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South Carolina Department of Health
and Environmental Control

Regulation Number 61-91
Standards for Licensing Ambulatory Surgical Facilities

Promulgated by the Board of Health and Environmental Control

Administered by the Division of Health Licensing

Including Changes

Published in the *State Register*, Volume 27, Issue 6, June 27, 2003

This is a courtesy copy of Regulation R61-91

DIVISION OF HEALTH LICENSING REGULATIONS

Provider-Wide Exceptions

In the interest of establishing reasonable standards that can be met by providers and yet do not compromise the health and well-being of the patients, residents, and participants cared for in South Carolina licensed facilities, it has been determined that alternative standards will be considered as acceptable. A Provider-Wide Exception (PWE) is the tool that is used to achieve a working relationship between the facility and their regulators.

Provider-Wide Exceptions for the facilities and activities that are licensed by the Division of Health Licensing can be downloaded from our Internet Website:

http://www.scdhec.gov/health/licen/pwe.htm

This website may also contain Position Statements that give guidance or interpretations of the regulation.

Provider-Wide Exceptions and Position Statements may also be obtained by contacting our office at (803) 545-4370. There is a ten-dollar ($10.00) processing and handling fee assessed when copies are obtained through our office. Copies obtained over the Internet through our Website are free of charge. Payment must be by credit card, personal check or money order (no cash can be accepted).

Note: Some Provider-Wide Exceptions pre-date the publishing dates of specific Regulations established by the *State Register* and may no longer be in effect. In these instances, if there is a conflict between a PWE that pre-dates the publishing date of the regulation, the standard in the regulation shall supercede the PWE.

REGULATION NO. 61-91 - *STANDARDS FOR LICENSING AMBULATORY SURGICAL FACILITIES*

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REGULATION NO. 61-91 - *STANDARDS FOR LICENSING AMBULATORY SURGICAL FACILITIES*

Statutory Authority - §44-7-260 S.C. Code Ann. (2002)

SECTION 100 - DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

101. Definitions

For the purpose of these standards, the following definitions shall apply:

A. Administrator. The individual designated by the facility licensee to have the authority and responsibility to manage the facility.

B. Administering Medication. The direct application of a single dose of a medication to the body of a patient by injection, ingestion, or any other means.

C. Advance Directive. A written statement such as a living will, a durable power of attorney for health care, or a do-not-resuscitate order relating to the provision of health care when the individual is incapacitated. The exercise by a patient of self-determination that encompasses making choices regarding life-sustaining treatment (including resuscitative services).

D. Advanced Practice Registered Nurse. An individual who has official recognition as such by the S.C. State Board of Nursing.

E. Ambulatory Surgical Facility. A distinct, freestanding, self-contained entity that is organized, administered, equipped, and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures, and/or services, *e.g.*, endoscopy, for which patients are scheduled to arrive, receive surgery or related care, treatment, procedures, and/or services, and be discharged on the same day.

1. The owner or operator shall make the facility available to other providers who comprise an organized professional staff, *i.e*., an open medical staff (see Section 101. BB).

2. This definition does not apply to any facility used as an office or clinic for the private practice of licensed healthcare professionals (see Section 101. JJ).

F. Anesthesiologist's Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

G. Anesthesiologist. A physician who has completed a residency in anesthesiology.

H. Anesthetic Agent. Any drug or combination of drugs administered parenterally or inhaled with the purpose of creating conscious or deep sedation.

I. Certified Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a certified registered nurse anesthetist by the S.C. State Board of Nursing.

J. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the S.C. Controlled Substances Act.

K. Consultation. A visit to a licensed facility by individuals authorized by the Department to provide information to facilities to enable facilities to better comply with the regulations.

L. Dentist. An individual currently licensed by the S.C. Board of Dentistry to practice dentistry.

M. Department. The S.C. Department of Health and Environmental Control (DHEC).

N. Direct Care Staff Member. An individual who provides care, treatment, surgery, and/or services, or performs procedures for a patient.

O. Endoscopy. Visual inspection of any cavity of the body by means of an endoscope.

P. Existing Facility. A facility that was in operation and/or one that began the construction or renovation of a building, for the purpose of operating the facility, prior to the promulgation of this regulation. The licensing standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under this regulation.

Q. Facility. An ambulatory surgical facility licensed by the Department.

R. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, physician's assistant, or advanced practice registered nurse, or by a registered nurse, pursuant to standing orders approved by a physician, as evidenced by the physician's signature in accordance with facility policy.

S. Inspection. A visit by authorized individuals to a facility or to a proposed facility for the purpose of determining compliance with this regulation.

T. Investigation. A visit by authorized individuals to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

U. Initial License. A license granted to a new facility.

V. Legally Authorized Healthcare Provider. An individual authorized by law and currently licensed in S.C. to provide specific medical care, treatment, procedures,

surgery, and/or services to patients. Examples of individuals who may be authorized by law to provide the aforementioned care, treatment, procedures, surgery, and/or services may include, but are not limited to, advanced practice registered nurses, and physician's assistants.

W. Legend Drug.

1. A drug required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only."

2. A drug required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only;

3. Any drug products designated by the S.C. Board of Pharmacy to be a public health threat; or

4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.

X. License. A certificate issued by the Department to a facility to provide care, treatment, procedures, surgery, and/or services.

Y. Licensed Nurse. An individual currently licensed by the S.C. State Board of Nursing as a registered nurse or licensed practical nurse.

Z. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care, treatment, procedures, surgery, and/or services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

AA. New Facility. All buildings or portions of buildings, new and existing, that are:

1. Being licensed for the first time;

2. Providing a different service that requires a change in the type of license;

3. Being licensed after the previous licensee's license has been revoked, suspended, or after the previous licensee has voluntarily surrendered the license and the facility has not continuously operated.

BB. Open Medical Staff. Members of the medical staff, which includes physicians, dentists, or podiatrists, of an ambulatory surgical facility, that have individually submitted application to the facility, and subsequently been approved to perform surgery/procedures in accordance with criteria established by the facility for

approving qualified applicants.

CC. Operating Room. A room in which surgery is performed.

DD. Nonlegend Medication. A medication that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws of this State and the federal government.

EE. Pharmacist. An individual currently registered as such by the S.C. Board of Pharmacy.

FF. Physical Examination. An examination of a patient by a physician that addresses those issues identified in Section 802 of this regulation.

GG. Physician. An individual currently licensed as such by the S.C. Board of Medical Examiners.

HH. Physician's Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

II. Podiatrist. An individual currently licensed as such by the S.C. Board of Podiatry Examiners.

JJ. Private Practice. An individually-licensed physician or group of licensed physicians who practice together at a certain location/address in a legally-constituted professional corporation, association, or partnership; patient encounters in the office or clinic are for the purpose of diagnosis and treatment, and not limited primarily to the performance of surgery and related care, treatment, procedures, and/or services.

KK. Procedure Room. A room where procedures not requiring general anesthesia can be safely performed.

LL. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care, treatment, procedures, surgery, and/or services, identify the ways to improve its performance, and take actions that result in higher quality of care, treatment, procedures, surgery, and/or services for the facility's patients.

MM. Recovery Area. An area used for the recovery of patients.

NN. Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a registered nurse anesthetist by the S.C. State Board of Nursing.

OO. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

PP. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or

conservator, or person with a health care power of attorney or other durable power of attorney.

QQ. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

RR. Same Day. That period of time between 12:01 a.m. and 11:59 p.m. on a calendar date.

SS. Staff Member. An adult who is a compensated employee of the facility on either a full or part-time basis.

TT. Surgery. Treatment of conditions by operative means involving incision, whether with a scalpel or a laser, followed by removal or repair of an organ or other tissue.

UU. Surgical Suite. An area that includes one or more operating rooms and a recovery area.

VV. Suspension of License. An action by the Department requiring a facility to cease operation for a period of time or to require a facility to cease admitting patients until such time as the Department rescinds that restriction.

102. References

The following publications/standards are referenced in this regulation:

A. Departmental:

1. R.61-4, *Controlled Substances*;

2. R.61-12, *Standards for Licensing Abortion Clinics*;

3. R.61-16, *Standards for Licensing Hospitals and Institutional General Infirmaries*;

4. R.61-20, *Communicable Diseases*;

5. R.61-25, *Retail Food Establishments*;

6. R.61-58, *State Primary Drinking Water Regulations*;

7. R.61-63, *Title A, Rules and Regulations for Radioactive Materials*;

8. R.61-64, *X-Rays, (Title B)*;

9. R.61-67, *Standards for Wastewater Facility Construction*;

10. R.61-105, *Infectious Waste Management Regulations*;

11. *Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*.

B. Non-Departmental:

1. American Association of Blood Banks;

2. American National Standards Institute (ANSI);

3. American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE);

4. Bloodborne Pathogens Standards, Occupational Safety and Health Act (OSHA) of 1970;

5. Civil Rights Act of 1964;

6. Centers for Disease Control and Prevention (CDC);

7. International Building Code (IBC);

8. National Fire Protection Association (NFPA);

9. Standard Building Code (SBC).

103. License Requirements (II)

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise/market) as an ambulatory surgical facility in S.C. without first obtaining a license from the Department. The provision of care, treatment, procedures, surgery, and/or services to patients prior to the effective date of licensure is a violation of §44-7-260(A)(6) of the S.C. Code Ann. (2002). When it has been determined by the Department that care, treatment, procedures, surgery, and/or services are being provided at a location, and the owner has not been issued a license from the Department to provide such care, treatment, procedures, surgery, and/or services, the owner shall cease operation immediately and ensure the safety, health, and well-being of the patients. Current and previous violations of the S.C. Code and/or Department regulations may jeopardize the issuance of a license for the facility or the licensing of any other facility, or addition to an existing facility that is owned or operated by the licensee. (I)

B. Compliance. An initial license shall not be issued to a proposed facility that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity licensed by the Department makes application for another facility or increase in licensed capacity, the currently licensed facility/activity

shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or an amended license to the existing facility. A copy of the licensing standards shall be maintained at the facility and accessible to all staff members. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

C. Compliance with Structural Standards. Facilities licensed at the time of promulgation of this regulation (existing facilities), and proposed facilities for which the licensee has received written approval from the Department to construct the proposed facility:

1. Shall be allowed to continue utilizing the previously-licensed structure without modification, and are not required to modify square footage of operating/ procedure rooms;

2. Shall comply with the remainder of the standards within this regulation.

D. Compliance with Structural Standards upon Change of Licensee. When changes in licensee occur, the new licensee shall, through coordination with the Department's Division of Health Facilities Construction, formulate a plan for the facility to be in compliance with current building and fire and life safety codes within 24 months of the date of the licensee change, unless specific standards are exempted by the Department. Should other changes in licensee occur within the 24-month period, the new licensee shall comply with the original plan approved by the Division of Health Facilities Construction by the end of the 24-month period which began with the date of the original licensee change. Facilities are not required to modify square footage of operating/procedure rooms.

E. Licensed Capacity. No facility that has been licensed for a set number of operating rooms or procedure rooms shall exceed that number of operating or procedure rooms or establish new care, treatment, procedures, surgery, and/or services without first obtaining authorization from the Department. (I)

F. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, treatment, procedures, surgery, and/or services, personal safety, fire safety, or the well-being of any patient or occupant of a facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this State.

4. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department.

A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, *e.g.*, interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

6. Separate licenses are not required, but may be issued, for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

7. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

8. A facility shall provide only the care, treatment, procedures, surgery, and/or services of which it is capable and equipped to provide, and has been authorized by the Department to provide pursuant to the definition in Section 101.E of this regulation.

9. Abortions shall not be performed in an ambulatory surgical facility unless it is also licensed as an abortion clinic pursuant to R.61-12.

G. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in S.C. The Department shall determine if names are similar. If the facility is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

H. Application. Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes the applicant's oath, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in the event his or her address is different from that of the facility, and the names of the persons in control of the facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or partnerships shall be registered with the S.C. Office of the Secretary of State.

I. Licensing Fees. The initial and annual license fee shall be $150.00 per operating/procedure room or $600.00, whichever is greater. Such fee shall be made payable by check or money order to the Department and is not refundable. The Department may charge an additional amount, if necessary, to cover the cost of inspection or investigation.

J. Late Fee. Failure to submit a renewal application after the license expiration date may result in a late fee of 25% of the licensing fee amount, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time-period specified by the Department may result in an enforcement action.

K. License Renewal. To renew a license, an applicant shall file an application with the Department and pay a license fee. If the license renewal is delayed due to enforcement action, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable. If an application is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure year.

L. Change of License.

1. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership;

b. Reallocation of types of operating or procedure rooms as shown on the license;

c. Change of facility location from one geographic site to another;

d. The addition or replacement of a surgical suite or any part thereof, or the deletion of operating or procedure rooms.

2. Changes in facility name or address (as notified by the post office) shall be accomplished by application or by letter from the licensee.

M. An ambulatory surgical facility license shall not be required for, nor shall such a license be issued to:

1. Facilities operated by the federal government;

2. Ambulatory surgical services or procedures provided in licensed hospitals (such services remain within the purview of R.61-16);

3. Private practices (see Section 101. JJ).

N. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by statute.

SECTION 200 - ENFORCING REGULATIONS

201. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

202. Inspections/Investigations

A. An inspection shall be conducted prior to initial licensing of a facility and subsequent inspections conducted as deemed appropriate by the Department. Other regulatory-related inspections may be considered in determining the appropriateness of Department inspections, *e.g.*, Joint Commission on Accreditation of Health Care Organizations (JCAHO), Accreditation Association for Ambulatory Health Care (AAAHC).

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records, and have the authority to require the facility to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (II)

D. A facility found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar);

3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the facility response, shall be made available upon written request with the redaction of the names of those individuals in the report as provided by §44-7-310 and 315 of the S.C. Code Ann. (2002).

SECTION 300 - ENFORCEMENT ACTIONS

301. General

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, and/or revoke its license.

302. Violation Classifications

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of persons in the facility. The citation of a Class II violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. The notations “(I)” or “(II)”, placed within sections of this regulation, indicate that those standards are considered Class I or II violations, if they are not met, respectively. Standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on health, safety, or well-being of the patients; efforts by the facility to correct cited violations; behavior of the licensee that reflects negatively on the licensee's character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations.

F. When a decision is made to impose monetary penalties, the following schedule shall be used as a guide to determine the dollar amount:

Frequency of violation of standard within a 36-month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$ 500 - 1,500	$ 300 - 800	$100 - 300
2nd	1,000 - 3,000	500 - 1,500	300 - 800
3rd	2,000 - 5,000	1,000 - 3,000	500 - 1,500
4th	5,000	2,000 - 5,000	1,000 - 3,000
5th	7,500	5,000	2,000 - 5,000
6th	10,000	7,500	5,000

G. Any enforcement action taken by the Department may be appealed in a manner pursuant to the Administrative Procedures Act, §1-23-310, *et seq.*, S.C. Code Ann. (2002).

SECTION 400 - POLICIES AND PROCEDURES

401. General (II)

A. Policies and procedures addressing each section of this regulation regarding care, treatment, procedures, surgery, and/or services, rights, and the operation of the facility shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation. The licensee shall establish a time-period for review of all policies and procedures. These policies and procedures shall be accessible in each facility at all times, either by hard copy or electronically.

B. Policies and procedures shall describe the means by which the facility shall assure that the standards described in this regulation that the licensee has agreed to meet, as confirmed by signature on the application for licensing, will be met (see Section 1601.B).

SECTION 500 - STAFF

501. General (II)

A. Appropriate staffing in sufficient numbers and training, in all facilities, shall be provided in order to:

1. Effectively meet the needs and condition of the patients, to include the demands of effective emergency on-site action that might arise;

2. Properly operate equipment in accordance with the equipment manufacturer's recommendations;

3. Adhere to current professional organizational standards;

4. Comply with all local, state, and federal laws.

B. Additional staff members shall be provided if it is determined by the Department that the facility staff on duty is inadequate to provide appropriate care, treatment, procedures, surgery, and/or services to the patients of a facility.

C. All staff members shall be assigned duties and responsibilities in accordance with the individual's capability that shall be in writing and be reviewed on an annual basis by the staff member and supervisor.

D. There shall be accurate current information maintained regarding all staff members of the facility, to include at least an address, phone number, and health and personal/work/training background. For those staff members who are licensed/certified, a copy of the license/certificate shall be available for review.

E. Direct care staff members of the facility shall not have a prior conviction or have pled no contest (nolo contendere) within the last 10 years for child or adult abuse, neglect, exploitation, or mistreatment, or for sexual assault or assault with a deadly weapon. Facilities may take certain considerations into account regarding criminal records when making hiring decisions, *i.e*., discretion may be exercised regarding convictions/nolo contendere pleas occurring more than 10 years ago and may determine that an applicant, who would otherwise be disqualified, could be hired. (I)

F. A staff member shall not have an active dependency on a psychoactive substance(s) that would impair his or her ability to perform assigned duties. (I)

502. Administrator (II)

A. The facility shall have an administrator who shall be capable of meeting the responsibilities of operating the facility to ensure that it is in compliance with these regulations, and shall demonstrate adequate knowledge of these regulations. An administrator appointed subsequent to the promulgation of this regulation shall be a registered nurse or shall have a baccalaureate or associate degree with at least three years experience in a health-related field within the past five years.

B. A staff member shall be designated, by name or position, in writing, to act in the absence of the administrator.

503. Medical Director (II)

A. There shall be a medical director of the facility who is a physician.

B. The administrator and medical director may be the same individual.

504. Medical Staff (I)

A. Physicians, dentists, and podiatrists performing surgery and/or procedures shall be appropriately licensed to perform these functions as well as adequately trained in any special requirements that are necessary to perform such surgery/ procedures.

B. Privileges for each physician, dentist, and podiatrist performing surgery/procedures shall be in accordance with criteria that the facility has established and approved.

C. There shall be a roster of medical staff having surgery, procedures, and anesthesia privileges at the facility, specifying the privileges and limitations of each and a current listing of all types of surgery and/or procedures offered by the facility.

D. A physician shall be physically present or available within 30 minutes until all patients have departed the premises.

E. There shall be at least one physician on staff who has admitting privileges at one or more local hospitals.

505. Nursing Staff (I)

A. An adequate number of licensed nurses shall be on duty to meet the total nursing needs of patients.

B. At least one registered nurse shall be on duty whenever patients are present in the facility.

C. Nursing staff shall be assigned to duties consistent with their scope of practice as determined through their licensure and educational preparation.

506. Advanced Cardiac Life Support (I)

An individual who possesses a valid Advanced Cardiac Life Support credential shall be on duty in the facility whenever patients are present in the facility.

507. Inservice Training (II)

A. Training for the tasks each staff member performs shall be conducted in order to provide the care, treatment, procedures, surgery, and/or services delineated in Sections 501.A and 800.

B. The following training shall be provided to staff members by appropriate resources, *e.g.*, licensed or registered persons, video tapes, books, *etc.*, to all staff members in context with their job duties and responsibilities, prior to patient contact and at a frequency determined by the facility, but at least annually:

1. Cause, effect, transmission, prevention, and elimination of infections, to include management and care of persons with contagious and/or communicable disease, *e.g.*, hepatitis, tuberculosis, HIV infection;

2. OSHA standards regarding bloodborne pathogens;

3. Confidentiality of patient information and records and the protection of patient rights;

4. Emergency procedures and disaster preparedness within 24 hours of their first day on the job in the facility (see Section 1200).

5. Fire response training within 24 hours of their first day on the job in the facility (see Section 1303);

6. Aseptic techniques such as handwashing and scrubbing practices, proper gowning and masking, dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of equipment and supplies.

C. All licensed nurses shall possess a valid cardio-pulmonary resuscitation (CPR) certificate within three months from the first day on the job in the facility; a staff member with a valid CPR certificate shall be on duty whenever patients are present in the facility.

D. All newly-hired staff members shall be oriented to acquaint them with the facility organization and physical plant, specific duties and responsibilities of staff members, and patients' needs.

508. Health Status (I)

A. All staff members who have contact with patients shall have, within 12 months prior to initial patient contact, a health assessment as defined in Section 101.R

B. The health assessment shall include a tuberculin skin test as described in Section 1505.

C. If a staff member is working at multiple facilities operated by the same licensee, copies of records for tuberculin skin testing and the pre-employment health assessment shall be acceptable at each facility. (II)

SECTION 600 - REPORTING

601. Incidents/Accidents (II)

A. A record of each incident and/or accident, involving patients or staff members, occurring in the facility or on the facility grounds, shall be retained.

1. Serious incidents/accidents and/or medical conditions as defined below and any illness resulting in death or inpatient hospitalization shall be reported via telephone to the next-of-kin or responsible party immediately and in writing to the Department's Division of Health Licensing within 10 days of the occurrence.

2. Serious medical conditions shall be considered as, but not limited to: major permanent loss of function, hemolytic transfusion reaction involving administration of blood or blood products, surgery on the wrong patient or wrong body part, fractures of major limbs or joints, severe burns, lacerations, or hematomas, and actual or suspected abuse or mistreatment of patients.

B. Reports made to the Division of Health Licensing shall contain at a minimum: facility name, patient age and sex, date of incident/accident, location, extent/type of injury, and how treated, *e.g.*, hospitalization.

C. Significant medication errors and significant adverse medication reactions that require intervention shall be reported immediately to the patient or next-of-kin or responsible party, prescriber, supervising staff member, and administrator. Significant medication errors and significant adverse medication reactions shall be considered as: unintended, undesirable, and unexpected effects of prescribed medications, or of medication errors that require discontinuing a medication or modifying the dose; require hospitalization; result in disability; require treatment with a prescription medication; result in cognitive deterioration or impairment; are life-threatening; or result in death.

D. Changes in the patient's condition, to the extent that serious health concerns are evident, *e.g.*, heart attack, shall be reported immediately to the attending physician, the next-of-kin or responsible party, and the administrator. (I)

602. Fire/Disasters (II)

A. The Department's Office of Fire and Life Safety and the Division of Health Licensing shall be notified immediately via telephone or facsimile regarding any fire in the facility, and followed by a complete written report, to include fire department reports, if any, to be submitted within a time-period determined by the facility, but not to exceed 72 hours from the occurrence of the fire.

B. Any natural disaster that requires displacement of the patients or jeopardizes or potentially jeopardizes the safety of the patients, shall be reported to the Department's Division of Health Licensing via telephone or facsimile immediately, with a complete written report submitted within a time-period as determined by the facility, but not to exceed 72 hours.

603. Communicable Diseases (I)

All cases of diseases that are required to be reported to the appropriate county health department shall be accomplished in accordance with R.61-20.

604. Administrator Change

The Department's Division of Health Licensing shall be notified in writing by the licensee within 10 days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual, documented qualifications as required by Section 502, and the effective date of the appointment.

605. Joint Annual Report

Facilities shall complete and return a "Joint Annual Report" to the Department's Planning and Certificate of Need Division within the time-period specified by that division.

606. Accounting of Controlled Substances (I)

Any facility registered with the Department's Bureau of Drug Control and the federal Drug Enforcement Agency shall report any theft or loss of controlled substances to local law enforcement and to the Bureau of Drug Control within three working days of the discovery of the loss/theft. Any facility permitted by the S.C. Board of Pharmacy shall report the loss or theft of drugs or devices within three working days of the discovery of the loss/theft.

607. Facility Closure

A. Prior to the permanent closure of a facility, the Department's Division of Health Licensing shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the facility shall notify the Division of Health Licensing of the provisions for the maintenance of the records. On the date of closure, the current original license shall be returned to the Division of Health Licensing.

B. In instances where a facility temporarily closes, the Division of Health Licensing shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the facility prior to its reopening. If the facility is closed for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

608. Zero Census

In instances when there have been no patients in a facility for any reason, for a period of 90 days or more, the facility shall notify in writing the Department's Division of Health Licensing no later than the 100th day following the date of the last procedure/surgery performed. If the facility has no patients for a period longer than one year, and there is a desire to re-open, the facility shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

SECTION 700 - PATIENT RECORDS

701. Content (II)

A. The facility shall initiate and maintain an organized record for each patient. The record shall contain: sufficient documented information to identify the patient; the person responsible for each patient; the description of the diagnosis and the care, treatment, procedures, surgery, and/or services provided, to include the course of action taken and results; and the response and reaction to the care, treatment, procedures, surgery, and/or services provided. All entries shall be indelibly written, authenticated by the author, and dated.

B. Specific entries/documentation shall include at a minimum:

1. Consultations by physicians or other legally authorized healthcare providers;

2. Physical examination report, including pertinent medical history;

3. Orders and recommendations for all care, treatment, procedures, surgery, and/or services from physicians or other legally authorized healthcare providers, completed prior to, or at the time of patient arrival at the facility, and subsequently, as warranted;

4. Care, treatment, procedures, surgery, and/or services provided;

5. Record of administration of each dose of medication;

6. Medications administered and procedures followed if an error is made;

7. Special procedures and preventive measures performed, *e.g.*, isolation for symptoms of tuberculosis;

8. Notes of observation during recovery, to include vital signs pre- and post-operative;

9. Discharge summary, including condition at discharge or transfer, instructions for self-care and instructions for obtaining postoperative emergency care;

10. Special information, *e.g.*, allergies, *etc.* Documentation regarding organ donation shall be included in the record at the patient's request;

11. Signed informed consent;

12. If applicable, anesthesia records of pertinent preoperative and postoperative reports including pre-anesthesia evaluation, type of anesthesia, technique and dosage used, and post-anesthesia follow-up note;

13. Operative report (dictated or written into the record after surgery/ procedure) to include at least:

a. Description of findings;

b. Techniques utilized to perform procedure/surgery;

c. Specimens removed, if applicable;

d. Primary surgeon and assistants.

14. Reports of all laboratory, radiological, and diagnostic procedures along with tests performed and the results appropriately authenticated.

C. Except as required by law, patient records may contain written and interpretative findings and reports of diagnostic studies, tests, and procedures, *e.g.*, interpretations of imaging technology and videotapes without the medium itself.

702. Authentication

A. Each document generated by a user shall be separately authenticated.

B. Written signatures or initials and electronic signatures or computer-generated signature codes are acceptable as authentication.

C. In order for a facility to employ electronic signatures or computer-generated signature codes for authentication purposes, staff shall be identified who are authorized to authenticate patient records utilizing electronic or computer-generated signatures.

1. At a minimum, authentication safeguards shall be provided to insure confidentiality, including, but not limited to, the following:

a. Each user shall be assigned a unique identifier that is generated through a confidential code;

b. The facility shall certify in writing that each identifier is kept strictly confidential. This certification shall include a user's commitment to terminate his or her use of an assigned identifier if it is found that the identifier has been misused,

meaning that the user has allowed another person(s) to use his or her personally-assigned identifier, or that the identifier has otherwise been inappropriately utilized;

c. The user shall certify in writing that he or she is the only person with access to the identifier and the only person authorized to use the signature code.

2. The authentication system shall include a verification process to insure that the content of authenticated entries is accurate. The verification process shall include, at a minimum, the following provisions:

a. Blanks, gaps, obvious contradictory statements, or other documentation that require the attention of the authorized user shall be considered authenticated until reviewed and corrected by the user and a revised report issued;

b. Opportunity shall be provided for the user to verify that the document is accurate and that the signature has been properly recorded.

3. A user may terminate authorization for use of electronic or computer-generated signature upon written notice to the individual responsible for the maintenance of patient records.

D. The use of rubber stamp signature is acceptable under the following conditions:

1. The individual whose signature the rubber stamp represents shall be the only individual who has possession of and utilizes the stamp;

2. The individual places in the administrative offices of the facility a signed statement indicating that he or she is the only individual who has possession of and shall utilize the stamp;

3. Rubber stamp signatures are not permitted on orders for medications listed as “controlled substances” pursuant to R.61-4.

703. Record Maintenance

A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection, security, and storage of patient records.

B. When a patient is transferred to an emergency facility, a transfer summary to include, at a minimum, the diagnosis and medication administration record, shall accompany the patient to the receiving facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the facility’s patient record. (I)

C. The patient record is confidential. Records containing protected or confidential health information shall be made available only to individuals granted access to that information, in accordance with state and federal laws. The facility

shall have a written policy designating the persons allowed to access confidential patient information. (II)

D. Records generated by organizations or individuals contracted by the facility for care, treatment, procedures, surgery, and/or services shall be maintained by the facility that has admitted the patient. Appropriate information shall be provided to assure continuity of care.

E. The facility shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by facility staff, as needed, and for regulatory compliance inspections.

F. Upon discharge of a patient, the record shall be completed within 60 days and filed in an inactive/closed file maintained by the licensee. Prior to the closing of a facility for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations and other applicable law. The licensee shall notify the Department's Division of Health Licensing, in writing, describing these arrangements and the location of the records.

G. Records of patients shall be maintained for at least six years following the discharge of the patient. Other documents required by the regulation, *e.g.*, fire drills, shall be retained at least 12 months or until the next Division of Health Licensing inspection, whichever is longer.

H. Patient records are the property of the facility; the original record shall not be removed without court order. (II)

SECTION 800 - CARE/TREATMENT/PROCEDURES/SURGERY/SERVICES

801. General (I)

A. Care, treatment, procedures, surgery, and/or services shall be provided, given, or performed effectively and safely in accordance with orders from physicians or other legally authorized healthcare providers, and precautions shall be taken for patients with special conditions, *e.g.*, pacemakers, pregnancy, Alzheimer's disease, *etc.,* and/or for those who may be susceptible to deleterious effects as a result of the treatment.

B. The facility shall comply with all current federal, state, and local laws and regulations related to patient care, treatment, procedures, surgery, and/or services, and protection.

C. When a facility engages a source other than the facility to provide services normally provided by the facility, *e.g.*, staffing, training, food service, maintenance, housekeeping, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and a statement that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to patient care, treatment, procedures, surgery, and/or services, confidentiality, and rights. (II)

802. Physical Examination (I)

A. A preoperative history and physical examination, pertaining to the procedure to be performed, shall be completed by a physician no earlier than 14 days prior to surgery/procedure, or 30 days prior to surgery/procedure with the condition that, on the day of surgery/procedure, the physician documents no notable changes in the original history and physical examination. If notable changes are discovered at that time, a history and physical examination shall be completed. A discharge summary from a health care facility that includes a history and physical examination may be acceptable as the preoperative history and physical examination, provided the summary is within the time requirements of this section, and is reviewed by the physician performing the surgery/procedure.

B. If a patient or potential patient has a communicable disease, a physician or other legally authorized healthcare provider shall insure that the facility has the capability to provide adequate care and prevent the spread of the disease, and that the staff members are adequately trained and qualified to manage the patient, or transfer the patient to an appropriate facility, if necessary.

803. Surgical Services (If Provided)

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

B. The facility shall maintain a chronological register of all surgical services performed. This shall include patient identification, preoperative diagnosis, type of procedure performed, type of anesthesia utilized, and any unusual occurrence.

804. Anesthesia Services (If Provided) (I)

A. Anesthesia shall be administered only by:

1. An anesthesiologist;

2. A physician, other than an anesthesiologist, or dentist or podiatrist who is qualified to administer anesthesia pursuant to the S.C. Code of Laws;

3. A certified registered nurse;

4. A registered nurse anesthetist;

5. An anesthesiologist's assistant.

B. After the administration of a general anesthetic, a patient shall be attended by a physician until the patient may be safely placed under post-operative/procedure supervision by the nursing staff who shall then attend the patient until he or she has regained full consciousness, or until the effects of the anesthetic have sufficiently subsided for the patient to be able to summon aid when needed.

805. Laboratory Services (II)

A. Each facility shall provide or make arrangements for obtaining laboratory services required in connection with the surgery/procedure to be performed.

B. Should the facility conduct tests that involve human specimens by utilizing any laboratory equipment such as finger-stick glucose, hemoglobin, monitoring devices, *etc.*, for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment, or assessment of health, the facility shall obtain a Certificate of Waiver from the Clinical Laboratories Improvement Amendments (CLIA) Program through the Department's CLIA Program.

C. Laboratory supplies shall not be expired.

D. A pathologist shall examine all surgical specimens except for those types of specimens that the medical staff has determined and documented do not require examination.

806. Radiology Services (II)

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

B. Those facilities where radiological equipment and materials are used shall be in compliance with R.61-63 and R.61-64.

807. Adverse Conditions (I)

Patients in whom any adverse condition exists or in whom a complication is known or suspected to have occurred during or after the performance of the operative procedure shall remain in the facility until the condition/complication is eliminated, as determined by the physician, and the patient is stabilized. Patients requiring care for periods in excess of those set forth in Section 101.RR shall be transferred to a hospital.

808. Patient Instruction (I)

Written instructions shall be issued to all patients upon discharge and shall include, at a minimum, the following:

A. Signs and symptoms of possible complications;

B. Telephone number of the facility or the attending physician or other knowledgeable professional staff member from the facility should any complication occur or question arise;

C. An emergency telephone number should any complication occur. It shall be the responsibility of the attending physician to arrange for needed care;

D. Limitations regarding activities, foods, *etc*.;

E. Date for follow-up or return visit, if applicable.

SECTION 900 - RIGHTS AND ASSURANCES

901. General (II)

A. The facility shall comply with all current federal, state, and local laws and regulations concerning patient care, treatment, procedures, surgery, and/or services, patient rights and protections, and privacy and disclosure requirements, *e.g.*, §44-81-10, *et seq.*, S.C. Code Ann. (2002).

B. The facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, *e.g.*, Title VII, Section 601 of the Civil Rights Act of 1964, and insure that there is no discrimination with regard to source of payment in the recruitment, location of patient, acceptance or provision of services to patients or potential patients, provided that payment offered is not less than the cost of providing services.

C. The facility shall develop and post in a conspicuous place in a public area of the facility a grievance/complaint procedure to be exercised on behalf of the patients that includes the address and phone number of the Department's Division of Health Licensing and a provision prohibiting retaliation should the grievance right be exercised.

D. Care, treatment, procedures, surgery, and/or services provided by the facility, and the charges for such, shall be delineated in writing. Patients shall be made aware of such charges and services, as verified by the signature of the patient or responsible party.

E. Patients shall be permitted to use the telephone and allowed privacy when making calls.

F. Adequate safeguards shall be provided for protection and storage of patients' personal belongings.

G. Patient rights shall be guaranteed, prominently displayed, and the facility shall inform the patient of these rights, to include, at a minimum:

1. The care, treatment, procedures, surgery, and/or services to be provided;

2. Informed consent for care, treatment, procedures, surgery, and/or services;

3. Respect for the patient's property;

4. Freedom from mental and physical abuse and exploitation;

5. Privacy while being treated and while receiving care;

6. Respect and dignity in receiving care, treatment, procedures, surgery, and/or services;

7. Refusal of treatment. The patient shall be informed of the consequences of refusal of treatment, and the reason shall be reported to the physician and documented in the patient record;

8. Refusal of experimental treatment and drugs. The patient's written consent for participation in research shall be obtained and retained in his or her patient record;

9. Confidentiality and privacy of records. Written consent by the patient shall be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's responsible party. The facility shall establish policies to govern access and duplication of the patient's record.

H. Except in emergencies, documentation regarding informed consent shall be properly executed prior to surgery/procedure.

SECTION 1000 - MEDICATION MANAGEMENT

1001. General (I)

A. Medications, including controlled substances, medical supplies, intravenous solutions, and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal laws and regulations, to include the securing, storing, and administering of medications, medical supplies, first aid supplies, biologicals and their disposal when discontinued or expired, or at discharge, death, or transfer of a patient.

B. Non-legend medications that can be obtained without a prescription may be retained and labeled as stock in the facility for administration as ordered by a physician or other legally authorized healthcare provider.

C. If controlled substances are to be used, a controlled substances registration from the Department's Bureau of Drug Control and a controlled substance registration from the federal Drug Enforcement Administration (DEA) shall be obtained. The registration(s) shall be displayed in a conspicuous location within the facility.

D. Each facility shall maintain, upon the advice and written approval of the Medical Director or consultant pharmacist, an emergency kit/cart of lifesaving medicines and equipment for the use of physicians or other legally authorized healthcare providers in treating the emergency needs of patients.

1. The kit/cart shall be sealed and stored in such a manner as to prevent unauthorized access and to ensure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

2. The exterior of each emergency medication kit/cart shall have displayed the following information:

a. “For Emergency Use Only”;

b. Name, address, and telephone number of the consultant pharmacist.

3. Whenever the kit/cart is opened, it shall be restocked and resealed within a reasonable time to prevent risk of harm to a patient.

4. Medications used from the kit/cart shall be replaced pursuant to orders from a physician or other legally authorized healthcare provider according to facility policy.

5. Contents of each section of the kit/cart shall be listed and maintained on or in the kit/cart, and shall correspond to the list. Documentation of monthly checks of expiration dates of medications and supplies is to be retained by the facility for a period of two years or until the Department’s Division of Health Licensing’s next inspection, whichever is longer.

E. Medications shall not be expired.

F. Applicable reference materials published within the previous year shall be available at the facility in order to provide staff members with adequate information concerning medications.

1002. Medication Orders (I)

A. Medications, to include oxygen, shall be administered in the facility to patients only upon orders of a physician or other legally authorized healthcare provider.

B. All orders (including verbal) shall be received only by licensed nurses or authorized healthcare providers, and shall be authenticated and dated by a physician or other legally authorized healthcare provider pursuant to the facility’s policies and procedures, but no later than 72 hours after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and identification of the physician or other legally authorized healthcare provider and the individual receiving the order.

C. Medications and medical supplies ordered for a specific patient shall not be provided to or administered to any other patient.

1003. Administering Medication (I)

A. Each medication dose administered shall be properly recorded in the patient's record as the medication is administered. The medication administration record shall include the name of the medication, dosage, mode of administration, date, time, and the signature of the individual administering the medication. Initials may be utilized when recording administration, provided identification of the individual's initials is located within the record.

B. Expired medications shall not be administered to patients.

1004. Pharmacy Services (I)

Facilities that maintain stocks of legend medications and biologicals for patient use within the facility shall obtain and maintain from the S.C. Board of Pharmacy a valid, current, nondispensing drug outlet permit, displayed in a conspicuous location in the facility, and have a consultant pharmacist on-call during facility operating hours.

1005. Medication Containers (I)

Medications for each patient shall be dispensed from their original container(s), to include unit dose systems. There shall be no transferring between containers or opening blister packs to remove medications for destruction or adding new medications for administration, except by direction of a pharmacist.

1006. Medication Storage (I)

A. Medications shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety and security. Medications shall be stored in accordance with manufacturer's directions and in accordance with all applicable state and federal laws and regulations.

B. Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be of sufficient size for clean and orderly storage, and shall be locked when not under direct observation by a licensed healthcare provider. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf-life.

C. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U. S. Pharmacopia (36 - 46 degrees F.). Food and drinks shall not be stored in the same refrigerator in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals.

D. Medications shall be stored:

1. Separately from poisonous substances, blood, or body fluids;

2. In a manner that provides for separation between oral and topical medications;

3. Separately from food.

E. Records shall be maintained of all stock controlled substances that indicate an accounting of all items received and/or administered in such a manner that the disposition of each dose of any particular item may be readily traced. Records shall be maintained for a minimum of two years or until the next inspection by the Department's Division of Health Licensing, whichever is longer.

F. Review of medication storage areas shall be conducted by the consultant pharmacist or his or her designee on at least a monthly basis. Records of such reviews shall be retained by the facility for at least two years or until the Department's Division of Health Licensing's next inspection, whichever is longer.

1007. Disposition of Medications (I)

A. Medications shall not be retained in stock after the expiration date on the label and no contaminated or deteriorated medications shall be maintained. Expired, damaged, or deteriorated medications and biologicals shall be disposed of in the following manner:

1. When noncontrolled legend medications are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the names of the individual performing the destruction and a witness. (This shall not be applicable to partial unused doses of medications.) The medications may also be disposed of by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.61-4.

B. Destruction records shall be retained by the facility for at least two years or until the Department's Division of Health Licensing's next inspection, whichever is longer.

SECTION 1100 - MEAL SERVICE

1101. General (II)

A. All facilities that prepare food on-site shall be approved by the Department's Division of Health Licensing, and shall be regulated, inspected, and graded pursuant to R.61-25.

B. When meals or snacks are catered to a facility, such meals shall be obtained from a food service establishment graded by the Department, pursuant to R.61-25, and there shall be a written executed contract with the food service establishment.

1102. Food Storage (II)

A. All food items shall be stored at a minimum of six inches above the floor on clean surfaces and in such a manner as to be protected from splash and other contamination.

B. Food stored in the refrigerator or freezer shall be covered, labeled, and dated. Prepared food shall not be stored in the refrigerator for more than 72 hours.

1103. Food Equipment and Utensils (II)

The equipment and utensils utilized, and the cleaning, sanitizing, and storage of such shall be in accordance with R.61-25.

1104. Ice and Drinking Water (II)

A. Ice from a water system that is in accordance with R.61-58, shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside of the ice container.

B. Potable drinking water shall be available and accessible to patients at all times.

C. The use of common drinking cups shall be prohibited.

D. Ice delivered to patient areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

1105. Equipment (II)

A. Liquid or powder soap in dispensers and sanitary paper towels shall be available at each food service handwash lavatory.

B. A separate handwash sink shall be provided, convenient to serving, food preparation, and dishwashing areas.

C. All walk-in refrigerators and freezers shall be equipped with opening devices that will permit opening of the door from the inside at all times. (I)

1106. Refuse Storage and Disposal (II)

Refuse storage and disposal shall be in accordance with R.61-25.

SECTION 1200 - EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1201. Emergency Services (I)

A. Appropriate equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital.

B. The facility shall have the capability of obtaining blood and blood products to meet emergency situations.

1202. Disaster Preparedness (II)

A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

1203. Emergency Call Numbers (I)

Although the facility may have access to "911," emergency call data shall be immediately available and shall include, at a minimum, the telephone numbers of fire and police departments, ambulance service, and the Poison Control Center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

1204. Continuity of Essential Services (II)

There shall be a written plan to be implemented to assure the continuation of essential patient support services for reasons such as power outage, water shortage, or in the event of the absence of any portion of the staff resulting from inclement weather or other causes.

SECTION 1300 - FIRE PREVENTION

1301. Arrangements for Fire Department Response/Protection (I)

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, *i.e.*, fire plan and evacuation plan.

B. Facilities located outside a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the facility.

1302. Tests and Inspections (I)

A. Fire protection and suppression systems shall be maintained and tested in accordance with NFPA 10, 13, 14, 15, 25, 70, 72, and 96.

B. Fire alarm systems shall be maintained in a safe, operable condition in accordance with NFPA 70 and 99 and shall be inspected at least annually.

1303. Fire Response Training (I)

A. Each staff member shall receive training within 24 hours of his or her first day of employment in the facility and at least annually thereafter, addressing at a minimum, the following:

1. Fire plan;

2. Reporting a fire;

3. Use of the fire alarm system, if applicable;

4. Location and use of fire-fighting equipment;

5. Methods of fire containment;

6. Specific responsibilities, tasks, or duties of each staff member.

B. A plan for the evacuation of patients, staff members, and visitors, to include evacuation routes and procedures in case of fire or other emergencies, shall be established and posted in conspicuous public areas throughout the facility.

1304. Fire Drills (I)

A. An unannounced fire drill shall be conducted at least quarterly for all shifts. Each staff member shall participate in a fire drill at least once each year. Records of drills shall be maintained at the facility, indicating the date, time, shift, description and evaluation of the drill, and the names of staff members directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, the provisions of the statute or regulation shall be complied with and shall supersede the requirements of this section.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1303 above.

SECTION 1400 - MAINTENANCE

1401. General (II)

A. The structure, including its component parts and equipment, shall be properly maintained to perform the functions for which it is designed.

B. Noise, dust, and other related patient intrusions shall be minimized when construction or renovation activities are underway.

1402. Equipment (II)

A. Equipment used in the provision of care, treatment, procedures, surgery, and/or services shall meet appropriate specifications and calibrations and shall be monitored and operated in accordance with the manufacturer's guidelines and with local, state, and federal laws.

B. If utilized, all equipment for the administration of anesthesia shall be readily available, clean or sterile, and operating properly.

1. Anesthesia apparatus shall be equipped with a device to measure the oxygen component of the gas being inhaled by the patient. The device shall emit audible and visual alarms should the proportion of oxygen fall below a safe level. (I)

2. Inspections shall be made prior to each use of the anesthesia equipment, as well as a record of all service and repair performed on all anesthesia machines, vaporizers, and ventilators, shall be maintained and retained for a minimum of two years or until the next Department's Division of Health Licensing inspection, whichever is longer.

1403. Preventive Maintenance of Life Support Equipment (II)

A. A written preventive maintenance program shall be developed and implemented for all life support equipment, to include, but not be limited to:

1. Patient monitoring equipment;

2. Isolated electrical systems;

3. Patient ground systems;

4. Medical gas systems.

B. This equipment shall be calibrated, if applicable, and/or tested at periodic intervals, but not less than annually, to insure proper operation. After repairs and/or alterations are made to any equipment or system, thorough testing for proper operation shall be accomplished prior to returning it to service. (I)

C. Records shall be maintained on all life support equipment to indicate its history of testing and maintenance.

SECTION 1500 - INFECTION CONTROL AND ENVIRONMENT

1501. Staff Practices (I)

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and

practices shall be in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; the Centers for Disease Control and Prevention (CDC) Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee; the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*, and R.61-105; and other applicable federal, state, and local laws and regulations.

1502. Vaccinations (I)

A. Hepatitis B.

1. All direct care staff who perform tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case the decision shall be documented.

2. Each staff member who elects vaccination shall have completed the initial dose of the three-dose series within 30 days of employment.

B. Influenza. All direct care staff shall have an annual influenza vaccination unless contraindicated or offered and declined. In either case the decision shall be documented.

C. MMR and Varicella. All direct care staff shall have been vaccinated or have evidence of immunity for measles, rubella, and varicella prior to patient contact unless contraindicated or offered and declined. In either case the decision shall be documented. Immunity to mumps is recommended.

1503. Live Animals

Live animals shall not be permitted in facilities.

EXCEPTION: This standard does not apply to patrol dogs accompanying security or police officers, guide dogs, or other service animals accompanying individuals with disabilities.

1504. Sterilization Procedures (I)

A. Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and operating room materials as well as laboratory equipment and supplies. The sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be tested at least quarterly; periodic calibration and/or preventive maintenance shall be provided as necessary and a history of testing and service maintained.

B. The dates of sterilization and expiration shall be marked on all supplies sterilized in the facility.

EXCEPTION: Facilities may utilize "event-related" methodologies for determining sterile integrity in lieu of "time-related" methods provided there is an established policy and procedure.

C. The facility shall provide for appropriate storage and distribution of sterile supplies and equipment pursuant to facility policies and procedures.

D. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment's purpose or use, shall be accomplished. A recognized method of monitoring disinfectant performance shall be employed. Disinfectants, *e.g.*, glutraldehyde, Cidex, Sporox, hydrogen peroxide, shall be tested and maintained according to manufacturer's instructions and shall include, at a minimum, a record of readings/testings and change dates of the disinfectant solution.

1505. Tuberculin Skin Testing (I)

A. Tuberculin skin testing, utilizing a two-step intradermal (Mantoux) method of five tuberculin units of stabilized purified protein derivative (PPD), is a procedure recommended by the CDC *Guidelines for Preventing Transmission of Mycobacterium Tuberculosis in Health Care Facilities* to establish baseline status. The two-step procedure involves one initial tuberculin skin test with a negative result, followed 7-21 days later by a second test. It is permissible for a licensed nurse to perform the tuberculin screening.

B. Testing Procedures.

1. Direct care staff members shall be required to have evidence of a two-step tuberculin skin test within three months prior to patient contact. If there is a documented negative tuberculin skin test (at least single-step) within the previous 12 months, the individual shall be required to have only one tuberculin skin test to establish a baseline status. If two-step testing is indicated, it is acceptable for staff and volunteers who are asymptomatic for TB to begin patient contact after completion of the first skin test with a documented negative result.

2. Individuals with negative test results from the initial two-step procedure shall be required to have an annual one-step skin test.

C. Positive Reactions/Exposure.

1. Individuals with tuberculin skin test reactions of 10mm or more of induration and known human immunodeficiency virus (HIV)-positive individuals with tuberculin skin test reactions of 5mm or more of induration shall be referred to a physician or other legally authorized healthcare provider for appropriate evaluation.

2. All persons who are known or suspected to have tuberculosis (TB) shall be evaluated by a physician or other legally authorized healthcare provider. These

individuals shall not be allowed to return to work until they have been declared noncontagious.

3. Patients with symptoms of TB shall be isolated and/or treated or referred as necessary by a physician or other legally authorized healthcare provider, and documented in the patient record.

4. Individuals who have a prior history of TB shall be required to have a chest radiograph and certification within one month prior to employment by a physician or other legally authorized healthcare provider that they are not contagious.

5. If an individual who was previously documented as skin test negative has an exposure to a documented case of TB, the facility shall immediately contact the local county health department or the Department's TB Control Division for consultation.

6. An individual with TB infection who remains asymptomatic shall not be required to have a chest radiograph but shall have an annual documented assessment by a physician or other legally authorized healthcare provider for symptoms suggestive of TB, *e.g.*, cough, weight loss, night sweats, fever, *etc.*

D. Treatment.

1. Preventive treatment of individuals who are new positive reactors is recommended unless specifically contraindicated.

2. Individuals who complete treatment either for disease or infection are exempt from further treatment unless they develop symptoms of TB.

1506. Housekeeping (II)

The facility and its grounds shall be neat, uncluttered, clean, and free of vermin and offensive odors.

A. Interior housekeeping shall at a minimum include:

1. Cleaning each specific area of the facility (dry sweeping and dusting shall be prohibited in restricted areas as identified in facility policies and procedures);

2. Cleaning of operating/procedure rooms in accordance with established written procedures after each operation/procedure.

B. Exterior housekeeping shall at a minimum include:

1. Cleaning of all exterior areas, *e.g.*, porches and ramps, and removal of safety impediments such as snow and ice;

2. Keeping facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

1507. Infectious Waste (I)

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in a manner compliant with OSHA Bloodborne Pathogens Standard, the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*, and R.61-105.

1508. Clean/Soiled Linen and Surgical Clothing (II)

A. A supply of clean, sanitary linen/surgical clothing shall be available at all times. In order to prevent the contamination of clean linen/surgical clothing by dust or other airborne particles or organisms, it shall be stored and transported in a sanitary manner, *i.e.*, enclosed and covered. Linen/Surgical clothing storage rooms shall be used only for the storage of linen/surgical clothing. Clean linen/Surgical clothing shall not be stored with other items.

B. Soiled linen/Surgical clothing.

1. Provisions shall be made for collecting, transporting, and storing soiled linen and surgical clothing;

2. Soiled linen/Surgical clothing shall be kept in enclosed/covered containers.

SECTION 1600 - QUALITY IMPROVEMENT PROGRAM

1601. General (II)

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care, treatment, procedures, surgery, and/or services provided by the facility.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is systematically, objectively, and regularly accomplished at a frequency as determined by the facility to ensure that policies and procedures and this regulation are met, but not less than every three months;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Establish ways to measure the quality of patient care and staff performance as well as the degree to which the policies and procedures are followed;

5. Analyze the necessity of care, treatment, procedures, surgery, and/or services rendered;

6. Analyze the effectiveness of the fire plan;

7. Analyze all serious incidents and accidents, to include all patient deaths and significant medication errors;

8. Analyze any other unusual occurrences that threaten the health, safety, or well-being of the patients;

9. At least every three months, review an established percentage of patient records to verify the accuracy and integrity of the system, and take corrective action as needed;

10. Establish a systematic method of obtaining feedback from patients and other interested persons, *e.g.*, family members and peer organizations, as expressed by the level of satisfaction with care, treatment, procedures, surgery, and/or services received.

SECTION 1700 - DESIGN AND CONSTRUCTION

1701. General (II)

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient.

1702. Local and State Codes and Standards (II)

A. Buildings shall comply with pertinent local and state laws, codes, ordinances, and standards with reference to design and construction. No facility shall be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the facility for code compliance.

B. The Department utilizes the basic codes indicated in Section 102.B.

C. Buildings designed in accordance with the above-mentioned codes shall be acceptable to the Department provided the requirements set forth in this regulation are also met.

1703. Applicable Code Editions (II)

A. All buildings of facilities, new and existing, being licensed for the first time, or changing their license to provide a different service, shall meet the current codes and regulations.

B. Unless specifically required otherwise in writing by the Department's Division of Health Facilities Construction, all existing facilities shall meet the construction

codes and regulations for the building and its essential equipment and systems in effect at the time the license was issued. Except for proposed facilities that have received a current and valid written approval to begin construction, current construction codes, regulations, and requirements shall apply to those facilities licensed after the date of promulgation of these regulations.

C. Any additions or renovations to an existing licensed facility shall meet the codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of the addition or renovation. When the cost of additions or renovations to the building exceeds 50% of the then market value of the existing building and its essential equipment and systems, the building shall meet the then current codes, regulations, and requirements.

D. Buildings of facilities under construction at the time of promulgation of these regulations shall meet the codes, regulations, and requirements in effect at the time of the plan's approval.

E. Any facility that closes, has its license revoked, or surrenders its license, and applies for re-licensure at the same site, shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for re-licensing.

1704. Submission of Plans and Specifications

A. New Buildings, Additions, or Major Alterations to Existing Buildings.

1. Plans for all new construction or existing structures proposed to be licensed by the Department and specifications shall be submitted to the Department's Division of Health Facilities Construction for review and approval.

2. Where the current building code as listed in Section 102.B, or other regulations require fire-rated walls or other fire-rated structural elements, these plans and specifications shall be prepared by an architect and shall bear his or her seal.

3. The architect preparing plans and specifications for construction or interior modification of buildings of 5000 square feet or more in total floor area or three stories or more in height, and for buildings involving construction of fire-rated assemblies, shall provide the Minimum Construction Administration Services, as defined in the *Code of Professional Ethics*, published by The Board of Architectural Examiners, S.C. Department of Labor, Licensing, and Regulation. The construction shall also comply with Section 1704.A.2 above,

4. When construction is contemplated for additions or alterations to existing licensed buildings, the facility shall contact the Division of Health Facilities Construction regarding code and regulatory requirements that apply to that project. Plans and specifications shall be submitted to that division for review.

5. All plans shall be drawn to scale with the title, location, and date indicated thereon.

6. Construction shall not begin until approval of the final drawings or written permission has been received from the Division of Health Facilities Construction. Any construction deviations from the approved documents shall be approved by the Division of Health Facilities Construction.

B. Plans and specifications shall be reviewed by the Division of Health Facilities Construction as necessary to obtain a set of approvable drawings showing all necessary information. These reviews may be, but are not required to be, in three stages: Preliminary, Design Development, and Final.

1. Preliminary submission shall include the following:

a. Plot plan showing:

(1) Size and shape of entire site;

(2) Footprint showing orientation and location of proposed building;

(3) Location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, *etc.*, properly designated;

(4) Size, characteristics, and location of all existing public utilities, including information concerning water supply available for fire protection, *i.e.,* distance to nearest fire hydrant; parking; any hazardous areas, *e.g.*, cliffs, roads, hills, railroads, industrial and/or commercial sites, and bodies of water, *etc.*

b. Floor plans showing blocked spaces (areas) of approximate size and shape and their relationship to other spaces.

2. Design Development drawings shall indicate the following as well as the above:

a. Cover sheet:

(1) Title and location of the project;

(2) Index of drawings;

(3) Code analysis listing applicable codes (both local jurisdiction and state);

(4) Occupancy classification per the current building code as listed in Section 102.B;

(5) Type of construction per the current building code as listed in Section 102.B.

b. Floor plans:

(1) Overall dimensions of buildings;

(2) Locations, size, and purpose of all rooms including furniture layout plan;

(3) Location and size of doors, windows, and other openings with swing of doors properly indicated;

(4) Life Safety plan showing all fire walls, exits, exit calculations, locations of smoke barriers if required, fire-rated walls, locations of stairs, elevators, dumbwaiters, vertical shafts, and chimneys;

(5) Fixed equipment.

c. Outline specifications that include a general description of construction including interior finishes and mechanical systems.

3. Final submission shall include the above in addition to complete working drawings and contract specifications, including layouts for site preparation and landscaping, architectural, plumbing, electrical, mechanical, and complete fire protection.

4. If the start of construction is delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

5. One complete set of “as-built” drawings shall be filed with the Division of Health Facilities Construction.

SECTION 1800 - GENERAL CONSTRUCTION REQUIREMENTS

1801. Height and Area Limitations (II)

Construction shall not exceed the allowable heights and areas provided by the current building code as listed in Section 102.B.

1802. Fire-Resistive Rating (I)

The fire-resistive ratings for the various structural components shall comply with the current building code as listed in Section 102.B. Fire-resistive ratings of various materials and assemblies not specifically listed in the current building code as listed in Section 102.B can be found in publications of recognized testing agencies such as *Underwriters Laboratories - Building Materials List* and *Underwriters Laboratories - Fire Resistance Directory*.

1803. Vertical Openings (I)

All vertical openings shall be protected in accordance with applicable sections of the current building code as listed in Section 102.B, State Fire Marshal Regulations, and NFPA 101.

1804. Wall and Partition Openings (I)

All wall and partition openings shall be protected in accordance with applicable sections of the current building code as listed in Section 102.B and NFPA 101.

1805. Ceiling Openings (I)

Openings into attic areas or other concealed spaces shall be protected by material consistent with the fire-rating of the assembly penetrated.

1806. Firewalls (I)

A. A building is defined by the outside walls and any interior four-hour firewalls and shall not exceed the height and area limitations set forth in the current building code as listed in Section 102.B for the type of construction.

B. An addition shall be separated from an existing building by a two-hour, fire-rated wall, unless the addition is of equal fire-resistive rating.

C. When an addition of a different type of construction from the existing building is planned, the type of construction and resulting maximum area and height limitations allowed by the current building code as listed in Section 102.B shall be determined by the lesser of the types of construction of the building.

D. If the addition is separated by a four-hour firewall, the addition is considered as a separate building, and the type of construction of the addition shall determine the maximum area and height limitations.

1807. Windows (II)

A. The window dimensions and maximum height from floor to sill shall be in accordance with the current building code as listed in Section 102.B and the Life Safety Code, as applicable.

B. Where clear glass is used in windows, with any portion of the glass being less than 18 inches from the floor, the glass shall be of “safety” grade, or there shall be a guard or barrier over that portion of the window. This guard or barrier shall be of sufficient strength and design so that it will prevent an individual from injuring him/herself by accidentally stepping into or kicking the glass.

1808. Floor and Wall Finishes (II)

A. Floor and wall coverings and finishes shall meet the requirements of the current building code as listed in Section 102.B.

B. All floors in operating and recovery areas shall be smooth resilient tile and be free from cracks and finished to facilitate effective cleaning.

C. Carpeting shall not be utilized as floor covering in operating and recovery areas.

D. All floor coverings and finishes shall be appropriate for use in each area of the facility and free of hazards, *e.g.*, slippery surfaces.

E. Floor finishes shall be composed of materials that are conducive to frequent cleaning, and when appropriate, disinfection.

F. Wall bases in operating rooms, soiled workrooms and other areas subject to frequent wet cleaning shall be installed and tightly sealed without voids that could harbor vermin. Walls shall be washable, and, in the immediate area of plumbing fixtures, the finish shall be smooth, moisture resistant, and easily cleaned.

G. Floor and wall penetrations by pipes, ducts, conduits, *etc.*, and joints of structural elements shall be tightly sealed to minimize entry of rodents and insects.

H. Thresholds and expansion joint covers shall be made flush with the floor surface to facilitate use of wheelchairs and carts.

I. Manufacturers' certifications or documentation of treatment for flame-spread and other safety criteria for combustible finishes shall be maintained.

J. All restroom floors shall have an approved nonabsorbent covering. Wall surfaces shall be nonabsorbent and washable to the highest level of splash.

1809. Ceilings

A. Ceilings in operating rooms shall be washable and without crevices that can retain dirt particles.

B. Finished ceilings are not required in mechanical and equipment spaces, shops, general storage areas, and similar spaces, except where required for fire rating.

C. Rooms containing ceiling mounted equipment and those that have ceiling mounted surgical light fixtures shall have height required to accommodate the equipment or fixture. All other rooms shall have not less than 8-foot ceilings except that corridors, storage rooms, toilet rooms and other minor rooms shall not be less

than 7 feet 8 inches. Suspended tracks, rails, pipe, *etc*., located in the path of normal traffic, shall be not less than 7 feet 6 inches above the floor.

SECTION 1900 - HAZARDOUS ELEMENTS OF CONSTRUCTION

1901. Furnaces and Boilers (I)

Furnaces and boilers shall be maintained in accordance with the applicable provisions of NFPA 31, 70, 85C, and 86.

1902. Dampers (I)

Smoke and fire dampers shall be installed on all heating, ventilating, and air conditioning systems as required by NFPA 90A and the current building code as listed in Section 102.B.

1903. Incinerators (I)

If an incinerator is provided, it shall conform to the requirements of the Department. When located within the licensed facility, incinerators shall be separated by construction having at least 2-hour fire-resistive rating with 1and1/2-hour fire-rated door(s) and frame(s).

1904. Furnishings/Equipment (I)

A. The physical plant shall be maintained free of fire hazards and impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted in the facility except as permitted by the State Fire Marshal Regulations.

C. Wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with NFPA 701, *Standard Methods of Fire Tests for Flame-Resistant Textiles and Films*.

EXCEPTION: Window blinds require no flame treatments or documentation thereof.

SECTION 2000 – EXITS

2001. General (I)

A. Exits, corridors, doors, stairs, ramp, and smoke partitions shall be provided, installed, and maintained in accordance with the provisions of NFPA 101 and the current building code as listed in Section 102.B.

B. Each operating/procedure room and each recovery room shall communicate directly with an approved exit corridor without passage through another occupied

space or shall have an approved exit directly to the outside at grade level in an area of safety. (I)

C. Rooms and/or suites greater than 1000 square feet shall have at least two exit access doors remote from each other.

D. If exit doors and cross-corridor doors are locked, the requirements for Special Locking Arrangements in the current building code, as listed in Section 102.B, shall be met.

E. Halls, corridors and all other means of egress from the building shall be maintained free of obstructions.

SECTION 2100 - FIRE PROTECTION EQUIPMENT AND SYSTEMS

2101. Firefighting Equipment (I)

A. Firefighting equipment such as fire extinguishers, standpipes and automatic sprinklers shall be provided as required by the current building code as listed in Section 102.B.

B. Extinguishers shall be so located that an individual would not be required to travel more than 50 feet from any point within the facility to reach an extinguisher.

C. Extinguishers shall be sized, located, installed, and maintained in accordance with NFPA No. 10 except that portable fire extinguishers intended for use in patient recovery areas shall be the stored-pressure type water extinguisher.

D. Suitable fire extinguishers shall also be installed in the following hazardous areas: kitchen, laundry, furnace rooms, and any other area having an unusual fire hazard.

E. The kitchen(s) or food/snack preparation area(s) shall be equipped with a minimum of one K-type and one 20-BC-type fire extinguisher.

2102. Fire Alarms (I)

A. A fire alarm system shall be provided in accordance with provisions of NFPA 72 and the current building code as listed in Section 102.B. The fire alarm system shall at least meet the requirements of a “Partial System” as defined by NFPA 72.

B. The system shall be arranged to transmit an alarm automatically to the fire department by an approved method.

C. The alarm system shall notify by audible and visual alarm all areas and floors of the building.

D. The alarm system shall cause the central re-circulating ventilation fans that serve the area(s) of alarm origination to cease operation and to shut the associated smoke dampers.

E. Fire alarm pull-stations shall be placed at all exits in accordance with NFPA 72.

F. All fire, smoke, heat, sprinkler-flow, fire-sensing detectors, manual pull-stations, hold-open devices on fire-rated doors, alarming devices, or other fire-related systems shall be connected to and monitored by the main fire alarm system, and activate the general alarm when any of these devices are activated.

G. The fire alarm system shall have the main fire alarm located at a readily-accessible location. An audible/visual trouble indicator shall be located where it can be observed by staff members.

H. The fire alarm system shall be tested initially by an individual licensed to install fire alarms, and at least annually thereafter.

2103. Smoke Detectors (I)

Smoke detectors shall be installed in all exit access corridors 30 feet on center in accordance with NFPA 72 and the current building code as listed in Section 102.B. No smoke detectors shall be placed within three feet of a HVAC supply or return vent.

2104. Flammable Liquids (I)

The storage and handling of flammable liquids shall be in accordance with NFPA 30 and 99.

2105. Gases (I)

A. Gases, *i.e.*, flammable and nonflammable, shall be handled and stored in accordance with the provisions of NFPA 99 and 101.

B. Installation, maintenance, and testing of piped gas systems shall meet the provisions of NFPA 99.

C. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. “No Smoking” signs shall be posted conspicuously inside the facility and on oxygen cylinders. All cylinders shall be properly secured in place.

SECTION 2200 - WATER SUPPLY/HYGIENE

2201. Design & Construction (II)

A. A water distribution system, provided by a public or private source, shall be approved by the Department's Bureau of Water before the facility can be constructed and/or placed into operation. (I)

B. Before the construction, expansion, or modification of a water distribution system, application shall be made to the Department for a Permit for Construction. The application shall include such engineering, chemical, physical, or bacteriological data as may be required by the Department and shall be accompanied by engineering plans, drawings, and specifications prepared by an engineer registered in S.C., and shall include his or her signature and official seal.

C. The design and construction of such systems shall be in accordance with standard engineering practices for such installations. The Department shall establish such rules, regulations, and/or procedures as may be necessary to protect the health of the public and to insure proper operation and functioning of the system. The facility's water system shall be in compliance with R.61-58 and other local, state, and federal laws and regulations.

D. Storage tanks shall be fabricated of corrosion-resistant metal or lined with noncorrosive material.

2202. Disinfection of Water Lines (I)

A. After construction, expansion, or modification, a water distribution system shall be disinfected in accordance with R.61-58.

B. Samples shall be taken from the water system and forwarded to an approved laboratory for bacteriological analysis in accordance with R.61-58. The water shall not be used as a potable supply until certified as satisfactory.

2203. Temperature (I)

A. Patient and staff handwashing lavatories and showers, if any, shall be supplied with hot and cold water at all times.

B. Plumbing fixtures that require hot water and which are accessible to patients shall be supplied with water that is thermostatically controlled to a temperature of at least 100 degrees F. and not to exceed 120 degrees F. at the fixture.

2204. Stop Valves

A. Each plumbing fixture shall have stop valves to permit repairs without disrupting service to other fixtures.

B. Each group of fixtures on a floor, each branch main, and each supply line shall be valved.

2205. Cross-connections (I)

A. There shall be no cross-connections in plumbing between safe and potentially unsafe water supplies.

B. Water shall be delivered at least two delivery pipe diameters above the rim or points of overflow to each fixture, equipment, or service unless protected against back-siphonage by approved vacuum breakers or other approved back-flow preventers.

C. A faucet or fixture to which a hose may be attached shall have an approved vacuum breaker or other approved back-flow preventer.

2206. Wastewater Systems (I)

A. A wastewater system, provided by a public or private source, shall be approved by the Department's Bureau of Water before the facility can be constructed and/or begins operation.

B. Plans, specifications, reports and studies, for the construction, expansion or alteration of a wastewater system shall be prepared by an engineer registered in S.C., and shall carry his or her signature and official seal.

C. The design and construction of wastewater systems shall be in accordance with standard engineering practice and R.61-67.

D. Liquid waste shall be disposed of in a wastewater system approved by the local authority, *e.g.*, sewage treatment facility.

SECTION 2300 - ELECTRICAL

2301. General (I)

A. Electrical installations shall be in accordance with NFPA 70 and 99.

B. Wiring in the facility shall be inspected at least once every two years by a licensed electrician, registered engineer, or certified building inspector.

C. All materials shall be listed as complying with available standards of Underwriters Laboratories, Inc. or other similarly established standards.

D. New systems shall be tested to indicate that the equipment is installed and operates as planned or specified.

2302. Panelboards (II)

A. Panelboards shall be installed and maintained in accordance with NFPA 70.

B. Panelboards serving lighting and appliance circuits shall be located on the same floor as the circuits served. (This requirement does not apply to life-safety system circuits.)

C. The panelboard directory shall be labeled to conform to the actual room designations.

D. Clear access to the panel shall be maintained, as per NFPA 70.

2303. Lighting

A. Spaces occupied by persons, machinery, equipment within buildings, approaches to buildings, and parking lots shall be lighted with adequate artificial light. (II)

B. Hallways, stairs, and other means of egress shall be lighted at all times in accordance with NFPA 101, *i.e.*, at a minimum, an average of one foot-candle at floor level. (I)

2304. Receptacles (II)

A. Recovery Area. Each bed in the recovery area shall have duplex grounding-type receptacles located per NFPA 70, to include one at the head of each bed.

B. Corridors. Duplex receptacles for general use shall be installed approximately 50 feet apart in all corridors and within 25 feet of the ends of corridors.

2305. Ground Fault Protection (I)

A. Ground fault circuit-interrupter protection shall be provided for all outside receptacles and restrooms in accordance with the provisions of NFPA 70.

B. Ground fault circuit-interrupter protection shall be provided for any receptacles within six feet of a sink or any other wet location. If the sink is an integral part of the metal splashboard grounded by the sink, the entire metal area is considered part of the wet location.

2306. Exit Signs (I)

A. Required exits and exit access passages shall be identified by electrically-illuminated exit signs bearing the words “Exit” in red letters, six inches in height, on a white background.

B. Changes in egress direction shall be marked with exit signs with directional arrows.

C. Exit signs in corridors shall be provided to indicate two directions of exit.

2307. Emergency Call System

A. An emergency call system shall be provided at each patient toilet fixture and patient change-room.

B. Activation shall be by a pull-cord that extends to within four inches above the floor.

C. This system will activate audio-visual signals in the recovery area work station.

D. The emergency call system shall be designed so that the audio-visual signal will remain activated until turned off at the patients' calling location (II)

2308. Emergency Electric Service (I)

A. Emergency electrical services shall be provided as required by the current building code as listed in Section 102.B, NFPA 101, and NFPA 110.

B. An emergency generator system shall be provided to provide electricity during an interruption of the normal electric supply. The emergency power system shall provide power for:

1. Illumination for means of egress;

2. Illumination for exit signs and exit directional signs;

3. Signal system;

4. Alarm systems;

EXCEPTION: In endoscopy facilities, batteries are an acceptable source of power for items 2308.B.1 through 4.

5. Illumination and selected receptacles in operating/procedure rooms and recovery areas, and in the vicinity of the generator set.

EXCEPTION: Endoscopy facilities shall not be required to provide emergency electrical power for Section 2308.B.5. If a generator is chosen to provide emergency electrical power, it must meet all of the requirements of Section 2308.

C. The generator system shall:

1. Be designed to meet the heating, ventilation, air conditioning (HVAC) requirements for operating/procedure rooms and recovery areas and other essential operational needs;

2. Have a minimum of 12 hours of fuel designed to operate at its rated load. The fuel quantity shall be based on its expected or known connected load consumption during power interruptions;

3. Provide emergency electrical power through an automatic transfer switch that shall automatically transfer the circuits to the emergency power source within 10 seconds of a power failure;

4. Be inspected and tested weekly for at least 30 minutes, and once each month, utilize actual load and operating temperature conditions, including automatic and manual transfer of equipment. A record shall be maintained for all inspections and tests and kept on file for a minimum of three years;

5. Have designated staff knowledgeable of generator operation.

D. An Uninterruptible Power System (UPS) is not acceptable as an alternative to the generator system.

E. In the event of natural disaster or electrical power failure, no new surgery/ procedures shall commence, and surgery/procedures in progress shall be concluded as soon as possible.

SECTION 2400 - HEATING, VENTILATION, AND AIR CONDITIONING

2401. General (II)

A. Prior to licensure of the facility, all mechanical systems shall be tested, balanced and operated to demonstrate that the installation and performance of these systems conform to the requirements of the plans and specifications.

B. If used, clinical vacuum (suction) system installations shall be in accordance with the requirements of NFPA No. 99. (I)

2402. Heating, Ventilation, Air Conditioning

A. Heating, ventilation, and air conditioning (HVAC) systems shall comply with NFPA 90A and all other applicable codes.

B. The HVAC system shall be inspected at least once a year by a certified/ licensed technician.

C. No HVAC supply or return grill shall be installed within three feet of a smoke detector. (I)

D. HVAC grills shall not be installed in floors.

E. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in such a manner that would be an irritant to the patients/staff.

F. Each restroom shall have approved mechanical ventilation.

2403. Ventilation Requirements

A. The ventilation rates shown herein shall be considered as minimum acceptable rates and shall not be construed as precluding the use of higher ventilation rates for operating rooms.

B. Temperatures and humidity. HVAC systems shall be designed to provide the temperature and humidity shown below:

AREA DESIGNATION	TEMPERATURE		RELATIVE HUMIDITY
	FAHRENHEIT	CENTIGRADE	
Operating Rooms	70 - 76º	21 - 24º	50 - 60%
Recovery Areas	75 - 80º	24 - 27º	50 - 60%
Procedure Rooms; Other	72 - 78º	22 - 26º	50 - 60%

C. All air-supply and air-exhaust systems for the surgical suite shall be mechanically operated.

D. All fans serving exhaust systems shall be located at the discharge end of the system.

E. Outdoor intakes shall be located as far as practical from the exhausts from any ventilating system, combustion equipment, and plumbing vents and at least three feet above the ground or roof.

F. 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.

G. At least two exhaust outlets shall be used in all operating rooms.

EXCEPTION: Only one exhaust outlet is required for facilities that perform endoscopy.

H. The bottom of any room supply air inlets, re-circulation, and exhaust air outlets shall be located not less than three inches above the floor.

I. All ventilation or air conditioning systems serving operating rooms shall have a minimum of two filter beds.

1. Filter bed #1 shall be located upstream of the air conditioning equipment and shall have a minimum efficiency of 25%.

2. Filter bed #2 shall be downstream of the supply fan and of recirculating spray water and water reservoir-type humidifiers. Filter bed #2 shall have a minimum efficiency of 90%.

3. 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% efficiency based on the DOP (dioctyophthalate) test method and there shall be equipment and/or procedure for the safe removal of contaminated filters.

4. Filter frames shall be durable and carefully dimensioned and shall provide an airtight fit with the enclosing duct-work. All joints between filter segments and the enclosing duct-work shall be gasketed or sealed to provide a positive seal against air leakage.

5. Each filter bed serving sensitive areas or central air systems shall have a manometer installed across each filter bed.

EXCEPTION: A single-step filter bed of 20% filters is required for endoscopy facilities.

J. All air supplied to soiled linen holding, janitor's closets or soiled workrooms shall be exhausted to the outside and shall not be re-circulated within the room. (II)

K. Air handling duct systems shall not have duct linings.

L. The ventilation systems shall be designed and balanced to provide the pressure relationship as shown in the table below:

AREA DESIGNATION	PRESSURE RELATION-SHIP TO ADJACENT AREAS	MINIMUM TOTAL AIR CHANGES PER HOUR SUPPLIED TO ROOM	ALL AIR EXHAUSTED DIRECTLY TO OUTDOORS	RE-CIRCULATED WITHIN ROOM UNITS
Operating Room	P	16	Optional	Only with approved filters
Recovery and Procedure Rooms	P	6	Optional	Only with approved filters
Soiled Workroom or Soiled Holding	N	10	Yes	No
Clean Workroom or Clean Holding	P	4	Optional	Optional

P = Positive N = Negative

SECTION 2500 - PHYSICAL PLANT

2501. Administrative Areas

A. The facility shall include:

1. Reception and information counter or desk;

2. Waiting space(s) that shall include:

a. Public toilet facilities;

b. Public telephone(s);

c. Drinking fountain(s).

3. Space(s) for private interviews relating to the procedure to be performed.

B. Secure storage areas for:

1. Patient records;

2. Patients' and staff's personal items.

2502. Surgical Suite(s)

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

A. Operating/Procedure Room(s).

1. The number shall depend on the projected caseload and types of procedures to be performed. Rooms shall have adequate space to accommodate necessary equipment and staff.

2. Each operating room shall have a minimum clear area of 180 square feet exclusive of fixed and movable cabinets and shelves. The minimum width shall be 12 feet.

3. Each procedure room shall have a minimum clear area of 140 square feet exclusive of fixed and movable cabinets and shelves. The minimum width shall be 10 feet.

4. Additional clear area may be required as described in the narrative program to accommodate special functions in one or more of these rooms.

5. An emergency communication system connecting with the surgical suite workstation shall be provided.

6. At least one x-ray film illuminator shall be provided in the facility.

EXCEPTION: Facilities performing endoscopy procedures are not required to have the illuminator.

7. A hard-wire clock shall be provided in each operating/procedure room.

8. Operating rooms using inhalation anesthetics shall be in accordance with current practices of NFPA 56A, *Standards for the Use of Inhalation Anesthetics*.

B. Surgery/Procedure and Recovery Equipment and Supplies

1. Each operating/procedure room shall be completely equipped and supplied for the types of procedures to be performed. (I)

2. Each recovery area shall be completely equipped and supplied for the proper care of post-anesthesia recovery of surgical patients. (I)

3. The following equipment and supplies shall be accessible to staff in the facility: (I)

a. Cardio-pulmonary resuscitation drugs and intubation equipment;

b. Cardiac monitor;

c. Resuscitator, including oxygen and suction equipment;

d. Aspirator;

e. Defibrillator;

f. Tracheotomy set.

C. Surgical/Procedure Service Areas. The following services shall be provided:

1. A workstation located to permit visual surveillance of persons entering the surgical/procedure areas and the recovery area;

2. Sterilizing equipment with autoclave(s) conveniently located to serve all operating rooms;

EXCEPTION: Sterilizing equipment is not required in endoscopy facilities; however, a high-level disinfection of equipment is required in such facilities.

3. A medication distribution station provided for storage and preparation of medication to be administered to patients;

4. Scrub facilities provided near the entrance to each operating room. Scrub facilities with foot or knee controls shall be arranged to minimize any incidental splatter on nearby staff or supply carts. At a minimum, the following shall be provided:

a. Scrub sink with knee, elbow, or foot controls;

b. Soap dispenser.

EXCEPTION: For endoscopy facilities, in lieu of scrub facilities, there shall be a handwash sink in each procedure room that is equipped with valves that can be operated without the use of hands.

5. A soiled workroom for the exclusive use of the surgical suite staff. The soiled workroom shall contain a clinical sink or equivalent flushing type fixture, waste receptacle, and covered soiled receptacle, unless there is a separate soiled linen storage room;

EXCEPTION: In endoscopy facilities, a designated soiled work area will suffice in lieu of a soiled workroom.

6. A system for appropriately managing, handling, storing, and transporting soiled linen.

7. A clean workroom when clean materials are assembled within the surgical suite prior to use. The workroom shall contain a work counter, a sink equipped for handwashing and space for clean and sterile supplies;

EXCEPTION: In endoscopy facilities, a designated clean work area will suffice in lieu of a clean workroom.

8. An area for cleaning, testing, and storing anesthesia equipment in accordance with accepted principles of aseptic technique.

EXCEPTION: An anesthesia area is not required in endoscopy facilities**.**

9. Medical gas supply storage area pursuant to the storage requirements of NFPA 30 and 99;

10. Equipment storage room(s) for equipment and supplies used in surgical suite;

11. Staff change areas that shall contain adequate dressing space for changing of scrubs and shall contain lockers, showers, toilets, lavatories, and receptacles and facilities for the appropriate disposition of soiled scrubs; these areas shall be arranged to allow a restricted traffic pattern of authorized staff from outside the surgical suite to change into appropriate attire and enter the surgical suite;

EXCEPTION: Showers and areas for donning of scrub suits and boots are not required in endoscopy facilities.

12. Patient change areas that shall be of adequate size and maintained in a manner that assures privacy; provisions shall be made available for secure storage of belongings;

13. A storage area for transport devices, *e.g.*, stretchers, wheelchairs that shall be out of the path of exit travel;

14. An area for the emergency kit/cart located out of traffic and convenient to operating and recovery rooms;

15. Provisions for emergency eye-washing.

D. Recovery Area. The following shall be provided:

1. An area for recovery of patients;

2. Handwashing facilities, secured medication storage space, clerical work space, and sufficient storage space for supplies and equipment;

3. At least four feet between beds or stretchers (two feet if next to a wall) and adequate space at the foot of the bed or stretcher as needed for work and staff circulation;

4. Partitions, walls and/or cubicle curtains (on built-in tracks) to afford visual privacy for each patient;

5. Recovery beds or reclining type of vinyl upholstered chairs or recovery stretchers;

6. Equipment for oxygen, resuscitation, and suction**.**

***2503. Clinical Facilities (If Provided*)**

A. Examination room(s). Room size shall be determined by functions to be performed and types of equipment to be used, but shall have a minimum floor area of 80 square feet, excluding such spaces as vestibule, toilet, closet, and work counter (whether fixed or movable). Arrangement shall permit at least four feet clearance at each side and at the foot of the examination table. A lavatory or sink equipped for handwashing and a space for writing shall be provided.

B. Treatment room(s) for minor and cast procedures. Rooms shall have a minimum floor area of 120 square feet, excluding such spaces as vestibule, toilet, closet and work counter (whether fixed or movable). The minimum room dimension shall be 10 feet. A lavatory or sink equipped for handwashing and a space for writing shall be provided. Treatment rooms may also be used as examination rooms.

2504. Doors (II)

A. Exit doors to stairwells and exit doors to the outside shall be at least 44 inches wide.

B. All doors subject to stretcher or bed passage shall be at least 44 inches wide.

C. The minimum width of doors for patient access to operating, procedure, examination, and treatment rooms shall be at least 34 inches.

D. Restroom door widths shall be at least 32 inches.

E. All exit doors shall swing in the direction of the nearest exit.

F. All operating and procedure rooms and recovery areas shall have at least one door opening to an exit access corridor meeting the requirements of Section 2504.B above. (I)

G. 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 that are not subject to occupancy.

H. All restrooms shall have opaque doors for the purpose of privacy.

I. All glass doors, including sliding or patio type doors, shall have a contrasting or other indicator that causes the glass to be observable, *e.g.*, a decal located at eye level.

J. Doorways from exit-access passageways to the outside of the facility shall be at least 80 inches in height.

K. Doors that have locks shall be unlockable and openable with one action.

L. If patient operating, procedure, examination, or treatment room doors are lockable, there shall be provisions for emergency entry.

M. Any locked room door must be unlockable and openable from inside the room.

N. All patient examination, operating, procedure rooms shall have solid-core doors with closures.

O. Doorways shall not open directly upon a flight of stairs.

P. Soiled linen storage room(s) over 100 square feet shall have a 3/4-hour fire rated door.

2505. Corridors (II)

A. Corridors and passageways in all facilities shall be in accordance with the current building code as listed in Section 102.B.

B. Minimum public corridor width shall be five feet.

C. There shall be at least one corridor that is no less than eight feet clear width between doors from the recovery area and/or operating/procedure rooms and an exit door. In a one-story building or on the ground floor of a multi-story building, if there is less than eight feet clear width, the corridors shall be so arranged as to allow a stretcher to exit from the recovery area or operating rooms directly into the corridor without turning and move to the required exit without having to make a turn. Minimum width shall be five feet.

D. The location of items such as drinking fountains, telephone booths, vending machines, and portable equipment shall not restrict corridor traffic or reduce the required corridor width. (II)

2506. Ramps (II)

A. At least one exterior ramp, accessible by all patients, staff members, and visitors, shall be installed from the first floor to grade.

B. The ramp shall serve all portions of the facility where patients are located.

C. The surface of a ramp shall be of nonskid materials.

D. Ramps shall be constructed in a manner in compliance with ANSI 117.1, *i.e.*, for every inch of height, the ramp shall be at least one foot long.

E. Ramps shall be of noncombustible construction. (I)

F. Ramps shall discharge onto a surface that is firm and negotiable by persons who are physically challenged in all weather conditions and to a location accessible for loading into a vehicle.

2507. Landings (II)

Exit doorways that open upon a flight of stairs shall have a landing that is at least the width of the door and is the same elevation as the finished floor at the exit. (II)

2508. Handrails/Guardrails (II)

A. Handrails shall be provided on at least one side of each corridor/hallway, and on all stairways, ramps, and porches with two or more steps. Ends of all installed handrails shall return to the wall.

B. All porches, walkways, and recreational areas (such as decks, *etc.*) that are elevated 30 inches or more above grade shall have guardrails 42 inches high. Open guardrails shall have intermediate rails less than six inches apart.

2509. Restrooms (II)

A. There shall be an appropriate number of restrooms in the facility, to accommodate patients, staff, and visitors.

B. The restrooms shall be accessible during all operating hours of the facility.

C. A restroom(s) shall be equipped with at least one toilet fixture, toilet paper installed in a holder, a lavatory supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle.

D. Restroom floor areas shall not be less than 15 square feet.

E. The waiting/lobby area must have at least one restroom.

F. Toilet fixtures in restrooms for patient use shall be provided in ample number, located within or adjacent to the recovery area. The minimum requirement is one toilet fixture for every surgical and procedure room. These toilet fixtures shall be located in at least two restrooms, one designated “male” and the other “female”.

G. There shall be at least one lavatory per every two toilet fixtures located within a restroom.

H. All toilet fixtures used by patients shall have approved grab bars securely fastened in a usable fashion.

I. Privacy shall be provided at toilet fixtures and urinals.

J. Facilities for persons with disabilities shall be provided as required by codes, whether or not any of the staff or patients are classified as disabled.

K. All restroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surfaces to the highest level of splash.

2510. Sinks and Handwashing Fixtures

A. A sink shall be provided in each utility room.

B. Handwashing fixtures shall be provided in the recovery area and in restrooms (see Section 2509.C).

C. All handwashing fixtures shall be equipped with valves that can be operated without the use of hands.

D. Single-use towel dispensers or air dryers shall be provided at all handwashing fixtures, except scrub sinks.

E. Scrub sinks shall be provided in accordance with the number and arrangement of the operating rooms (see Section 2502.C).

2511. Janitor's Closets

A. A sufficient number of lockable janitor's closets shall be provided throughout the facility as required to maintain a clean and sanitary environment.

B. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies, *e.g.,* mops.

2512. Storage Areas

A. Adequate general storage areas shall be provided for patient and staff/ volunteer belongings, equipment, and supplies as well as clean linen, soiled linen, wheelchairs, and general supplies and equipment.

B. Soiled linen shall be stored in an enclosed room. This room may also be the soiled workroom (see Section 2502.C.5).

C. Areas used for storage of combustible materials and storage areas exceeding 100 square feet in area shall be provided with an NFPA-approved automatic sprinkler system. (I)

D. In storage areas provided with a sprinkler system, a minimum vertical distance of 18 inches shall be maintained between the top of stored items and the sprinkler heads. The tops of storage cabinets and shelves attached to or built into the perimeter walls may be closer than 18 inches below the sprinkler heads. In nonsprinklered storage areas, there shall be at least 24 inches of space from the ceiling. (I)

E. All ceilings, floor assemblies, and walls enclosing storage areas of 100 square feet or greater shall be composed of not less than one-hour fire-resistive construction. (I)

F. Storage buildings on the premises shall meet the requirements of the current building code as listed in Section 102.B regarding distance from the licensed building. Storage in buildings other than on the facility premises shall be secure and accessible. An appropriate controlled environment shall be provided if necessary for storage of items requiring such an environment.

G. In mechanical rooms used for storage, stored items shall be located away from mechanical equipment and shall not be a type of storage that might create a fire or other hazard. (I)

H. Supplies/Equipment shall not be stored directly on the floor. Supplies/ Equipment susceptible to water damage/contamination shall not be stored under sinks or other areas with a propensity for water leakage.

I. Chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be safely stored in cabinets or well-lighted closets/rooms.

2513. Elevators (II)

A. Elevators, if utilized, shall be installed and maintained in accordance with the provisions of the current building code as listed in Section 102.B, ANSI17.1, *Safety Code for Elevators and Escalators*, and NFPA 101, as applicable.

B. Elevators shall be inspected and tested upon installation, prior to first use, and annually thereafter by a certified elevator inspector.

2514. Telephone Service

At least one landline telephone shall be available on each floor of the facility for use by patients and/or visitors for their private, discretionary use; pay phones for this purpose are acceptable.

2515. Location

A. Transportation. The facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have a parking area to reasonably satisfy the needs of patients, staff members, and visitors.

C. Access to firefighting equipment. Facilities shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

SECTION 2600 - SEVERABILITY

2601. General

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2700 - GENERAL

2701. General

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

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(Those items in capital letters indicate a major section title.)