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South Carolina Department of Health
and Environmental Control

Regulation Number 61-108
Standards for Licensing Freestanding or Mobile Technology

Promulgated by the Board of Health and Environmental Control

Administered by the Division of Health Licensing

Including Changes

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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. 61-108 - *STANDARDS FOR LICENSING FREESTANDING OR MOBILE TECHNOLOGY*

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REGULATION NO. 61-108 - *STANDARDS FOR LICENSING FREESTANDING OR MOBILE TECHNOLOGY*

Statutory Authority: §44-7-265 S.C. Code Ann. (1976, as amended)

SECTION 100 - DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

101. Definitions

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

A. 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.

B. Advanced Practice Registered Nurse. An individual who has official recognition to practice as an advanced practice registered nurse by the S.C. State Board of Nursing.

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

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

E. Anesthetic Agent. Any drug or combination of drugs administered parenterally or inhaled with the purpose of creating conscious (moderate) or deep sedation.

F. Cardiac Catheterization. The passage of a small catheter, usually through a blood vessel into chambers of the heart, under roentgenologic control, permitting the securing of blood samples, determination of intracardiac pressure, and detection of cardiac anomalies.

G. 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.

H. Computerized Tomography (CT). The recording of internal body images in which an emergent X-ray beam is measured by a scintillation counter. The electronic impulses are recorded on a magnetic disk and then are processed by a mini-computer for reconstruction display of the body in cross-section on a cathode ray tube.

I. Conduction Anesthesia. The administration of anesthetic agents to interrupt nerve impulses without loss of consciousness. Major conduction blocks include regional nerve blocks (epidural, caudal, and spinal anesthesia). Minor conduction blocks include local infiltration, local nerve blocks, and nerve blocks by direct pressure and refrigeration.

J. Conscious (Moderate) Sedation. The administration of drugs to obtund or reduce the intensity of pain and awareness without the loss of defensive reflexes.

K. 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.

L. Consultation. A visit by individuals authorized by the Department to provide information to the licensee to enable better compliance with these regulations.

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

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

O. Existing Equipment. Equipment that was in operation prior to the promulgation of this regulation. The licensing standards governing new equipment apply if and when existing equipment is not continuously operated and licensed under this regulation.

P. Freestanding or Mobile Technology. Medical equipment which is to be used for diagnosis or treatment and is owned or operated by a person, other than a health care facility (as defined in S.C. Code Ann. § 44-7-130 (1976, as amended)), for which the total cost is in excess of that prescribed by R.61-15 and for which specific standards or criteria are prescribed in the State Health Plan.

Q. Gamma Knife. Stereotactic radiosurgery by which intracranial lesions are treated with high dose, high energy photons, i.e., a non-invasive procedure utilizing narrow bands of radiant energy that are directed at a treatment target in the head.

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. Host/Host Hospital. An acute care facility or other entity that leases or otherwise arranges for the provision of services of a mobile technology unit.

T. Ionized Radiation. Radiation that causes a neutral atom or molecule to acquire a positive or negative charge.

U. Inspection. A visit by an authorized individual(s) for the purpose of determining compliance with this regulation.

V. Investigation. A visit by an authorized individual(s) for the purpose of determining the validity of allegations received by the Department relating to this regulation.

W. Initial License. A license granted for new equipment.

X. Legally Authorized Health Care Provider. An individual authorized by law and currently licensed in S.C. to provide specific medical care, treatment, procedures, and/or services to patients. Examples of individuals who may be authorized by law to provide specific medical care, treatment, procedures, and/or services within the lawful scope of practice may include, but are not limited to, advanced practice registered nurses, radiological technicians, and physician's assistants.

Y. 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.

Z. License. A certificate issued by the Department to freestanding or mobile technology that authorizes equipment operation subject to the provisions of this regulation.

AA. Licensed Nurse. An individual authorized by the S.C. State Board of Nursing to practice as a registered nurse or licensed practical nurse.

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

CC. Magnetic Resonance Imaging (MRI). A diagnostic procedure used to create cross-sectional images of the body by the use of magnetic fields and radio frequency fields. It can also show certain biochemical activity and is non-invasive.

DD. Monitoring. The observation of a patient using instruments to measure, display, and/or record (continuously or intermittently) the values of certain physiologic variables such as pulse, blood pressure, oxygen saturation, and respiration.

EE. New Equipment. Equipment that is:

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 equipment has not been continuously operated.

FF. 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.

GG. On-Site Manager. The individual designated by the licensee to have the authority and responsibility to manage/operate the equipment. This person, or an individual designated to act in his/her absence, is the main contact with Department personnel.

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

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

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

KK. Positron Emission Tomography (PET). A procedure that allows the study of metabolic processes, such as oxygen consumption and utilization of glucose and fatty acids, by capturing images of cellular activity or metabolism by tracking the movement of radioactive tracers throughout the body.

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

MM. Quality Improvement Program. The process used to examine methods and practices of providing care, treatment, procedures, and/or services, identify the ways to improve performance, and take actions that result in higher quality of care, treatment, procedures, and/or services for patients.

NN. Radiation Therapist. A person, other than an individual licensed to practice within the lawful scope of practice of medicine in this State, who applies radiation to humans for therapeutic purposes.

OO. Radiation Therapy. The use of a stream of high-energy particles or waves such as X-rays, gamma rays, and alpha and beta particles to destroy or damage cancer cells.

PP. Radiographer. A person, other than an individual licensed to practice, medicine, dentistry, podiatry, chiropractic, or osteopathy in this State, who applies radiation to humans for diagnostic purposes, including, but not limited to, mammography, cardiovascular-interventional technology, and computed tomography.

QQ. Radiologic Technologist. A person who is a limited practice radiographer, radiographer, podiatric limited practice radiographer, limited chest radiographer, radiation therapist, or nuclear medicine technologist certified by the American Registry of Radiologic Technologists or who is certified by the S.C. Radiation Quality Standards Association (SCRQSA) or who has obtained a certificate acceptable to the SCRQSA.

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

SS. Repeat Violation. The recurrence of any 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.

TT. 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.

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

VV. Staff Member. An individual who is 18 years or older and is a compensated employee on either a full or part-time basis.

WW. Suspension of License. An action by the Department requiring a licensee to cease operation for a period of time until such time as the Department rescinds that restriction.

XX. Vendor. A person who owns and/or operates mobile technology and contracts with acute care hospitals or other hosts for the purpose of providing diagnostic or therapeutic services.

YY. Volunteer. An individual who performs tasks at the direction of the on-site manager or his or her designee without compensation.

102. References

The following publications/standards are referenced in this regulation:

A. Departmental:

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

2. R.61-15, *Certification of Need for Health Facilities and Services*;

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

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

5. R.61-63, *Radioactive Materials*;

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

7. R.61-105, *Infectious Waste Management*;

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

9. Guidelines for Preventing Transmission of Mycobacterium Tuberculosis in Health Care Facilities;

10. South Carolina Health Plan.

B. Non-Departmental:

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

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

3. *Health Insurance Portability and Accountability Act of 1996 (HIPAA);*

4. National Fire Protection Association (NFPA);

5. Environmental Protection Agency (EPA);

6. Federal Food and Drug Administration (FDA).

103. License Requirements (II)

A. Compliance. An initial license shall not be issued to an owner/operator who has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed equipment is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity/freestanding or mobile technology licensed by the Department makes application for another facility/activity/freestanding or mobile technology or increase in licensed capacity of a facility, the currently licensed facility/activity/freestanding or mobile technology shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility/activity/freestanding or mobile technology.

B. A copy of the licensing standards shall be maintained by the licensee and accessible to all staff members.

C. No licensee who has been issued a license for a particular type of equipment shall establish new care, treatment, procedures, and/or services without first obtaining authorization from the Department. (I)

D. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place near the licensed equipment.

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

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. Equipment that is licensed pursuant to this regulation and is acquired by a licensed health care facility through purchase, contract, lease, or assuming/obtaining possession, shall be included as a part of the health care facility's license, and the original equipment license shall become null and void.

5. A license shall be effective for specified equipment 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.

6. Equipment 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.

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

E. 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) of the equipment 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 type of equipment, including the year, model of equipment, all equipment upgrades, location of the equipment for which the license is sought and of the owner in the event his or her address is different from that of the location of the equipment, and the names of the persons in control of the equipment. A copy of the nonapplicability, exemption, or Certificate of Need shall be included as part of the initial application. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or limited partnerships shall be registered with the S.C. Office of the Secretary of State.

F. Licensing Fees. The initial and annual license fee shall be $600.00. Such fees shall be made payable by check or money order to the Department and are not refundable. The Department may charge an additional amount, if necessary, to cover the cost of inspection or investigation.

G. Late Fee. Failure to submit a renewal application or fee 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.

H. 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 period.

I. Registered Equipment. Licensees utilizing equipment that is required to be registered by the Department's Bureau of Radiological Health shall not be licensed until such equipment is properly registered.

J. Change of License.

1. A licensee shall request issuance of a new or amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership of equipment;

b. Change of types of equipment as shown on the license;

c. Change of equipment location from one geographic site to another.

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

3. Replacement of equipment shall be accomplished by letter from the licensee.

K. A freestanding or mobile technology license shall not be required for, nor shall such a license be issued to, equipment operated by the federal government.

L. 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 in order to enforce this regulation.

202. Inspections/Investigations

A. An inspection shall be conducted prior to initial licensing of equipment and subsequent inspections conducted as deemed appropriate by the Department. Regulatory related

accreditations may be considered in determining the appropriateness of Department inspections.

B. All equipment and those areas of the location that impact treatment/procedures provided by the equipment 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 that are pertinent to the operation of equipment and have the authority to require the licensee 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 licensee 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 on-site manager 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 response, shall be made available upon written request with the redaction of the names of those individuals in the report as provided by S.C. Code Ann. §§ 44-7-310 and -315 (1976, as amended).

203. Consultations

Consultations may be provided by the Department as requested by the facility or as deemed appropriate by the Department.

SECTION 300 - ENFORCEMENT ACTIONS

301. General

When the Department determines that a licensee is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such equipment, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, 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 patients for whom the equipment is used 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 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 patients for whom equipment is used. 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. Failure to meet 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 licensee 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 Department may invoke S.C. Code Ann. § 44-7-320(C) (1976, as amended), to determine the dollar amount or may utilize the following schedule:

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

MONETARY PENALTY ACTIONS

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 and more	10,000	7,500	5,000

G. Any enforcement action taken by the Department may be appealed pursuant to the Administrative Procedures Act, S.C. Code Ann. § 1-23-310 (1976, as amended).

SECTION 400 - POLICIES AND PROCEDURES

401. General (II)

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

SECTION 500 - STAFF

501. General (II)

A. Appropriate staffing in sufficient numbers and training shall be provided to operate equipment in a manner that shall safely and effectively meet the needs and condition of the patients, to include the demands of effective emergency on-site action that might arise. Such staffing numbers and training shall:

1. Meet the recommendations of the equipment manufacturers;

2. Adhere to current professional organizational standards;

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

B. Additional staff members shall be provided if it is determined by the Department that the staff on duty is inadequate to effectively and safely operate the equipment.

C. All staff members operating and/or maintaining equipment shall be assigned duties and responsibilities in accordance with the individual's capability. Such duties 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 who operate and/or maintain equipment 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. Staff members who operate and/or maintain equipment 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. The licensee 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)

502. On-Site Manager (II)

A. Licensees shall have an on-site manager who shall be capable of meeting the responsibilities of operating and/or maintaining the equipment to ensure that it is in compliance with these regulations and shall demonstrate adequate knowledge of these regulations

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

C. Mobile units shall maintain a list of individuals approved by the licensee to be the on-site manager(s) on a day-to-day basis.

503. Medical Director (II)

A. There shall be a medical director who shall be a physician who is responsible for the quality of medical equipment services provided to patients.

B. The on-site manager and medical director may be the same person.

504. Medical Staff (I)

A. Physicians and other legally authorized health care providers performing treatment/procedures shall be appropriately licensed to perform these functions as well as adequately trained in any special requirements that are necessary to perform such treatment/procedures.

B. Privileges for each medical staff member to perform treatment/procedures and anesthesia shall be in accordance with criteria that the medical staff has established and approved.

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

505. Qualifications (I)

A. Those persons who practice within the lawful scope of their practice utilizing ionizing radiation such as cardiac catheterization (fluoroscopy) shall be appropriately qualified in accordance with R.61-63 and R.61-64.

B. Those individuals providing the following services shall have the following qualifications:

1. Magnetic Resonance Imaging (MRI).

a. Physicians responsible for reviewing all indications for examinations, specifying the use and dosage of contrast agents, etc. shall be certified in radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada with documented evidence of MRI training and meet the guidelines of the American College of Radiology Standard for Continuing Medical Education.

b. Individuals conducting MRI's shall be licensed nurses or Radiologic Technologists with documented evidence of appropriate MRI training.

2. Cardiac Catheterization.

a. Any physician performing cardiac catheterization shall have:

(1) Board certification in internal medicine and the subspecialty of cardiovascular disease or be board-eligible in the subspecialty of cardiovascular disease and be examined for certification within two years of initial eligibility;

(2) Completed current training in cardiac catheterization;

(3) Met the experience requirements of the American Board of Internal Medicine.

b. All direct care personnel in the cardiac catheterization laboratory shall be certified in basic cardiac life support (BCLS), with at least one staff member/volunteer with a current certification in Advanced Cardiac Life Support (ACLS) whenever patients are present.

3. Anesthesia Services (If Provided)

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 anesthetist;

(4) A registered nurse anesthetist;

(5) An anesthesiologist's assistant.

506. Inservice Training (II)

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

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

1. Cause, effect, transmission, prevention, and elimination of infections, to include standard precautions, 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 the employee's first day on the job (see Section 1100);

5. Fire response training within 24 hours of the employee's first day on the job (see Section 1203);

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

C. A staff member with a valid cardio-pulmonary resuscitation certification shall be on duty whenever patients are present.

D. All newly hired staff members shall receive orientation regarding the organization and physical plant, specific duties and responsibilities of staff members, and patients' needs.

507. 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 tuberculin screening as described in Section 1404.

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

SECTION 600 - REPORTING

601. Incidents/Accidents (II)

A. A record of each incident and/or accident occurring in the equipment location area involving patients or staff members 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, a procedure 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 means of treatment, 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 include events that are unintended and undesirable, as well as unexpected effects of prescribed medications or of medication errors that:

1. Require discontinuing a medication or modifying the dose;

2. Require hospitalization;

3. Result in disability;

4. Require treatment with a prescription medication;

5. Result in cognitive deterioration or impairment;

6. Are life-threatening;

7. 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 on-site manager. (I)

602. Fire/Disasters (II)

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 occurring at the equipment location and followed by a complete written report to include fire department reports, if any, submitted within a time period determined by the policies and procedures, but not to exceed 10 days from the occurrence of the fire.

603. Communicable Diseases (I)

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

604. On-site Manager Change

The Department's Division of Health Licensing shall be notified in writing by the licensee of freestanding technology within 10 days of any change in on-site manager. 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

Licensees, if required by the Department's Planning and Certificate of Need Division to submit a "Joint Annual Report," shall complete and return this report within the time period specified by that Division.

606. Accounting of Controlled Substances and Devices (I)

In accordance with R.61-4, any licensee whose licensed equipment is housed in a facility registered with the Department's Bureau of Drug Control shall report any theft or significant loss of controlled substances to the Bureau of Drug Control upon discovery of the loss/theft. Pursuant to S.C. Code Ann. § 40-43-91 (1976, as amended), any licensee whose licensed equipment is housed in a facility permitted by the S.C. Board of Pharmacy shall report the loss or theft of controlled substances or devices within thirty working days of the discovery of the loss/theft to the S.C. Board of Pharmacy.

607. Equipment Change

The Department's Division of Health Licensing shall be notified in writing by the licensee within 10 days of any change, upgrade and/or replacement of licensed equipment.

608. Equipment Location Closure

A. Prior to the permanent closure of a business where equipment is licensed, 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 Division of Health Licensing shall be notified 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. When a business where equipment is licensed 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 is not 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 standards to the equipment prior to its usage. If the location is closed for a period longer than one year, and there is a desire to re-open, the licensee shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application.

SECTION 700 - PATIENT RECORDS

701. Content (II)

A. An organized record shall be initiated and maintained 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, and/or services provided, to include the course of action taken and results; and the response and reaction to the care, treatment, procedures, and/or services provided. All entries shall be indelibly written, signed by the author, and dated.

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

1. Consultations by physicians or other legally authorized health care providers;

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

3. Care, treatment, procedures, and/or services provided;

4. Record of administration of each dose of medication and procedures followed if an error is made;

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

6. Notes of observation during recovery, to include vital signs pre- and post-treatment/procedure;

7. Discharge summary, including condition at discharge or transfer, instructions for self-care and instructions for obtaining post-treatment/procedure emergency care;

8. Special information, e.g., allergies, etc.

9. Signed informed consent for treatment as required by HIPAA and, if applicable, consent for participation in research;

10. If applicable, anesthesia records of pertinent pre-treatment/procedure reports including pre-anesthesia evaluation, type of anesthesia, technique and dosage used, and post-anesthesia follow-up note.

11. Treatment/procedure report (dictated or written into the record immediately after treatment/ procedure) to include at least:

a. Description of findings;

b. Techniques utilized to perform treatment/procedure;

c. Specimens removed, if applicable;

d. Primary physician and assistants.

12. 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 video tapes without the medium itself.

702. 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, care, treatment, procedures, and/or services provided, 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 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 licensee shall have a written policy designating the persons allowed to access confidential patient information. 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. (II)

D. Records generated by organizations or individuals with whom the licensee contracts for care, treatment, procedures, and/or services shall be maintained at the equipment location. Appropriate information shall be provided to assure continuity of care.

E. The licensee shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by 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 an equipment location 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 retained for at least six years following the discharge of the patient. Records of minors shall be retained until after the expiration of the period of election following achievement of majority as prescribed by statute. Other documents required by this regulation, e.g., fire drills, shall be retained at least 12 months or until the next Division of Health Licensing inspection.

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

SECTION 800 - CARE/TREATMENT/PROCEDURES/SERVICES

801. General (I)

A. Care, treatment, procedures, and/or services shall be provided, given, or performed effectively and safely in accordance with orders from physicians or other legally authorized health care 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. If a patient or potential patient has a communicable disease, a physician or other legally authorized health care provider shall insure that adequate care can be provided to 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.

C. When the licensee engages a source to provide services normally provided by the staff, e.g., staffing, training, equipment maintenance, 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, and/or services, confidentiality, and rights. (II)

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

E. A current listing of all types of treatment and procedures offered shall be available. A chronological record of all treatment and procedures performed shall be maintained that shall include patient identification, pre-treatment/procedure diagnosis, type of treatment/procedure performed, type of anesthesia utilized (if applicable), and any unusual occurrence.

802. Anesthesia Services (If Provided) (I)

A. Anesthesia shall be administered only by those individuals indicated in Section 505.B.3.a.

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.

803. Licensees Utilizing Ionizing Radiation (II)

All equipment where ionizing radiation is utilized shall be in compliance with those professional organizational standards specified in R.61-63 and R.61-64.

804. Laboratory Services (II)

A. Laboratory services required in connection with the treatment/procedure to be performed shall be provided or arrangements made to obtain such services.

B. Should tests be conducted 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, a Certificate of Waiver from the Clinical Laboratories Improvement Amendments (CLIA) Program shall be obtained through the Department's CLIA Program.

C. Laboratory supplies shall not be expired.

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

805. Adverse Conditions (I)

Should a patient experience any adverse condition or complication during or after the performance of the treatment/procedure, he or she shall remain at the equipment location until the condition/complication is eliminated, as determined by the physician, and the patient is stabilized. Patients requiring care beyond the capability of the equipment or staff shall be transferred to an appropriate facility.

806. Patient Instruction (If applicable) (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 at the location of the equipment or the attending physician or other knowledgeable professional staff member, should any complication occur or questions 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 licensee shall comply with all current federal, state, and local laws and regulations concerning patient care, treatment, procedures, and/or services, patient rights and protections, discrimination, and privacy and disclosure requirements, e.g., S.C. Code Ann. § 44-81-10 (1976, as amended).

B. The licensee shall develop and post in a conspicuous place in a public area 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.

C. Care, treatment, procedures, and/or services provided, 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.

D. Patients shall be permitted to use a telephone and allowed privacy when making calls.

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

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

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

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

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

8. Refusal of experimental treatment and drugs;

9. Confidentiality and privacy of records.

G. Except in emergencies, documentation regarding informed consent shall be properly executed prior to the treatment/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 may be retained and labeled as stock for administration as ordered by a physician or other legally authorized health care 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.

D. Upon the advice and written approval of the Medical Director or consultant pharmacist, an emergency kit or cart of lifesaving medicines and equipment shall be

maintained for the use of physicians or other legally authorized health care 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 emergency medication kit/cart shall display 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. 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 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 in order to provide staff members with adequate information concerning medications.

1002. Medication Orders (I)

A. Medications, to include oxygen, shall be administered to patients only upon orders of a physician or other legally authorized health care provider.

B. All orders (including verbal) shall be received only by licensed nurses or other legally authorized health care providers and shall be authenticated and dated by a physician or other legally authorized health care provider pursuant to 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 health care 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)

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.

1004. Pharmacy Services (I)

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

1005. Medication Containers (I)

Medications for each patient shall be dispensed from their original container(s), including 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 physician or other legally authorized health care provider.

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 health care 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. Pharmacopeia (36 - 46 degrees F.). Food and drinks and laboratory specimens 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.

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 name of the individual performing the destruction and a witness. 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.

SECTION 1100 - EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1101. 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 licensee shall make arrangements for obtaining blood and blood products to meet emergency situations.

1102. Disaster Preparedness (II)

The licensee shall establish plans, based on equipment and staff capabilities, to meet its responsibilities for providing emergency care.

1103. Emergency Call Numbers (I)

Although the equipment may be in a location that has 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.

SECTION 1200 - FIRE PREVENTION

1201. Arrangements for Fire Department Response/Protection (I)

A. Each licensee 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. When equipment is located outside a service area or range of a public fire department, the licensee shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department.

1202. 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.

1203. Fire Response Training (I)

A. Each staff member shall receive training within 24 hours of his or her first day on the job 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.

1204. 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, 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 1203 above.

SECTION 1300 - EQUIPMENT MAINTENANCE

1301. General (II)

Equipment utilized for providing treatment/procedures, including its component parts, shall be properly maintained to perform the functions for which it is designed.

1302. Equipment (II)

A. Equipment used in the provision of care, treatment, procedures, 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. Records shall be maintained to indicate all testing and maintenance.

B. If equipment for the administration of anesthesia is utilized, it 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. A record of the inspections 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.

1303. 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 1400 - INFECTION CONTROL AND ENVIRONMENT

1401. 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.

1402. 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.

1403. Sterilization (If applicable) (I)

A. If applicable, sterilizing equipment of the appropriate type shall be available and of adequate capacity to properly sterilize instruments and treatment/procedure 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 or licensees may utilize "event-related" methodologies for determining sterile integrity in lieu of "time-related" methods provided there is an established policy and procedure.

C. Provisions shall be made for appropriate storage and distribution of sterile supplies and equipment pursuant to 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 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. Disinfectants must bear the U.S. Environmental Protection Agency (EPA) registration number and be approved by EPA or FDA for the particular use.

1404. Tuberculin Screening (I)

A. Tuberculin screening, 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. A licensed nurse may perform the tuberculin screening.

B. Testing Procedures.

1. Direct care staff members shall have 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 health care 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 health care provider. These individuals shall not be allowed to return to work until they have been declared non-contagious.

3. Patients with symptoms of TB shall be isolated and/or treated or referred as necessary by a physician or other legally authorized health care 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 health care 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 local county health department or the Department's TB Control Division shall be contacted immediately 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 health care 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.

1405. Housekeeping (II)

The equipment location shall be neat, uncluttered, clean, and free of vermin and offensive odors; housekeeping shall at a minimum include:

A. Cleaning each specific area;

B. Cleaning treatment/procedure rooms in accordance with established written procedures.

1406. Infectious Waste (I)

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

1407. Clean/Soiled Linen (II)

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

B. Soiled linen.

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

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

SECTION 1500 - QUALITY IMPROVEMENT PROGRAM

1501. 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, and/or services provided.

B. The quality improvement program, as 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 policies and procedures 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. Analyze all serious incidents and accidents, to include all patient deaths and significant medication errors;

5. 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;

6. 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, and/or services received.

SECTION 1600 - DESIGN AND CONSTRUCTION

1601. General (II)

The building in which equipment is utilized shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient.

1602. Local and State Codes and Standards (II)

Buildings and mobile units shall meet requirements for "Business Occupancy," and shall comply with State Fire Marshal regulations and pertinent local and state laws, codes, ordinances, and standards with reference to design and construction. No equipment shall

be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the building in which it is housed.

SECTION 1700 - FIRE PROTECTION EQUIPMENT AND SYSTEMS

1701. Firefighting Equipment (I)

Firefighting equipment such as fire extinguishers, standpipes and automatic sprinklers shall be provided as required by the State Fire Marshal.

1702. Flammable Liquids (I)

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

1703. 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 and placed on oxygen cylinders. All cylinders shall be properly secured in place.

1704. 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 at the equipment location 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 1800 - MOBILE UNITS

1801. Care/Services

A. All mobile units, e.g., self-contained vans or tractor trailers, that transport equipment from one host site to another, shall meet the current standards of this regulation and of the local, state, and federal Departments of Transportation for the permitting and safe operation

of the vehicle. Such compliance includes approval by the Federal Food and Drug Administration (FDA) for the provision of diagnostic or therapeutic services in the mobile unit.

B. A mobile cardiac catheterization laboratory shall only provide services on the campus of a host hospital that has emergency medical and intensive coronary care services.

C. A procedure shall not be performed on a patient in a mobile cardiac catheterization laboratory if any of the following are present:

1. Recent myocardial infarction (within 10 days or less);

2. Uncontrolled arrhythmias;

3. Severe uncontrolled congestive heart failure;

4. Current hospitalization with highly unstable angina;

5. The patient is under 18 years of age.

SECTION 1900 - SEVERABILITY

1901. 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 2000 - GENERAL

2001. 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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