall be a written agreement between the facility and a nearby hospital to facilitate the transfer of patients who are in need of emergency care. A facility which has documentation of its efforts to establish such a transfer agreement with a hospital which provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .0500 - ANESTHESIA SERVICES

10A NCAC 13C .0501 PROVIDING ANESTHESIA SERVICES

Only a physician, dentist or qualified anesthetist shall administer anesthetic agents (general and regional). Podiatrists shall administer only local anesthesia. The governing authority shall establish written policies and procedures concerning the provision of anesthesia services, including the designation of those persons authorized to administer anesthetics.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .0502 EQUIPMENT

All equipment for the administration of anesthetics shall be readily available, kept clean or sterile, and maintained in good working condition.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .0503 POST ANESTHESIA NOTE

Patient's anesthesiologist or anesthetist shall write a post anesthetic follow-up note prior to the patient's discharge. The note shall include the general condition of the patient and any instructions to the patient pertaining to his care and protection.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .0504 REQUIREMENT OF PERSON TRAINED IN CPR

A person with training and experience in cardio-pulmonary resuscitation shall be on the premises of the facility until all surgical patients are discharged.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .0600 - PATHOLOGY SERVICES

10A NCAC 13C .0601 PROVISION FOR LABORATORY TESTS

(a) Each facility shall have the capability of providing or obtaining laboratory tests required in connection with the surgery to be performed.

(b) The governing authority shall establish written policies requiring examination by a pathologist of all surgical specimens except for those types of specimens which the governing authority has determined do not require examination.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .0602 DISPOSAL OF WASTE

Methods for the disposal of pathological waste, contaminated dressings and other similar material shall meet the approval of governing local and state authorities.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .0700 - RADIOLOGY SERVICES

10A NCAC 13C .0701 PROVISION FOR RADIOLOGY SERVICES

Each facility shall have the capability of providing or obtaining diagnostic radiology services in connection with the surgery to be performed.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .0702 REGULATIONS FOR PERFORMED SERVICES

Radiation protection shall be provided in accordance with the rules and regulations adopted by the Radiation Protection Commission found in 10 NCAC 3G, and the recommendations of the National Council on Radiation Protection and Measurements. Records shall be kept of at least annual checks and calibration of all ionizing radiation therapy equipment used in the facility.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .0800 - PHARMACEUTICAL SERVICES

10A NCAC 13C .0801 DRUG DISPENSING

The governing authority, with the advice of a registered pharmacist, shall assure that there are appropriate methods, procedures and controls for obtaining, dispensing, and administering drugs and biologicals.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .0802 REGULATIONS FOR DISPENSING

When the facility maintains its own pharmaceutical services, it shall comply with applicable regulations adopted by the North Carolina Board of Pharmacy pursuant to General Statute 90-62.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .0900 - NURSING SERVICES

10A NCAC 13C .0901 NURSING ADMINISTRATION

(a) The facility shall have an organized nursing Department under the supervision of a director of nursing who is currently licensed as a registered nurse and who has responsibility and accountability for all nursing services.

(b) The director of nursing shall be responsible and accountable to the chief executive officer for:

- (1) provision of nursing services to patients;
- (2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. December 24, 1979.*

10A NCAC 13C .0902 NURSING PERSONNEL

(a) An adequate number of licensed and ancillary nursing personnel shall be on duty to assure that staffing levels meet the total nursing needs of patients based on the number of patients in the facility and their individual nursing care needs.

(b) At least one registered nurse shall be in the facility during the hours it is in operation. Nursing personnel shall be assigned to duties consistent with their training and experience.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .1000 - MEDICAL RECORDS SERVICES

10A NCAC 13C .1001 MEDICAL RECORD SYSTEM

The facility shall maintain a medical record system designed to provide readily available information on each patient. The medical record system shall be under the supervision of a designated qualified person.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .1002 INDIVIDUAL PATIENT RECORDS

(a) Each patient's medical record shall be maintained in accordance with professional standards and shall include at least the following information:

- (1) patient's identification, including name, address, date of birth, next of kin and a patient number;
- (2) admitting diagnosis;
- (3) preoperative history and physical examination pertaining to the procedure to be performed;
- (4) anesthesia report;
- (5) surgeon's operative report;
- (6) anesthesiologist's or anesthetist's report if applicable;
- (7) pertinent laboratory, pathology and X-ray reports;
- (8) postoperative orders and follow-up care;
- (9) discharge summary, including discharge diagnosis;
- (10) record of informed consent; and
- (11) physician's, dentist's, and nurse's progress notes.

(b) The administrator shall be responsible for safeguarding information on the medical record against loss, tampering, or use by unauthorized persons.

(c) Medical records shall be the property of the facility and shall not be moved from the premises wherein they are filed except by subpoena or court order.

(d) For licensing purposes the length of time that medical records are to be retained is dependent upon the need for their use in continuing patient care and for legal, research, or educational purposes. This length of time shall not be less than 20 years.

(e) Should a facility cease operation, there shall be an arrangement for preservation of records to insure compliance with these regulations. The Department shall be notified, in writing, concerning the arrangements.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .1100 - SURGICAL FACILITIES AND EQUIPMENT

10A NCAC 13C .1101 OPERATING SUITE

(a) Each operating suite shall be adequately equipped for the types of procedures to be performed.

(b) Each recovery area shall be adequately equipped for the proper care of post anesthesia recovery of surgical patients.

(c) The following equipment shall be available in the operating suite and recovery area:

- (1) cardio-pulmonary resuscitation drugs and intubation equipment,
- (2) cardiac monitor,
- (3) resuscitator including oxygen and suction equipment,
- (4) suitable surgical instruments customarily available for the planned surgical procedure,
- (5) defibrillator, and
- (6) tracheostomy set.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .1102 CARE OF OPERATING SUITE

(a) Dry sweeping and dusting shall be prohibited in treatment areas.

(b) Adequate and conveniently located spaces shall be provided for the storage of janitorial supplies and equipment.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .1200 - FUNCTIONAL SAFETY

10A NCAC 13C .1201 GENERAL

- (a) The governing authority shall develop written policies and procedures designed to enhance safety within the facility and on its grounds and minimize hazards to patients, staff and visitors.
- (b) The policies and procedures shall include establishment of the following:
- (1) safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs;
 - (2) provisions for reporting and the investigation of accidental events regarding patients, visitors and personnel (incidents) and corrective action taken;
 - (3) provision for dissemination of safety-related information to employees and users of the facility; and
 - (4) provision for syringe and needle storage, handling and disposal.
- (c) Smoking shall be permitted only in designated areas which shall not include patient care and treatment areas.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. December 24, 1979.*

10A NCAC 13C .1202 PREVENTIVE MAINTENANCE

A schedule of preventive maintenance shall be developed for all of the medical and surgical equipment in the facility to assure satisfactory operation when needed.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. April 1, 2003.*

SECTION .1300 - CONTROL AND SANITATION

10A NCAC 13C .1301 GENERAL

The governing authority shall employ procedures to minimize sources and transmission of infections. Professionally recognized surveillance methods shall be used. The governing authority shall provide space, equipment, and personnel to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. November 1, 1989.*

10A NCAC 13C .1302 STERILIZATION PROCEDURES

- (a) Policies and procedures shall be established in writing for storage, maintenance and distribution of sterile supplies and equipment.
- (b) Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust proof and moisture free units. They shall be properly labeled.
- (c) Sterilizing equipment shall be available and of the necessary type and capacity to sterilize instruments and operating room materials, as well as laboratory equipment and supplies. The sterilizing equipment shall have design control and safety features intact. The accuracy of instrumentation and equipment shall be checked quarterly by any professionally recognized method and periodic calibration and preventive maintenance shall be provided as necessary, and a log maintained.
- (d) The date of expiration shall be marked on all supplies sterilized in the facility.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. November 1, 1989.*

10A NCAC 13C .1303 HOUSEKEEPING

Operating rooms shall be appropriately cleaned in accordance with established written procedures after each operation. Recovery rooms shall be maintained in a clean condition.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .1304 LINEN AND LAUNDRY

- (a) An adequate supply of clean linen or disposable materials shall be maintained.
- (b) Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately.
- (c) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

10A NCAC 13C .1305 SANITATION

- (a) All parts of the facility, the premises and equipment shall be kept clean and free of insects, rodents, litter and rubbish.
- (b) All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978.*

SECTION .1400 - PHYSICAL PLANT CONSTRUCTION

10A NCAC 13C .1401 OPERATING SUITE

The size and design of the suite shall be in accordance with individual programs, but the following basic elements designed to ensure no flow of through traffic must be incorporated in all facilities:

- (1) Operating Room(s). The number shall depend on the projected case load and types of procedures to be performed. Rooms used for surgery shall have adequate space to accommodate necessary equipment and personnel.
- (2) Service Areas. The following supporting services shall be provided:
 - (a) scrub-up facilities with foot or knee controls;
 - (b) personnel locker and dressing areas so located that personnel enter from uncontrolled areas and exit directly into a surgical suite. Locker space shall be provided for each employee; and a toilet, shower, and dressing area shall be provided in each personnel dressing room;
 - (c) separate rooms for clean and for soiled supplies and equipment;
 - (d) anesthesia workroom;
 - (e) one clerical-control station; and
 - (f) a janitor's closet conveniently located to serve only the licensed facility.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. December 24, 1979.*

10A NCAC 13C .1402 RECOVERY AREA

Recovery area with handwashing facilities, secured medication storage space, clerical work space, storage for clerical supplies, linens, and patient care supplies and equipment shall be provided.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. December 24, 1979.*

10A NCAC 13C .1403 SUPPORTING ELEMENTS

In addition to those areas covered in Rules .1401 and .1402 of this Section, the facility shall provide space for the following:

- (1) the receiving and registering of patients in privacy for obtaining confidential information;

- (2) waiting space with public toilets, public telephone, drinking fountain, and wheelchair storage;
- (3) preoperative preparation and post operative space for both males and females with dressing rooms and toilet facilities; and
- (4) secure storage for patients' personal effects.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. April 1, 2003.*

10A NCAC 13C .1404 DETAILS AND FINISHES

All details and finishes must meet the following requirements:

- (1) Details
 - (a) The type of construction shall meet the requirement of the current edition of the North Carolina State Building Code for "Business Occupancy-(B)," except that in the construction of new facilities required exit doors to stairs or to the outside shall be no less than 44" wide doors.
 - (b) Exit corridors, in addition to meeting the appropriate requirements of the North Carolina State Building Code, shall:
 - (i) be no less than 7'0" clear width between doors from the recovery area or operating rooms and required exit doors; or
 - (ii) if in a one-story building or on the ground floor of a multi-story building and is less than 7'0" clear width be so arranged as to allow a stretcher to exit from the recovery area or operating room directly into the corridor without turning and move to the required exit without having to make a turn.
 - (c) Doors between preoperative preparation, operating rooms and recovery areas and recovery rooms and corridors shall be no less than 44" wide. All recovery areas shall have at least one door opening to an exit passage way meeting the requirements of (b)(i) and (b)(ii) of this Rule.
 - (d) Items such as drinking fountains, telephone booths, vending machines, and portable equipment shall be located so as not to restrict corridor traffic or reduce the corridor width below the required minimum.
 - (e) No doors shall swing into corridors in a manner that might obstruct traffic flow or reduce the required corridor width except doors to spaces such as small closets which are not subject to occupancy.
 - (f) Thresholds and expansion joint covers shall be made flush with the floor surface to facilitate use of wheelchairs and carts.
 - (g) Single use towel dispensers or air driers shall be provided at all handwashing fixtures except scrub sinks.
 - (h) All other rooms shall have not less than 8'0" (2.44 m.) high ceilings except that corridors, storage rooms, toilet rooms, and other minor rooms may be not less than 7'-8" (2.34 m.). Suspended tracks, rails, pipes, etc., located in the path of normal traffic, shall be not less than 7'-6" (2.28 m.) above the floor.
- (2) Finishes
 - (a) Floors shall be easily cleanable and have wear resistance appropriate for the locations involved. Joints in tile and similar material in such areas shall be resistant to food acids.
 - (b) Wall bases in operating rooms, soiled workrooms, and other areas subject to frequent wet cleaning shall be integral and covered with the floor, tightly sealed within the wall, and constructed without voids that can harbor vermin.
 - (c) Walls shall be washable; and, in the immediate area of plumbing fixtures, the finish shall be smooth, moisture resistant, and easily cleaned.
 - (d) Floor and wall penetrations by pipes, ducts, conduits, etc., shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.
 - (e) Ceilings in operating rooms shall be readily washable and without crevices that can retain dirt particles. Finished ceilings may be omitted in mechanical and equipment spaces, shops, general storage areas, and similar spaces except where required for fire rating.

History Note: Authority G.S. 131E-149;

Eff. October 14, 1978;
Amended Eff. November 1, 1989; December 24, 1979.

10A NCAC 13C .1405 MECHANICAL REQUIREMENTS

(a) Temperatures and Relative Humidity

- (1) The heating and air conditioning systems shall be designed to provide the temperature and humidities shown below:

Area Designation	Temperature	Relative Humidity Percent
Operating	70-75° F* 21-24° C*	50-60
Recovery	70-75° F* 21-24° C*	30-60

*Variable Range Required

- (2) For all other occupied or use areas, a minimum design temperature of 72°F. (22°C) at winter design conditions shall be provided.
- (b) All air-supply and air-exhaust systems for the operating suite and recovery area shall be mechanically operated. All fans serving exhaust systems shall be located at the discharge end of the system. The ventilation rates shown in this Paragraph shall be minimum acceptable rates and shall not be construed as precluding the use of higher ventilation rates.
- (1) Outdoor intakes for operating rooms shall be located not less than 30 feet (9.14 m.) from exhausts from other ventilating systems, combustion equipment and plumbing vents and at least 3 feet 0 inches (.92 m.) above the roof and 6 feet (1.83 m.) above ground level.
- (2) The ventilation systems shall be designed and balanced to provide the pressure relationship as shown in this Paragraph.
- (3) All air supplied to operating rooms shall be delivered at or near the ceiling of the area served and all exhaust from the area shall be removed near floor level. At least two exhaust outlets shall be used in all operating rooms.
- (4) The bottom of any room supply air inlets, recirculation, and exhaust air outlets shall be located not less than 3 inches (7.62 cm.) above the floor.
- (5) Corridors shall not be used to supply air to or exhaust air from any room, except that exhaust from corridors may be used to exhaust-ventilate bathrooms, toilet rooms, janitors' closets and electrical or telephone closets opening directly on corridors.
- (6) All ventilation or air conditioning systems serving operating rooms shall have a minimum of two filter beds:
- (A) Filter bed No. 1 shall be located upstream of the air conditioning equipment and shall have a minimum efficiency of 25 percent. Filter bed No. 2 shall be downstream of the supply fan and of recirculating spray water and water reservoir-type humidifiers. Filter bed No. 2 shall have a minimum efficiency of 90 percent.
- (B) All filter efficiencies shall be certified by an independent testing agency and shall be based on the atmospheric dust spot efficiency determination in accordance with ASHRAE Standard 52-68; except that the exhausts from all laboratory hoods in which infectious or radioactive materials are processed shall be equipped with filters having a 99 percent efficiency based on the DOP (dioctyophthalate) test method and there shall be equipment and procedure for the safe removal of contaminated filters.
- (C) Filter frames shall provide an airtight fit with the enclosing ductwork. All joints between filter segments and the enclosing ductwork shall be gasketed or sealed to provide a positive seal against air leakage. Each filter bed serving sensitive areas or central air systems shall have a manometer installed across each filter bed.
- (D) Ventilation systems serving recovery rooms shall not be tied in with soiled holding or work rooms, janitors' closets, or waiting rooms if the air is to be recirculated in any manner except through approved filters.
- (7) Air handling duct systems shall not have duct linings.
- (8) The following general air pressure relationships and ventilation shall apply:

Area Designation	Pressure Relationship to Adjacent Areas	Minimum Total Air Changes per Hour Supplied to Room	All Air Exhausted Directly to Outdoors	Recirculated Within Room Units
Operating Room	P	25	Optional	Only with approved filters. See Sub-paragraph (b)(6)(D) of this Rule.
Recovery Room	E	6	Optional	
Soiled Workroom or Soiled Holding Clean Workroom	N	10	Yes	No
Clean Holding Examination Room	P +/-	4 6	Optional	Optional
Treatment Room	+/-	6	Optional	Optional
Medication room	P	4	Optional	Optional
X-Ray (Diagnostic And Treatment)	+/-	6	Optional	Optional
Laboratory (general)	N	6	Optional	Optional

P = Positive N = Negative E = Equal +/- = continuous Directional control not required

- (9) Operating rooms or procedure rooms which are used with either life sustaining electrical equipment or identified as a critical care location shall comply with the requirements for ventilation in NFPA 99, Chapter 5, Environmental Systems.
- (10) Prior to occupancy of the facility, the facility shall obtain documentation verifying that all mechanical systems have been tested, balanced, and operated to demonstrate that the installation and performance of these systems conform to the approved design. Test results shall be maintained in the facility maintenance files.
- (11) Upon completion of equipment installation, the facility shall acquire and maintain a complete set of manufacturers' operating, maintenance, and preventive maintenance instructions, parts lists, and procurement information including equipment numbers and descriptions.
- (12) Operating staff shall be provided with instructions for properly operating systems and equipment.

(c) Medical gases: The performance, maintenance, installation, and testing of medical gas systems shall comply with the requirements of National Fire Protection Association Standard 99. When any piping or supply of medical gases is installed, altered, or augmented, the altered zone shall be tested and certified as required by National Fire Protection Association Standard 99. Testing shall be conducted by the facility and at least one other independent testing organization to ensure that the system is safe for patient use.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. April 1, 2003; December 24, 1979.*

10A NCAC 13C .1406 PLUMBING AND OTHER PIPING SYSTEMS

(a) All building plumbing systems shall be installed in accordance with the requirements of the North Carolina State Building Code, Volume II.

(b) Plumbing Fixtures

- (1) The material used for plumbing fixtures shall be of non-absorptive acid-resistant material.

- (2) Lavatories and sinks required shall have the water supply spout mounted so that its discharge point is a minimum distance of five inches (12.7 cm.) above the rim of the fixture. All fixtures used by medical and nursing staff shall be trimmed with valves which can be operated without the use of hands. Where blade handles are used for this purpose, they shall not exceed four and one-half inches (11.43 cm.) in length, except that handles on scrub sinks and clinical sinks shall be not less than six inches (15.24 cm.) long.
 - (3) Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.
- (c) Water Supply Systems
- (1) Systems shall be designed to supply water to the fixtures and equipment at a sufficient pressure to operate all fixtures and equipment during maximum demand periods.
 - (2) Each water service main, branch main, riser and branch to a group of fixtures shall be valved. Stop valves shall be provided at each fixture.
 - (3) Backflow preventers shall be installed on hose bibbs and on all fixtures to which hoses or tubing can be attached.
 - (4) Hot water distribution systems shall be arranged to provide hot water at each hot water outlet at all times. Hot water at the handwashing and bathing facilities shall not exceed 116° F (46.6°C).
- (d) Drainage Systems
- (1) Drain lines from sinks in which acid wastes may be poured shall be fabricated from an acid-resistant material.
 - (2) Piping systems shall be designed to avoid, insofar as is possible, installations in the ceiling directly over operating rooms.
 - (3) Floor drains shall not be installed in operating rooms.
 - (4) Building sewers shall discharge into a community sewerage system. Where such a system is not available, a facility providing sewage treatment which conforms to applicable local and state regulations is required.
- (e) Non-flammable medical gas system installations shall be in accordance with the requirements of NFPA Standard 99 and NFPA 50. Clinical vacuum (suction) system installations shall be in accordance with the requirements of NFPA Standard 99. The minimum number of outlets is shown below.

Minimum Medical Gas Station Outlets and Vacuum Station Inlets

Location	Oxygen	Vacuum	Medical Air
Operating Room	2/room	3/room	1/room
Recovery Room	1/bed	3/bed	1/bed

- (f) Service outlets for built-in housekeeping vacuum systems, if used, shall not be located within operating rooms.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. April 1, 2003.*

10A NCAC 13C .1407 ELECTRICAL REQUIREMENTS

- (a) General
- (1) All material including equipment, conductors, controls and signaling devices shall be installed to provide a complete electrical system with the necessary characteristics and capacity to supply the electrical facilities shown in the specifications or indicated on the plans. All materials shall be listed as complying with applicable standards of Underwriters' Laboratories, Inc., or other similarly established standards, where such standards have been established.
 - (2) All material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of North Carolina State Building Code, Volume VII IV, Electrical. A written record of performance tests on electrical systems and equipment shall show compliance with applicable codes and standards.
 - (3) Lighting and appliance panelboards shall be located on the same floor as the circuits they serve.

(b) Lighting

- (1) All spaces occupied by people and equipment shall have electric lighting.
- (2) Operating rooms shall have general lighting for the room in addition to local lighting provided by special lighting units at the surgical and obstetrical tables. Each fixed special lighting unit at the tables, except for portable units, shall be connected to an independent circuit.

(c) Power

- (1) If non-flammable anesthetics are to be used, the facility shall meet the requirements of NFPA 99, Health Care Facilities Code.
- (2) Procedures that create a direct electrical pathway to the heart or create conditions meeting the definition of a wet location shall be provided with an isolated power system (IPS) in the patient care area.
- (3) Procedures that require electrically powered devices that because of patient safety cannot tolerate an outage due to equipment faults shall be provided with an isolated power system (IPS) in the patient care area.
- (4) Procedures that can be safely carried out with conventional grounded power systems shall be provided with ground fault circuit interrupters on each circuit installed in the operating or procedure room serving the patient care area.
- (5) Critical care areas require a Type 1 essential electrical system.
- (6) Procedures requiring the use of electrical life support equipment require a Type 1 essential electrical system.
- (7) All facilities shall have as a minimum a Type 3 essential electrical system.
- (8) All devices, switches, receptacles connected to the essential electrical system shall be distinctively identified so that personnel can easily select which device is expected to operate during failure of normal source of power.
- (9) Fuel for the essential electrical system generator shall be stored on site in sufficient quantity to provide for not less than 24 hours of operation.

(d) Receptacles

- (1) Each operating or procedure room shall have at least eight 120 volt duplex receptacles.
- (2) In locations where mobile X-ray is used, an additional receptacle, distinctively marked for X-ray use, shall be provided.
- (3) Fixed and mobile X-ray equipment installations shall conform to Article 660 of the North Carolina State Building Code, Electrical.

*History Note: Authority G.S. 131E-149;
Eff. October 14, 1978;
Amended Eff. April 1, 2003.*

10A NCAC 13C .1408 GENERAL

The design, construction, maintenance and operation of a facility shall be in accordance with those codes and standards listed in Rule .1409, LIST OF REFERENCED CODES AND STANDARDS, and codes, ordinances, and regulations enforced by city, county, or other state jurisdictions with the following requirements:

- (1) The facility shall notify the Division when all construction or renovation has been completed, inspected and approved by the architect and engineer having responsibility, and the facility is ready for a final inspection. Prior to using the completed project, the facility shall receive from the Division, written approval for use.
- (2) In the absence of any requirements by other authorities having jurisdiction, the facility shall develop a master fire and disaster plan with input from the local fire department and local emergency management agency to fit the needs of the facility. The plan shall require:
 - (A) Training of facility employees in the fire plan implementation, in the use of fire-fighting equipment, and in evacuation of patients and staff from areas in danger during an emergency condition;
 - (B) Conducting of quarterly fire drills on each shift;
 - (C) A written record of each drill shall be on file at the facility for at least three years;
 - (D) The testing and evaluation of the emergency electrical system(s) once each year by simulating a utility power outage by opening of the main facility electrical breaker(s). Documentation of the testing and results shall be completed at the time of the test and retained by the facility for three years; and

- (E) Disaster planning to fit the specific needs of the facility's geographic location and disaster history, with at least one documented disaster drill conducted each year;
- (3) The facility structure, component parts, and building systems shall be kept in good repair and maintained with consideration for the safety and comfort of patients, staff and visitors; and
- (4) There shall be a definite assignment of maintenance functions to qualified personnel under supervision.

*History Note: Authority G.S. 131E-149;
Eff. April 1, 2003.*

10A NCAC 13C .1409 LIST OF REFERENCED CODES AND STANDARDS

The following codes and standards are adopted by reference including subsequent amendments. Copies of these publications can be obtained from the various organizations at the addresses listed:

- (1) The North Carolina State Building Code, current edition, all volumes. Copies of this code may be purchased from the N.C. Department of Insurance Engineering Division located at 410 North Boylan Avenue, Raleigh, NC 27603 at a cost of four hundred eight dollars (\$408.00).
- (2) The National Fire Protection Association codes and standards listed below, current editions. Copies of these codes and standards may be obtained from the National Fire Protection Association, 1 Batterymarch Park, PO Box 9101, Quincy, MA 02269-9101 at the cost shown for each code or standard listed.
 - (a) 10 Portable Fire Extinguishers \$29.75
 - (b) 13 Installation of Sprinkler Systems \$42.75
 - (c) 20 Installation of Centrifugal Fire Pumps \$29.75
 - (d) 22 Water Tanks for Private Fire Protection \$29.75
 - (e) 25 Water-Based Fire Protection Systems \$32.75
 - (f) 30 Flammable and Combustible Liquids Code \$32.25
 - (g) 31 Installation of Oil-Burning Equipment \$29.75
 - (h) 37 Stationary Combustion Engines and Gas Turbines \$26.75
 - (i) 50 Bulk Oxygen Systems at Consumer Sites \$22.25
 - (j) 53 Fire Hazards in Oxygen-Enriched Atmospheres \$29.75
 - (k) 54 National Fuel Gas Code \$35.25
 - (l) 55 Compressed and Liquefied Gases in Portable Cylinders \$22.25
 - (m) 58 Storage and Handling of Liquefied Petroleum Gases \$35.25
 - (n) 59A Liquefied Natural Gas (LNG) \$26.75
 - (o) 72 National Fire Alarm Code \$42.75
 - (p) 80 Fire Doors and Windows \$29.75
 - (q) 82 Incinerators, Waste and Linen Handling Systems and Equipment \$22.25
 - (r) 90A Installation of Air Conditioning and Ventilating Systems \$26.75
 - (s) 90B Installation of Warm Air Heating and Air Conditioning Systems \$22.25
 - (t) 92A Smoke-Control Systems \$26.75
 - (u) 92B Smoke Management Systems in Malls, Atria, Large Areas \$26.75
 - (v) 99 Health Care Facilities \$42.75
 - (w) 101 Safety to Life from Fire in Buildings and Structures \$53.50
 - (x) 101A Alternative Approaches to Life Safety \$35.25
 - (y) 105 Smoke-Control Door Assemblies \$22.25
 - (z) 110 Emergency and Standby Power Systems \$26.75
 - (aa) 221 Fire Walls and Fire Barrier Walls \$22.25
 - (bb) 241 Construction, Alteration, and Demolition Operations \$26.75
 - (cc) 780 Lightning Protection Code \$29.75
 - (dd) 801 Facilities Handling Radioactive Materials \$26.75
- (3) American Society of Heating, Refrigerating & Air Conditioning Engineers, (ASHRAE) HVAC APPLICATIONS, current edition. Copies of this document may be obtained from the American Society of Heating, Refrigerating & Air Conditioning Engineers at United Engineer Center, 345 East 47th Street, New York, NY 10017 at a cost of one hundred forty-four dollars (\$144.00).

*History Note: Authority G.S. 131E-149;
Eff. April 1, 2003.*

10A NCAC 13C .1410 APPLICATION OF PHYSICAL PLANT REQUIREMENTS

The physical plant requirements for each facility shall be applied as follows:

- (1) All newly licensed facilities shall comply with the requirements of Section .1400;
- (2) Existing licensed facilities shall meet licensure and code requirements in effect at the time of construction, alteration, or modification;
- (3) New additions, alterations, modifications, and repairs of existing licensed facilities shall meet the technical requirements of Section .1400, however, where strict conformance with current requirements would be impractical, the authority having jurisdiction shall approve alternative measures where the facility can demonstrate to the Division's satisfaction that the alternative measures do not reduce the safety or operating effectiveness of the facility;
- (4) Rules contained in Section .1400 are minimum requirements and not intended to prohibit buildings, systems or operational conditions that exceed minimum requirements;
- (5) Equivalency: Alternate methods, procedures, design criteria, and functional variations from the physical plant requirements, because of extraordinary circumstances, new programs, or unusual conditions, shall be approved by the authority having jurisdiction when the facility can effectively demonstrate to the Division's satisfaction, that the intent of the physical plant requirements are met and that the variation does not reduce the safety or operational effectiveness of the facility; and
- (6) Where rules, codes, or standards have any conflict, the most stringent requirement shall apply.

*History Note: Authority G.S. 131E-149;
Eff. April 1, 2003.*

10A NCAC 13C .1411 ACCESS AND SAFETY

Projects involving replacement of, alterations of, and additions to existing licensed facilities shall be planned and phased so that construction will minimize disruptions of facility operations. Facility access, exit ways, safety provisions, and building and life safety systems shall be maintained so that the health and safety of the occupants will not be jeopardized during construction. Additional safety and operating measures shall be planned, documented, and executed to compensate for hazards related to construction or renovation activities to maintain an equivalent degree of health, safety, and operational effectiveness to that required by rules, standards, and codes for a facility not under construction or renovation.

*History Note: Authority G.S. 131E-149;
Eff. April 1, 2003.*