



Department of State Health Services

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Subchapter A. General Provisions.

§133.1. Purpose.

(a) The purpose of this chapter is to implement the Health and Safety Code, Chapter 241, which requires general and special hospitals to be licensed by the Department of State Health Services.

(b) This chapter provides procedures for obtaining a hospital license; minimum standards for hospital functions and services; patient rights standards; discrimination or retaliation standards; patient transfer and other policy and protocol requirements; reporting, posting and training requirements relating to abuse and neglect; standards for voluntary agreements; waiver provisions; inspection and investigation procedures; enforcement standards; fire prevention and protection requirements; general safety standards; physical plant and construction requirements for existing and new hospitals, and mobile transportable and relocatable units; and standards for the preparation, submittal, review and approval of construction documents.

(c) Compliance with this chapter does not constitute release from the requirements of other applicable federal, state, or local laws, codes, rules, regulations and ordinances. This chapter must be followed where it exceeds other codes and ordinances.

§133.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

- (1) Act--The Texas Hospital Licensing Law, Health and Safety Code, Chapter 241.
- (2) Action plan--A written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of system improvements in reducing, controlling or eliminating identified problem areas.
- (3) Advanced practice nurse (APN)--A registered nurse who is currently licensed and authorized by the Board of Nurse Examiners for the State of Texas to practice as a nurse practitioner, nurse-midwife, nurse anesthetist, or clinical nurse specialist.
- (4) Adverse event--An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.
- (5) Applicant--The person legally responsible for the operation of the hospital, whether by lease or ownership, who seeks a hospital license from the department.
- (6) Available--When referring to on-site personnel, on the premises and able to rapidly perform hands-on care in an emergency situation.

(7) Chemical dependency services--A planned, structured, and organized program designed to initiate and promote a person's chemical-free status or to maintain the person free of illegal drugs. It includes, but is not limited to, the application of planned procedures to identify and change patterns of behavior related to or resulting from chemical dependency that are maladaptive, destructive, or injurious to health, or to restore appropriate levels of physical, psychological, or social functioning lost due to chemical dependency.

(8) Community-wide plan--An agreement entered into between one or more health care facilities, entities administering a sexual assault program, district attorney's offices, or law enforcement agencies that designates one or more health care facilities in the community as a primary health care facility to furnish emergency medical services and evidence collection to sexual assault survivors on a community or area-wide basis.

(9) Comprehensive medical rehabilitation--The provision of rehabilitation services that are designed to improve or minimize a person's physical or cognitive disabilities, maximize a person's functional ability, or restore a person's lost functional capacity through close coordination of services, communication, interaction, and integration among several professions that share responsibility to achieve team treatment goals for the person.

(10) Comprehensive medical rehabilitation hospital--A general hospital that specializes in providing comprehensive medical rehabilitation services, including surgery and related ancillary services.

(11) Comprehensive medical rehabilitation unit--An identifiable part of a hospital which provides comprehensive medical rehabilitation services to patients admitted to the unit.

(12) Cooperative agreement--An agreement among two or more hospitals for the allocation or sharing of health care equipment, facilities, personnel, or services.

(13) Dentist--A person licensed to practice dentistry by the Texas State Board of Dental Examiners. This includes a doctor of dental surgery or a doctor of dental medicine.

(14) Department--The Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756-3199.

(15) Dietitian--A person who is currently licensed by the Texas State Board of Examiners of Dietitians as a licensed dietitian or provisional licensed dietitian, or who is a registered dietitian with the American Dietetic Association.

(16) Director--The hospital licensing director, Department of State Health Services.

(17) Emergency medical condition--A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in one or all of the following:

(A) placing the health of the individual (or with respect to a pregnant woman, the

health of the woman or her unborn child) in serious jeopardy;

(B) serious impairment to bodily functions;

(C) serious dysfunction of any bodily organ or part; or

(D) with respect to a pregnant woman who is having contractions:

(i) that there is inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) that transfer may pose a threat to the health or safety of the woman or the unborn child.

(18) General hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals requiring diagnosis, treatment, or care for illness, injury, deformity, abnormality, or pregnancy; and

(B) regularly maintains, at a minimum, clinical laboratory services, diagnostic X-ray services, treatment facilities including surgery or obstetrical care or both, and other definitive medical or surgical treatment of similar extent.

(19) Governing body--The governing authority of a hospital which is responsible for a hospital's organization, management, control, and operation, including appointment of the medical staff; includes the owner or partners for hospitals owned or operated by an individual or partners.

(20) Governmental unit--A political subdivision of the state, including a hospital district, county, or municipality, and any department, division, board, or other agency of a political subdivision.

(21) Hospital--A general hospital or a special hospital.

(22) Hospital administration--Administrative body of a hospital headed by an individual who has the authority to represent the hospital and who is responsible for the operation of the hospital according to the policies and procedures of the hospital's governing body.

(23) Inpatient--An individual admitted for an intended length of stay of 24 hours or greater.

(24) Inpatient services--Services provided to an individual admitted to a hospital for an intended length of stay of 24 hours or greater.

(25) Intellectual Disability--Significantly sub-average general intellectual functioning that is concurrent with deficits in adaptive behavior and originates during the developmental period.

(26) Licensed vocational nurse (LVN)--A person who is currently licensed under the Nursing Practice Act by the Board of Nurse Examiners for the State of Texas as a licensed vocational nurse or who holds a valid vocational nursing license with multi-state licensure privilege from another compact state.

(27) Licensee--The person or governmental unit named in the application for issuance of a hospital license.

(28) Medical staff--A physician or group of physicians and a podiatrist or group of podiatrists who by action of the governing body of a hospital are privileged to work in and use the facilities of a hospital for or in connection with the observation, care, diagnosis, or treatment of an individual who is, or may be, suffering from a mental or physical disease or disorder or a physical deformity or injury.

(29) Mental health services--All services concerned with research, prevention, and detection of mental disorders and disabilities and all services necessary to treat, care for, supervise, and rehabilitate persons who have a mental disorder or disability, including persons whose mental disorders or disabilities result from alcoholism or drug addiction.

(30) Niche hospital--A hospital that:

(A) classifies at least two-thirds of the hospital's Medicare patients or, if data is available, all patients:

- (i) in not more than two major diagnosis-related groups; or
- (ii) in surgical diagnosis-related groups;

(B) specializes in one or more of the following areas:

- (i) cardiac;
- (ii) orthopedics;
- (iii) surgery; or
- (iv) women's health; and

(C) is not:

- (i) a public hospital;

(ii) a hospital for which the majority of inpatient claims are for major diagnosis-related groups relating to rehabilitation, psychiatry, alcohol and drug treatment, or children or newborns; or

(iii) a hospital with fewer than 10 claims per bed per year.

(31) Nurse--A registered, vocational, or advanced practice registered nurse licensed by the Texas Board of Nursing or entitled to practice in this state under Occupations Code, Chapters 301, 304, or 305.

(32) Outpatient--An individual who presents for diagnostic or treatment services for an intended length of stay of less than 24 hours; provided, however, that an individual who requires continued observation may be considered as an outpatient for a period of time not to exceed a total of 48 hours.

(33) Outpatient services--Services provided to patients whose medical needs can be met in less than 24 hours and are provided within the hospital; provided, however, that services that require continued observation may be considered as outpatient services for a period of time not to exceed a total of 48 hours.

(34) Owner--One of the following persons or governmental unit which will hold or does hold a license issued under the statute in the person's name or the person's assumed name:

(A) a corporation;

(B) a governmental unit;

(C) a limited liability company;

(D) an individual;

(E) a partnership if a partnership name is stated in a written partnership agreement or an assumed name certificate;

(F) all partners in a partnership if a partnership name is not stated in a written partnership agreement or an assumed name certificate; or

(G) all co-owners under any other business arrangement.

(35) Patient--An individual who presents for diagnosis or treatment.

(36) Pediatric and adolescent hospital--A general hospital that specializes in providing services to children and adolescents, including surgery and related ancillary services.

(37) Person--An individual, firm, partnership, corporation, association, or joint stock company, and includes a receiver, trustee, assignee, or other similar representative of those entities.

(38) Physician--A physician licensed by the Texas Medical Board.

(39) Physician assistant--A person licensed as a physician assistant by the Texas State Board of Physician Assistant Examiners.

(40) Podiatrist--A podiatrist licensed by the Texas State Board of Podiatric Medical Examiners.

(41) Practitioner--A health care professional licensed in the State of Texas, other than a physician, podiatrist, or dentist. A practitioner shall practice in a manner consistent with their underlying practice act.

(42) Premises--A premises may be any of the following:

(A) a single building where inpatients receive hospital services; or

(B) multiple buildings where inpatients receive hospital services provided that the following criteria are met:

(i) all buildings in which inpatients receive hospital services are subject to the control and direction of the same governing body;

(ii) all buildings in which inpatients receive hospital services are within a 30-mile radius of the primary hospital location;

(iii) there is integration of the organized medical staff of each of the hospital locations to be included under the single license;

(iv) there is a single chief executive officer for all of the hospital locations included under the license who reports directly to the governing body and through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of the hospital;

(v) there is a single chief medical officer for all of the hospital locations under the license who reports directly to the governing body and who is responsible for all medical staff activities of the hospital;

(vi) each hospital location to be included under the license that is geographically separate from the other hospital locations contains at least one nursing unit for inpatients which is staffed and maintains an active inpatient census, unless providing only diagnostic or laboratory services, or a combination of diagnostic or laboratory services, in the building for hospital inpatients; and

(vii) each hospital that is to be included in the license complies with the emergency services standards:

(I) for a general hospital, if the hospital provides surgery or obstetrical care or both; or

(II) for a special hospital, if the hospital does not provide surgery or obstetrical care.

(43) Presurvey conference--A conference held with department staff and the applicant or the applicant's representative to review licensure rules and survey documents and provide consultation prior to the on-site licensure inspection.

(44) Psychiatric disorder--A clinically significant behavioral or psychological syndrome or pattern that occurs in an individual and that is typically associated with either a painful syndrome (distress) or impairment in one or more important areas of behavioral, psychological, or biological function and is more than a disturbance in the relationship between the individual and society.

(45) Quality improvement--A method of evaluating and improving processes of patient care which emphasizes a multidisciplinary approach to problem solving, and focuses not on individuals, but systems of patient care which might be the cause of variations.

(46) Registered nurse (RN)--A person who is currently licensed by the Texas Board of Nursing for the State of Texas as a registered nurse or who holds a valid registered nursing license with multi-state licensure privilege from another compact state.

(47) Special hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals who are regularly admitted, treated, and discharged and who require services more intensive than room, board, personal services, and general nursing care;

(B) has clinical laboratory facilities, diagnostic X-ray facilities, treatment facilities, or other definitive medical treatment;

(C) has a medical staff in regular attendance; and

(D) maintains records of the clinical work performed for each patient.

(48) Stabilize--With respect to an emergency medical condition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or that the woman has delivered the child and the placenta.

(49) Surgical technologist--A person who practices surgical technology as defined in Health and Safety Code, Chapter 259.

(50) Transfer--The movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated,

directly or indirectly, with) the hospital, but does not include such a movement of an individual who has been declared dead, or leaves the facility without the permission of any such person.

(51) Universal precautions--Procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments as those procedures are defined by the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services. This term includes standard precautions as defined by CDC which are designed to reduce the risk of transmission of blood borne and other pathogens in hospitals.

(52) Violation--Failure to comply with the licensing statute, a rule or standard, special license provision, or an order issued by the commissioner of state health services (commissioner) or the commissioner's designee, adopted or enforced under the licensing statute. Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty.

Subchapter B. Hospital License.

§133.21. General.

(a) License required.

(1) A hospital shall obtain a license prior to admitting patients.

(2) Upon written request, the Department of State Health Services (department) shall furnish a person with an application for a hospital license.

(3) The license application shall be submitted in accordance with §133.22 of this title (relating to Application and Issuance of Initial License). The applicant shall retain copies of all application documents submitted to the department.

(b) Compliance. A hospital shall comply with the provisions of the Act and this chapter during the licensing period.

(c) Scope of hospital license.

(1) A hospital license is issued for the premises and person or governmental unit named in the application.

(2) A hospital license shall not include off-site outpatient facilities.

(3) Multiple hospitals may share one building.

(A) Each hospital shall be licensed separately.

(B) No part of the building may be dually licensed by more than one hospital; and

(C) Each hospital in the building shall comply with the requirements of §133.165 of this title (relating to Building with Multiple Occupancies).

(4) Multiple hospitals may be licensed under one license provided the following conditions are met.

(A) The hospitals must comply with the requirements for multiple hospitals under a single license as specified under §133.2(41) of this title (relating to Definitions).

(B) Each hospital location under the hospital license must;

(i) provide emergency services in compliance with §133.41(e) of this title (relating to Hospital Functions and Services); and

(ii) meet the requirements as an existing hospital in accordance with §133.161 of this title (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located) as determined by the department; or

(iii) meet the requirements of a new hospital in accordance with §133.162 of this title (relating to New Construction Requirements) as determined by the department.

(C) The administration of the primary hospital location must submit to the department the following:

(i) a complete and accurate multiple-location application;

(ii) a licensing fee for the number of design beds at the multiple-location hospital in accordance with §133.26(b) of this title (relating to Fees);

(iii) a copy of a hospital fire safety survey of the multiple-location hospital indicating approval by the local fire authority in whose jurisdiction the hospital is based that is dated no earlier than one year prior to the multiple-location application; and

(iv) if the main hospital is accredited by a Centers for Medicare and Medicaid Services-approved organization, a letter extending the accreditation of the main hospital to the multiple location.

(D) If a change of ownership is concurrent with the request for a hospital to become a multiple location of another, the department will require the new owners to submit the documents in subparagraph (C) of this paragraph and a signed copy of the bill of sale or lease agreement that reflects the effective date of the sale or lease. No change of ownership application will be required.

(5) A hospital license and an ambulatory surgical center license shall not be issued for the same premises.

(d) Display. A hospital shall prominently and conspicuously display the hospital license in a public area of the licensed premises that is readily visible to patients, employees, and visitors.

(e) Alteration. A hospital license shall not be altered.

(f) Transfer or assignment prohibited. A hospital license shall not be transferred or assigned. The hospital shall comply with the provisions of §133.24 of this title (relating to Change of Ownership) in the event of a change in the ownership of a hospital.

(g) Changes which affect the license.

(1) A hospital shall notify the department in writing prior to the occurrence of any of the following:

(A) addition or deletion of those services indicated on the license application;

(B) changes in design bed capacity as the phrase is used in §133.26(b)(1)(A)-(C) of this title;

(C) request to change license classification; and

(D) any construction, renovation, or modification of the hospital buildings.

(2) A hospital shall notify the department in writing at the time of the occurrence of any of the following:

(A) cessation of operation of the hospital. The hospital shall include in the written notice the location where the medical records will be stored and the identity and telephone number of the custodian of the medical records;

(B) change in certification or accreditation status;

(C) change in hospital name, telephone number or administrator; and

(D) change in the emergency contact name and phone number.

§133.22. Application and Issuance of Initial License.

(a) Application submittal. The applicant shall submit the following documents to the Department of State Health Services (department) no earlier than 60 calendar days prior to the projected opening date of the hospital:

(1) an accurate and complete application form;

(2) a copy of the hospital's patient transfer policy which is developed in accordance with §133.44 of this title (relating to Hospital Patient Transfer Policy) and is signed by both the chairman and secretary of the governing body attesting to the date the policy was adopted by the governing body and the effective date of the policy;

(3) a copy of the hospital's memorandum of transfer form which contains at a minimum the information described in §133.44(c)(10)(B) of this title;

(4) if the application is for a special hospital license, a copy of a written agreement the special hospital has entered into with a general hospital which provides for the prompt transfer to and the admission by the general hospital of any patient when special services are needed but are unavailable at the special hospital. This agreement is required and is separate from any voluntary patient transfer agreements the hospital may enter into in accordance with §133.61 of this title (relating to Hospital Patient Transfer Agreements);

(5) copies of any patient transfer agreements entered into between the hospital and another hospital in accordance with §133.61 of this title;

(6) for existing facilities, a copy of a hospital fire safety survey indicating approval by the local fire authority in whose jurisdiction the hospital is based that is dated no earlier than one year prior to the hospital opening date. For new construction, addition, and renovation projects, written approval by the local building department and local fire authority shall be submitted during the final construction inspection by the department;

(7) the appropriate license fee as required in §133.26 of this title (relating to Fees);
and

(8) the following ownership information:

(A) the name and social security number of the sole proprietor, if the applicant is a sole proprietor;

(B) the name and social security number of each general partner who is an individual, if the applicant is a partnership;

(C) the name and social security number of any individual who has an ownership interest of more than 25% in the corporation, if the applicant is a corporation; and

(D) if the applicant is a niche hospital, the names and license numbers of any physicians licensed by the Texas Medical Board who have a financial interest in the applicant or any entity which has an ownership interest in the applicant.

(b) Additional documentation for new hospitals or conversions from nonhospital buildings. In addition to the document submittal requirements in subsection (a) of this section, the following shall be completed prior to the issuance of a hospital license to newly constructed

hospitals or hospitals from conversions of nonhospital buildings.

(1) Final construction documents shall be reviewed and approved by the department in accordance with §133.167 of this title (relating to Preparation, Submittal, Review and Approval of Plans and Retention of Records).

(2) For new construction, necessary intermediate inspections and final construction inspections shall be conducted by the department in accordance with §133.168(b) of this title (relating to Construction, Inspections, and Approval of Project) to determine that the hospital was constructed or remodeled in accordance with this chapter.

(3) When an applicant intends to reopen and relicense a building formerly licensed as a hospital, an on-site inspection shall be conducted by the department in accordance with §133.168 of this title to determine compliance with applicable construction and fire safety requirements.

(4) All plan review and construction inspection fees shall be paid to the department.

(5) A certificate of occupancy approved by the local fire authority, and issued by the city building inspector, if applicable, shall be obtained and a copy submitted to the department.

(6) A complete and accurate Final Construction Approval form shall be submitted to the department.

(c) Presurvey conference. The applicant or the applicant's representative shall attend a presurvey conference at the office designated by the department. The designated survey office may waive the presurvey conference requirement.

(d) Issuance of license. When it is determined that the hospital has complied with subsections (a)-(c) of this section, the department shall issue the license to the applicant.

(1) Effective date. The license shall be effective on the date the hospital is determined to be in compliance with subsections (a)-(c) of this section. The effective date shall not be prior to the date of the final construction inspection conducted by the department.

(2) Expiration date.

(A) If the effective date of the license is the first day of a month, the license expires on the last day of the 23rd month after issuance.

(B) If the effective date of the license is the second or any subsequent day of a month, the license expires on the last day of the 24th month after issuance.

(e) Withdrawal of application. If an applicant decides not to continue the application process for a license or renewal of a license, the application may be withdrawn. If a license has

been issued, the applicant shall return the license to the department with its written request to withdraw. The department shall acknowledge receipt of the request to withdraw.

(f) Denial of a license. Denial of a license shall be governed by §133.121 of this title (relating to Enforcement Action).

(g) Inspection. During the licensing period, the department shall conduct an inspection of the hospital to ascertain compliance with the provisions of the Act and this chapter.

(1) If a hospital has applied to participate in the federal Medicare program, the inspection may be conducted in conjunction with the inspection to determine compliance with 42 Code of Federal Regulations, Part 482 (relating to Conditions of Participation for Hospitals).

(2) A hospital shall have admitted and be providing services to at least one inpatient in the hospital at the time of the inspection.

§133.23. Application and Issuance of Renewal License.

(a) Renewal notice. The Department of State Health Services (department) shall send a renewal notice to a hospital at least 60 calendar days before the expiration date of a license.

(1) If the hospital has not received the renewal notice from the department within 45 calendar days prior to the expiration date, it is the duty of the hospital to notify the department and request a renewal application for a license.

(2) If the hospital fails to submit the application and fee within 15 calendar days prior to the expiration date of the license, the department shall send by certified mail to the hospital a letter advising that unless the license is renewed, the hospital must cease operations upon the expiration of the hospital's license.

(b) Renewal license. The department shall issue a renewal license to a hospital which meets the minimum requirements for a license.

(1) The hospital shall submit the following to the department prior to the expiration date of the license:

(A) a complete and accurate application form;

(B) a copy of a hospital fire safety survey indicating approval by the local fire authority in whose jurisdiction the hospital is based. The hospital fire safety survey shall be conducted annually and both surveys shall be submitted.

(C) the renewal license fee;

(D) if the applicant is accredited by a Centers for Medicare and Medicaid Services-approved organization, a copy of documentation from the accrediting body showing the current accreditation status of the hospital; and

(E) the following ownership information:

(i) the name and social security number of the sole proprietor, if the applicant is a sole proprietor;

(ii) the name and social security number of each partner who is an individual, if the applicant is a partnership;

(iii) the name and social security number of any individual who has an ownership interest of more than 25% in the corporation, if the applicant is a corporation; and

(iv) if the applicant is a niche hospital, the names and license numbers of any physicians licensed by the Texas Medical Board who have a financial interest in the applicant or any entity which has an ownership interest in the applicant.

(2) The department may conduct an inspection prior to issuing a renewal license in accordance with §133.101 of this title (relating to Inspection and Investigation Procedures).

(3) Renewal licenses will be valid for 24 months.

(c) Notice to cease operation and return license. If a hospital fails to submit the application, documents, and fee by the expiration date of the hospital's license, the department shall notify the hospital by certified mail that it must cease operation and immediately return the license by certified mail to the department. If the hospital wishes to provide services after the expiration date of the license, it shall apply for a license under §133.22 of this title (relating to Application and Issuance of Initial License).

§133.24. Change of Ownership.

(a) Change of ownership defined. A change of ownership of a hospital occurs when there is a change in the person legally responsible for the operation of the hospital, whether by lease or by ownership.

(1) If a corporate licensee amends its articles of incorporation to revise its name and the tax identification number does not change, this subsection does not apply, except that the corporation must notify the department within 10 calendar days after the effective date of the name change.

(2) The sale of stock of a corporate licensee does not cause this subsection to apply.

(b) License application required. The new owner shall submit an application for an initial license to the Department of State Health Services (department) prior to the date of the change of ownership or not later than 10 calendar days following the date of a change of ownership. The application shall be in accordance with §133.22 of this title (relating to the Application and

Issuance of Initial License) except that the applicant need not submit any transfer agreements previously approved by the department and the current applicant has affirmatively indicated it has adopted the transfer agreement. In addition to the documents required in §133.22 of this title, the applicant shall include a copy of the signed bill of sale or lease agreement that reflects the effective date of the sale or lease.

(c) Inspections. The on-site construction and health inspections required by §133.22 of this title may be waived by the department.

(d) Issuance of license. When the new owner has complied with the provisions of §133.22 of this title, the department shall issue a license which shall be effective the date of the change of ownership.

(e) Expiration of license. The expiration date of the license shall be in accordance with §133.22(d)(2) of this title.

(f) License void. The previous owner's license shall be void on the effective date of the new owner's license.

§133.25. Time Periods for Processing and Issuing Hospital Licenses.

(a) General.

(1) The receipt date for an application for an initial license or a renewal license is the date the application is received by the Facility Licensing Group, Department of State Health Services (department).

(2) An application for an initial license is complete when the department has received, reviewed, and found acceptable the information described in §133.22(a)-(b) of this title (relating to Application and Issuance of Initial License).

(3) An application for a renewal license is complete when the department has received, reviewed, and found acceptable the information described in §133.23(b) of this title (relating to Application and Issuance of Renewal License).

(b) Time periods. An application for a hospital initial license or renewal license shall be processed in accordance with the following time periods.

(1) The first time period begins on the date the department receives the application and ends on the date the hospital license is issued, or, if the application is received incomplete, the period ends on the date the hospital is issued a written notice that the application is incomplete. The written notice shall describe the specific information that is required before the application is considered complete. The first time period is 20 working days.

(2) The second time period begins on the date the department receives the last item necessary to complete the application and ends on the date the hospital license is issued. The second time period is 20 working days.

(c) Reimbursement of fees.

(1) In the event the application is not processed in the time periods as stated in subsection (b) of this section, the applicant has the right to request the department to reimburse in full the fee paid in that particular application process. If the department does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request shall be denied.

(2) Good cause for exceeding the period established is considered to exist if:

(A) the number of applications for licenses to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(B) another public or private entity utilized in the application process caused the delay; or

(C) other conditions existed which gave good cause for exceeding the established periods.

(d) Appeal. If the request for full reimbursement authorized by subsection (c) of this section is denied, the applicant may then appeal to the commissioner of state health services (commissioner) for a resolution of the dispute. The applicant shall give written notice to the commissioner requesting full reimbursement of all filing fees paid because the application was not processed within the adopted time period. The department shall submit a written report of the facts related to the processing of the application and good cause for exceeding the established time periods. The commissioner shall make the final decision and provide written notification of the decision to the applicant and the department.

§133.26. Fees.

(a) General.

(1) All fees paid to the Department of State Health Services (department) are nonrefundable with the exception of inspection fees for inspections that were not conducted.

(2) All fees shall be paid by check or money order made payable to the Department of State Health Services.

(b) License fees.

(1) The fee for an initial license or a renewal license is \$39 per bed based upon the design bed capacity of the hospital. The design bed capacity of a hospital is determined as follows.

(A) The design bed capacity is the maximum number of patient beds that a hospital can accommodate in rooms that comply with the requirements for patient room suites in

§133.163 of this title (relating to Spatial Requirements for New Construction) including beds, bassinets or cribs in critical care units (including neonatal nurseries), continuing care nursery beds, hospital-based skilled nursing units, medical nursing units, mental health and chemical dependency nursing units, pediatric and adolescent nursing units, obstetrical suites (including labor/delivery/recovery/postpartum (LDRP) beds), intermediate care beds, universal care beds, antepartum beds and postpartum beds. The design bed capacity does not include labor/delivery/recovery (LDR) beds, newborn nursery bassinets, or recovery beds.

(B) The maximum design bed capacity includes beds that comply with the requirements in §133.163 of this title even if the beds are unoccupied or the space is used for other purposes such as offices or storage rooms, provided such rooms can readily be returned to patient use. All required support and service areas must be maintained in place. For example, the removal of a nurse station in an unused patient bedroom wing of 20 beds would effectively eliminate those 20 beds from the design capacity. Eliminating access to the medical gas outlets and nurse call would also remove bed(s) from the design capacity.

(C) The number of licensed beds in a multiple-occupancy room shall be determined by the design even if the number of beds actually placed in the room is less than the design capacity.

(2) A hospital shall submit a license fee for each design bed added as a result of adding a multiple-location hospital to its license. The fee is \$39 per bed, regardless of the number of months remaining in the license period.

(3) A hospital shall submit an additional license fee with the Final Construction Approval form for each new design bed resulting from an approved construction project. The fee is \$39 per bed, regardless of the number of months remaining in the license period. The hospital shall also submit an additional plan review fee if the construction cost increases to the next higher fee schedule according to subsection (c)(4) of this section.

(4) A hospital will not receive a refund of previously submitted fees should the hospital's design capacity decrease as a result of an approved construction project.

(c) Plan review fees. This subsection outlines the fees which must accompany the application for plan review and all proposed plans and specifications covering the construction of new buildings or alterations to existing buildings which must be submitted for review and approval by the department in accordance with §133.167 of this title (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records).

(1) Construction plans will not be reviewed or approved until the required fee and an application for plan review are received by the department.

(2) Plan review fees are based upon the estimated construction project costs which are the total expenditures required for a proposed project from initiation to completion, including at least the following items.

assets such as: (A) Construction project costs shall include expenditures for physical

(i) site acquisition;
(ii) soil tests and site preparation;
project; (iii) construction and improvements required as a result of the

(iv) building, structure, or office space acquisition;

(v) renovation;

(vi) fixed equipment; and

(vii) energy provisions and alternatives.

services including: (B) Construction project costs shall include expenditures for professional

(i) planning consultants;

(ii) architectural fees;

(iii) fees for cost estimation;

(iv) legal fees;

(v) management fees; and

(vi) feasibility study.

(C) Construction project costs shall include expenditures or costs associated with financing, excluding long-term interest, but including:

(i) financial advisor;

(ii) fund-raising expenses;

(iii) lender's or investment banker's fee; and

(iv) interest on interim financing.

(D) Construction project costs shall include expenditure allowances for contingencies including:

- (i) inflation;
- (ii) inaccurate estimates;
- (iii) unforeseen fluctuations in the money market; and
- (iv) other unforeseen expenditures.

(3) Regarding purchases, donations, gifts, transfers, and other comparable arrangements whereby the acquisition is to be made for no consideration or at less than the fair market value, the project cost shall be determined by the fair market value of the item to be acquired as a result of the purchase, donation, gift, transfer, or other comparable arrangement.

(4) The plan review fee schedule based on cost of construction is:

- (A) \$100,000 or less--\$300;
- (B) \$100,001 to \$600,000--\$850;
- (C) \$600,001 to \$2,000,000--\$2,000;
- (D) \$2,000,001 to \$5,000,000--\$3,000;
- (E) \$5,000,001 to \$10,000,000--\$4,000; and
- (F) \$10,000,001 and over--\$5,000.

(5) If an estimated construction cost cannot be established, the estimated cost shall be based on \$225 per square foot. No construction project shall be increased in size, scope, or cost unless the appropriate fees are submitted with the proposed changes.

(d) Construction inspection fees. A fee of \$500 and an application for construction inspection for each inspection shall be submitted to the department at least three weeks prior to the anticipated inspection date. Construction inspections will not be conducted until all required fees are received by the department. If additional construction inspections of the proposed project are requested by the hospital, the appropriate additional fees shall be submitted prior to any inspections conducted by the staff of the department. When follow-up construction inspections are performed to verify plans of correction, the fee shall be submitted upon completion of the inspection.

(e) Cooperative agreement application fee. The application fee for a cooperative agreement is \$10,000. The application fee shall be submitted with an application for a cooperative agreement and other documents in accordance with §133.62 of this title (relating to Cooperative Agreements).

(f) Subscription and convenience fee. The department is authorized to collect subscription and convenience fees, in amounts determined by the TexasOnline Authority, to recover costs

associated with application and renewal application processing through TexasOnline, in accordance with Texas Government Code, §2054.111. At each renewal application, in addition to the license fee, there shall be a \$20 TexasOnline subscription fee.

Subchapter C. Operational Requirements.

133.41. Hospital Functions and Services.

(a) Anesthesia services. If the hospital furnishes anesthesia services, these services shall be provided in a well-organized manner under the direction of a qualified physician in accordance with the Medical Practice Act and the Nursing Practice Act. The hospital is responsible for and shall document all anesthesia services administered in the hospital.

(1) Organization and staffing. The organization of anesthesia services shall be appropriate to the scope of the services offered. Only personnel who have been approved by the facility to provide anesthesia services shall administer anesthesia. All approvals or delegations of anesthesia services as authorized by law shall be documented and include the training, experience, and qualifications of the person who provided the service.

(2) Delivery of services. Anesthesia services shall be consistent with needs and resources. Policies on anesthesia procedure shall include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies shall ensure that the following are provided for each patient.

(A) A pre-anesthesia evaluation by an individual qualified to administer anesthesia under paragraph (1) of this subsection shall be performed within 48 hours prior to surgery.

(B) An intraoperative anesthesia record shall be provided. The record shall include any complications or problems occurring during the anesthesia including time, description of symptoms, review of affected systems, and treatments rendered. The record shall correlate with the controlled substance administration record.

(C) A post-anesthesia follow-up report shall be written by the person administering the anesthesia before transferring the patient from the post-anesthesia care unit and shall include evaluation for recovery from anesthesia, level of activity, respiration, blood pressure, level of consciousness, and patient's oxygen saturation level.

(i) With respect to inpatients, a post-anesthesia evaluation for proper anesthesia recovery shall be performed after transfer from the post-anesthesia care unit and within 48 hours after surgery by the person administering the anesthesia, registered nurse (RN), or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

(ii) With respect to outpatients, immediately prior to discharge, a post-anesthesia evaluation for proper anesthesia recovery shall be performed by the person administering the anesthesia, RN, or physician in accordance with policies and procedures

approved by the medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

(b) Chemical dependency services.

(1) Chemical dependency unit. A hospital may not admit patients to a chemical dependency services unit unless the unit is approved by the Department of State Health Services (department) as meeting the requirements of §133.163(q) of this title (relating to Spatial Requirements for New Construction).

(2) Admission criteria. A hospital providing chemical dependency services shall have written admission criteria that are applied uniformly to all patients who are admitted to the chemical dependency unit.

(A) The hospital's admission criteria shall include procedures to prevent the admission of minors for a condition which is not generally recognized as responsive to treatment in an inpatient setting for chemical dependency services.

(i) The following conditions are not generally recognized as responsive to treatment in a treatment facility for chemical dependency unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to intellectual disability;

(II) learning disabilities; or

(III) psychiatric disorders.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to chemical dependency services.

(iii) A minor patient shall be separated from adult patients.

(B) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(C) A voluntarily admitted patient shall sign an admission consent form prior to admission to a chemical dependency unit which includes verification that the patient has been informed of the services to be provided and the estimated charges.

(3) Compliance. A hospital providing chemical dependency services in an identifiable unit within the hospital shall comply with Chapter 448, Subchapter B of this title (relating to Standard of Care Applicable to All Providers).

(c) Comprehensive medical rehabilitation services.

(1) Rehabilitation units. A hospital may not admit patients to a comprehensive medical rehabilitation services unit unless the unit is approved by the department as meeting the requirements of §133.163(z) of this title.

(2) Equipment and space. The hospital shall have the necessary equipment and sufficient space to implement the treatment plan described in paragraph (7)(C) of this subsection and allow for adequate care. Necessary equipment is all equipment necessary to comply with all parts of the written treatment plan. The equipment shall be on-site or available through an arrangement with another provider. Sufficient space is the physical area of a hospital which in the aggregate, constitutes the total amount of the space necessary to comply with the written treatment plan.

(3) Emergency requirements. Emergency personnel, equipment, supplies and medications for hospitals providing comprehensive medical rehabilitation services shall be as follows.

(A) A hospital that provides comprehensive medical rehabilitation services shall have emergency equipment, supplies, medications, and designated personnel assigned for providing emergency care to patients and visitors.

(B) The emergency equipment, supplies, and medications shall be properly maintained and immediately accessible to all areas of the hospital. The emergency equipment shall be periodically tested according to the policy adopted, implemented and enforced by the hospital.

(C) At a minimum, the emergency equipment and supplies shall include those specified in subsection (e)(4) of this section.

(D) The personnel providing emergency care in accordance with this subsection shall be staffed for 24-hour coverage and accessible to all patients receiving comprehensive medical rehabilitation services. At least one person who is qualified by training to perform advanced cardiac life support and administer emergency drugs shall be on duty each shift.

(E) All direct patient care licensed personnel shall maintain current certification in cardiopulmonary resuscitation (CPR).

(4) Medications. A rehabilitation hospital's governing body shall adopt, implement and enforce policies and procedures that require all medications to be administered by licensed nurses, physicians, or other licensed professionals authorized by law to administer medications.

(5) Organization and Staffing.

(A) A hospital providing comprehensive medical rehabilitation services shall be organized and staffed to ensure the health and safety of the patients.

(i) All provided services shall be consistent with accepted professional standards and practice.

(ii) The organization of the services shall be appropriate to the scope of the services offered.

(iii) The hospital shall adopt, implement and enforce written patient care policies that govern the services it furnishes.

(B) The provision of comprehensive medical rehabilitation services in a hospital shall be under the medical supervision of a physician who is on duty and available, or who is on-call 24 hours each day.

(C) A hospital providing comprehensive medical rehabilitation services shall have a medical director or clinical director who supervises and administers the provision of comprehensive medical rehabilitation services.

(i) The medical director or clinical director shall be a physician who is board certified or eligible for board certification in physical medicine and rehabilitation, orthopedics, neurology, neurosurgery, internal medicine, or rheumatology as appropriate for the rehabilitation program.

(ii) The medical director or clinical director shall be qualified by training or at least two years training and experience to serve as medical director or clinical director. A person is qualified under this subsection if the person has training and experience in the treatment of rehabilitation patients in a rehabilitation setting.

(6) Admission criteria. A hospital providing comprehensive medical rehabilitation services shall have written admission criteria that are applied uniformly to all patients who are admitted to the comprehensive medical rehabilitation unit.

(A) The hospital's admission criteria shall include procedures to prevent the admission of a minor for a condition which is not generally recognized as responsive to treatment in an inpatient setting for comprehensive medical rehabilitation services.

(i) The following conditions are not generally recognized as responsive to treatment in an inpatient setting for comprehensive medical rehabilitation services unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to intellectual disability;

(II) learning disabilities; or

(III) psychiatric disorders.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to comprehensive medical rehabilitation services.

(B) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(7) Care and services.

(A) A hospital providing comprehensive medical rehabilitation services shall use a coordinated interdisciplinary team which is directed by a physician and which works in collaboration to develop and implement the patient's treatment plan.

(i) The interdisciplinary team for comprehensive medical rehabilitation services shall have available to it, at the hospital at which the services are provided or by contract, members of the following professions as necessary to meet the treatment needs of the patient:

(I) physical therapy;

(II) occupational therapy;

(III) speech-language pathology;

(IV) therapeutic recreation;

(V) social services and case management;

(VI) dietetics;

(VII) psychology;

(VIII) respiratory therapy;

(IX) rehabilitative nursing;

(X) certified orthotics;

(XI) certified prosthetics;

(XII) pharmaceutical care; and

(XIII) in the case of a minor patient, persons who have specialized education and training in emotional, mental health, or chemical dependency problems, as well as the treatment of minors.

(ii) The coordinated interdisciplinary team approach used in the rehabilitation of each patient shall be documented by periodic entries made in the patient's medical record to denote:

(I) the patient's status in relationship to goal attainment; and

(II) that team conferences are held at least every two weeks to determine the appropriateness of treatment.

(B) An initial assessment and preliminary treatment plan shall be performed or established by the physician within 24 hours of admission.

(C) The physician in coordination with the interdisciplinary team shall establish a written treatment plan for the patient within seven working days of the date of admission.

(i) Comprehensive medical rehabilitation services shall be provided in accordance with the written treatment plan.

(ii) The treatment provided under the written treatment plan shall be provided by staff who are qualified to provide services under state law. The hospital shall establish written qualifications for services provided by each discipline for which there is no applicable state statute for professional licensure or certification.

(iii) Services provided under the written treatment plan shall be given in accordance with the orders of physicians, dentists, podiatrists or practitioners who are authorized by the governing body, hospital administration, and medical staff to order the services, and the orders shall be incorporated in the patient's record.

(iv) The written treatment plan shall delineate anticipated goals and specify the type, amount, frequency, and anticipated duration of service to be provided.

(v) Within 10 working days after the date of admission, the written treatment plan shall be provided. It shall be in the person's primary language, if practicable. What is or would have been practicable shall be determined by the facts and circumstances of each case. The written treatment plan shall be provided to:

(I) the patient;

(II) a person designated by the patient; and

(III) upon request, a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(vi) The written treatment plan shall be reviewed by the interdisciplinary team at least every two weeks.

(vii) The written treatment plan shall be revised by the interdisciplinary team if a comprehensive reassessment of the patient's status or the results of a patient case review conference indicates the need for revision.

(viii) The revision shall be incorporated into the patient's record within seven working days after the revision.

(ix) The revised treatment plan shall be reduced to writing in the person's primary language, if practicable, and provided to:

(I) the patient;

(II) a person designated by the patient; and

(III) upon request, a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(8) Discharge and continuing care plan. The patient's interdisciplinary team shall prepare a written continuing care plan that addresses the patient's needs for care after discharge.

(A) The continuing care plan for the patient shall include recommendations for treatment and care and information about the availability of resources for treatment or care.

(B) If the patient's interdisciplinary team deems it impracticable to provide a written continuing care plan prior to discharge, the patient's interdisciplinary team shall provide the written continuing care plan to the patient within two working days after the date of discharge.

(C) Prior to discharge or within two working days after the date of discharge, the written continuing care plan shall be provided in the person's primary language, if practicable, to:

(i) the patient;

(ii) a person designated by the patient; and

(iii) upon request, to a family member, guardian, or individual who has demonstrated on a routine basis responsibility and participation in the patient's care or treatment, but only with the patient's consent unless such consent is not required by law.

(d) Dietary services. The hospital shall have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company or an arrangement with another hospital may meet this requirement if the company or other hospital has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company or other hospital maintains at least the minimum requirements specified in this section, and provides for the frequent and systematic liaison with the hospital medical staff for recommendations of dietetic policies affecting patient treatment. The hospital shall ensure that there are sufficient personnel to respond to the dietary needs of the patient population being served.

(1) Organization.

(A) The hospital shall have a full-time employee who is qualified by experience or training to serve as director of the food and dietetic service, and be responsible for the daily management of the dietary services.

(B) There shall be a qualified dietitian who works full-time, part-time, or on a consultant basis. If by consultation, such services shall occur at least once per month for not less than eight hours. The dietitian shall:

(i) be currently licensed under the laws of this state to use the titles of licensed dietitian or provisional licensed dietitian, or be a registered dietitian;

(ii) maintain standards for professional practice;

(iii) supervise the nutritional aspects of patient care;

(iv) make an assessment of the nutritional status and adequacy of nutritional regimen, as appropriate;

(v) provide diet counseling and teaching, as appropriate;

(vi) document nutritional status and pertinent information in patient medical records, as appropriate;

(vii) approve menus; and

(viii) approve menu substitutions.

(C) There shall be administrative and technical personnel competent in their respective duties. The administrative and technical personnel shall:

(i) participate in established departmental or hospital training pertinent to assigned duties;

(ii) conform to food handling techniques in accordance with paragraph (2)(E)(viii) of this subsection;

sheets; and

- (iii) adhere to clearly defined work schedules and assignment

- (iv) comply with position descriptions which are job specific.

(2) Director. The director shall:

- (A) comply with a position description which is job specific;

- (B) clearly delineate responsibility and authority;

- (C) participate in conferences with administration and department heads;

- (D) establish, implement, and enforce policies and procedures for the overall operational components of the department to include, but not be limited to:

- (i) quality assessment and performance improvement program;

- (ii) frequency of meals served;

- (iii) nonroutine occurrences; and

- (iv) identification of patient trays; and

- (E) maintain authority and responsibility for the following, but not be limited to:

- (i) orientation and training;

- (ii) performance evaluations;

- (iii) work assignments;

- (iv) supervision of work and food handling techniques;

- (v) procurement of food, paper, chemical, and other supplies, to include implementation of first-in first-out rotation system for all food items;

- (vi) ensuring there is a four-day food supply on hand at all times;

- (vii) menu planning; and

- (viii) ensuring compliance with §§229.161 - 229.171 of this title (relating to Texas Food Establishments).

(3) Diets. Menus shall meet the needs of the patients.

(A) Therapeutic diets shall be prescribed by the physician(s) responsible for the care of the patients. The dietary department of the hospital shall:

(i) establish procedures for the processing of therapeutic diets to include, but not be limited to:

(I) accurate patient identification;

(II) transcription from nursing to dietary services;

(III) diet planning by a dietitian;

(IV) regular review and updating of diet when necessary;

and

(V) written and verbal instruction to patient and family. It shall be in the patient's primary language, if practicable, prior to discharge. What is or would have been practicable shall be determined by the facts and circumstances of each case;

(ii) ensure that therapeutic diets are planned in writing by a qualified dietitian;

(iii) ensure that menu substitutions are approved by a qualified dietitian;

(iv) document pertinent information about the patient's response to a therapeutic diet in the medical record; and

(v) evaluate therapeutic diets for nutritional adequacy.

(B) Nutritional needs shall be met in accordance with recognized dietary practices and in accordance with orders of the physician(s) or appropriately credentialed practitioner(s) responsible for the care of the patients. The following requirements shall be met.

(i) Menus shall provide a sufficient variety of foods served in adequate amounts at each meal according to the guidance provided in the Recommended Dietary Allowances (RDA), as published by the Food and Nutrition Board, Commission on Life Sciences, National Research Council, Tenth edition, 1989, which may be obtained by writing the National Academies Press, 500 Fifth Street, NW Lockbox 285, Washington, D.C. 20055, telephone (888) 624-8373.

(ii) A maximum of 15 hours shall not be exceeded between the last meal of the day (i.e. supper) and the breakfast meal, unless a substantial snack is provided. The hospital shall adopt, implement, and enforce a policy on the definition of "substantial" to meet each patient's varied nutritional needs.

(C) A current therapeutic diet manual approved by the dietitian and medical staff shall be readily available to all medical, nursing, and food service personnel. The therapeutic manual shall:

- (i) be revised as needed, not to exceed 5 years;
- (ii) be appropriate for the diets routinely ordered in the hospital;
- (iii) have standards in compliance with the RDA;
- (iv) contain specific diets which are not in compliance with RDA;

and

- (v) be used as a guide for ordering and serving diets.

(e) Emergency services. All licensed hospital locations, including multiple-location sites, shall have an emergency suite that complies with §133.161(a)(1)(A) of this title (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located) or §133.163(f) of this title, and the following.

(1) Organization. The organization of the emergency services shall be appropriate to the scope of the services offered.

(A) The services shall be organized under the direction of a qualified member of the medical staff who is the medical director or clinical director.

(B) The services shall be integrated with other departments of the hospital.

(C) The policies and procedures governing medical care provided in the emergency suite shall be established by and shall be a continuing responsibility of the medical staff.

(D) Medical records indicating patient identification, complaint, physician, nurse, time admitted to the emergency suite, treatment, time discharged, and disposition shall be maintained for all emergency patients.

(2) Personnel.

(A) There shall be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the hospital.

(B) Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation:

(i) there shall be on duty and available at all times at least one person qualified as determined by the medical staff to initiate immediate appropriate lifesaving measures; and

(ii) in general hospitals where the emergency treatment area is not contiguous with other areas of the hospital that maintain 24 hour staffing by qualified staff (including but not limited to separation by one or more floors in multiple-occupancy buildings), qualified personnel must be physically present in the emergency treatment area at all times.

(C) Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, the hospital shall provide that one or more physicians shall be available at all times for emergencies, as follows.

(i) General hospitals, except for hospitals designated as critical access hospitals (CAHs) by the Centers for Medicare & Medicaid Services (CMS), located in counties with a population of 100,000 or more shall have a physician qualified to provide emergency medical care on duty in the emergency treatment area at all times.

(ii) Special hospitals, hospitals designated as CAHs by the CMS, and general hospitals located in counties with a population of less than 100,000 shall have a physician on-call and able to respond in person, or by radio or telephone within 30 minutes.

(D) Schedules, names, and telephone numbers of all physicians and others on emergency call duty, including alternates, shall be maintained. Schedules shall be retained for no less than one year.

(3) Supplies and equipment. Adequate age appropriate supplies and equipment shall be available and in readiness for use. Equipment and supplies shall be available for the administration of intravenous medications as well as facilities for the control of bleeding and emergency splinting of fractures. Provision shall be made for the storage of blood and blood products as needed. The emergency equipment shall be periodically tested according to the policy adopted, implemented and enforced by the hospital.

(4) Required emergency equipment. At a minimum, the age appropriate emergency equipment and supplies shall include the following:

(A) emergency call system;

(B) oxygen;

(C) mechanical ventilatory assistance equipment, including airways, manual breathing bag, and mask;

(D) cardiac defibrillator;

(E) cardiac monitoring equipment;

(F) laryngoscopes and endotracheal tubes;

(G) suction equipment;

(H) emergency drugs and supplies specified by the medical staff;

(I) stabilization devices for cervical injuries;

(J) blood pressure monitoring equipment; and

(K) pulse oximeter or similar medical device to measure blood oxygenation.

(5) Participation in local emergency medical service (EMS) system.

(A) General hospitals shall participate in the local EMS system, based on the hospital's capabilities and capacity, and the locale's existing EMS plan and protocols.

(B) The provisions of subparagraph (A) of this paragraph do not apply to a comprehensive medical rehabilitation hospital or a pediatric and adolescent hospital that generally provides care that is not administered for or in expectation of compensation.

(6) Emergency services for survivors of sexual assault.

(A) The hospital shall develop, implement and enforce policies and procedures to ensure that a sexual assault survivor who presents to the hospital following a sexual assault receives one of the following:

- (i) the care specified under subparagraph (B) of this paragraph; or
- (ii) stabilization and transfer to a health care facility designated in a community-wide plan as the health care facility for treating sexual assault survivors, where the survivor will receive the care specified under subparagraph (B) of this paragraph.

(B) A hospital providing care to a sexual assault survivor shall provide the survivor with the following:

- (i) a forensic medical examination in accordance with Government Code, Chapter 420, Subchapter B, when the examination has been requested by a law enforcement agency under Code of Criminal Procedure, Article 56.06, or is conducted under Code of Criminal Procedure, Article 56.065. If a sexual assault survivor is age 18 or older and has not reported the assault to a law enforcement agency, a hospital shall provide this forensic medical examination, when the sexual assault survivor has arrived at the facility not later than 96 hours after the time the assault occurred and has consented to the examination;

(ii) a private area, if available, to wait or speak with the appropriate medical, legal, or sexual assault crisis center staff or volunteer until a physician, nurse, or physician assistant is able to treat the survivor;

(iii) access to a sexual assault program advocate, if available, as provided by Code of Criminal Procedure, Article 56.045;

(iv) the information form required by Health and Safety Code, §323.005;

(v) a private treatment room, if available;

(vi) if indicated by the history of contact, access to appropriate prophylaxis for exposure to sexually transmitted infections; and

(vii) the name and telephone number of the nearest sexual assault crisis center.

(C) The hospital must obtain documented consent before providing the forensic medical examination and treatment.

(D) Upon request, the hospital shall submit to the department their plan for the provision of service to sexual assault survivors. The plan must describe how the hospital will ensure that the services required under subparagraph (B) of this paragraph will be provided.

(i) The hospital shall submit the plan by the 60th day after the department makes the request.

(ii) The department will approve or reject the plan not later than 120th day following the submission of the plan.

(iii) If the department is not able to approve the plan, the department will return the plan to the hospital and will identify the specific provisions with which the hospital's plan failed to comply.

(iv) The hospital shall correct and resubmit the plan to the department for approval not later than the 90th day after the plan is returned to the hospital.

(f) Governing body.

(1) Legal responsibility. There shall be a governing body responsible for the organization, management, control, and operation of the hospital, including appointment of the medical staff. For hospitals owned and operated by an individual or by partners, the individual or partners shall be considered the governing body.

(2) Organization. The governing body shall be formally organized in accordance with a written constitution and bylaws which clearly set forth the organizational structure and responsibilities.

(3) Meeting records. Records of governing body meetings shall be maintained.

(4) Responsibilities relating to the medical staff.

(A) The governing body shall ensure that the medical staff has current bylaws, rules, and regulations which are implemented and enforced.

(B) The governing body shall approve medical staff bylaws and other medical staff rules and regulations.

(C) In hospitals that provide obstetrical services, the governing body shall ensure that the hospital collaborates with physicians providing services at the hospital to develop quality initiatives, through the adoption, implementation, and enforcement of appropriate hospital policies and procedures, to reduce the number of elective or nonmedically indicated induced deliveries or cesarean sections performed at the hospital on a woman before the 39th week of gestation.

(D) In hospitals that provide obstetrical services, the governing body shall ensure that the hospital implements a newborn audiological screening program, consistent with the requirements of Health and Safety Code, Chapter 47 (Hearing Loss in Newborns), and performs, either directly or through a transfer agreement, audiological screenings for the identification of hearing loss on each newborn or infant born at the facility before the newborn or infant is discharged. These audiological screenings are required to be performed on all newborns or infants before discharge from the facility unless:

(i) a parent or legal guardian of the newborn or infant declines the screening;

(ii) the newborn or infant requires emergency transfer to a tertiary care facility prior to the completion of the screening; or

(iii) the screening previously has been completed.

(E) The governing body shall determine, in accordance with state law and with the advice of the medical staff, which categories of practitioners are eligible candidates for appointment to the medical staff.

(i) In considering applications for medical staff membership and privileges or the renewal, modification, or revocation of medical staff membership and privileges, the governing body must ensure that each physician, podiatrist, and dentist is afforded procedural due process.

(I) If a hospital's credentials committee has failed to take action on a completed application as required by subclause (VIII) of this clause, or a physician, podiatrist, or dentist is subject to a professional review action that may adversely affect his medical staff membership or privileges, and the physician, podiatrist, or dentist believes that mediation of the dispute is desirable, the physician, podiatrist, or dentist may require the hospital to participate in mediation as provided in Civil Practice and Remedies Code (CPRC), Chapter 154. The mediation shall be conducted by a person meeting the qualifications required by CPRC §154.052 and within a reasonable period of time.

(II) Subclause (I) of this clause does not authorize a cause of action by a physician, podiatrist, or dentist against the hospital other than an action to require a hospital to participate in mediation.

(III) An applicant for medical staff membership or privileges may not be denied membership or privileges on any ground that is otherwise prohibited by law.

(IV) A hospital's bylaw requirements for staff privileges may require a physician, podiatrist, or dentist to document the person's current clinical competency and professional training and experience in the medical procedures for which privileges are requested.

(V) In granting or refusing medical staff membership or privileges, a hospital may not differentiate on the basis of the academic medical degree held by a physician.

(VI) Graduate medical education may be used as a standard or qualification for medical staff membership or privileges for a physician, provided that equal recognition is given to training programs accredited by the Accreditation Council for Graduate Medical Education and by the American Osteopathic Association.

(VII) Board certification may be used as a standard or qualification for medical staff membership or privileges for a physician, provided that equal recognition is given to certification programs approved by the American Board of Medical Specialties and the Bureau of Osteopathic Specialists.

(VIII) A hospital's credentials committee shall act expeditiously and without unnecessary delay when a licensed physician, podiatrist, or dentist submits a completed application for medical staff membership or privileges. The hospital's credentials committee shall take action on the completed application not later than the 90th day after the date on which the application is received. The governing body of the hospital shall take final action on the application for medical staff membership or privileges not later than the 60th day after the date on which the recommendation of the credentials committee is received. The hospital must notify the applicant in writing of the hospital's final action, including a reason for denial or restriction of privileges, not later than the 20th day after the date on which final action is taken.

(ii) The governing body is authorized to adopt, implement and enforce policies concerning the granting of clinical privileges to advanced practice nurses and physician assistants, including policies relating to the application process, reasonable qualifications for privileges, and the process for renewal, modification, or revocation of privileges.

(I) If the governing body of a hospital has adopted, implemented and enforced a policy of granting clinical privileges to advanced practice nurses or physician assistants, an individual advanced practice nurse or physician assistant who qualifies for privileges under that policy shall be entitled to certain procedural rights to provide fairness of process, as determined by the governing body of the hospital, when an application for privileges is submitted to the hospital. At a minimum, any policy adopted shall specify a reasonable period for the processing and consideration of the application and shall provide for written notification to the applicant of any final action on the application by the hospital, including any reason for denial or restriction of the privileges requested.

(II) If an advanced practice nurse or physician assistant has been granted clinical privileges by a hospital, the hospital may not modify or revoke those privileges without providing certain procedural rights to provide fairness of process, as determined by the governing body of the hospital, to the advanced practice nurse or physician assistant. At a minimum, the hospital shall provide the advanced practice nurse or physician assistant written reasons for the modification or revocation of privileges and a mechanism for appeal to the appropriate committee or body within the hospital, as determined by the governing body of the hospital.

(III) If a hospital extends clinical privileges to an advanced practice nurse or physician assistant conditioned on the advanced practice nurse or physician assistant having a sponsoring or collaborating relationship with a physician and that relationship ceases to exist, the advanced practice nurse or physician assistant and the physician shall provide written notification to the hospital that the relationship no longer exists. Once the hospital receives such notice from an advanced practice nurse or physician assistant and the physician, the hospital shall be deemed to have met its obligations under this section by notifying the advanced practice nurse or physician assistant in writing that the advanced practice nurse's or physician assistant's clinical privileges no longer exist at that hospital.

(IV) Nothing in this clause shall be construed as modifying Subtitle B, Title 3, Occupations Code, Chapter 204 or 301, or any other law relating to the scope of practice of physicians, advanced practice nurses, or physician assistants.

(V) This clause does not apply to an employer-employee relationship between an advanced practice nurse or physician assistant and a hospital.

(F) The governing body shall ensure that the hospital complies with the requirements concerning physician communication and contracts as set out in Health and Safety Code, §241.1015 (Physician Communication and Contracts).

(G) The governing body shall ensure the hospital complies with the requirements for reporting to the Texas Medical Board the results and circumstances of any professional review action in accordance with the Medical Practice Act, Occupations Code, §160.002 and §160.003.

(H) The governing body shall be responsible for and ensure that any policies and procedures adopted by the governing body to implement the requirements of this chapter shall be implemented and enforced.

(5) Hospital administration. The governing body shall appoint a chief executive officer or administrator who is responsible for managing the hospital.

(6) Patient care. In accordance with hospital policy adopted, implemented and enforced, the governing body shall ensure that:

(A) every patient is under the care of:

(i) a physician. This provision is not to be construed to limit the authority of a physician to delegate tasks to other qualified health care personnel to the extent recognized under state law or the state's regulatory mechanism;

(ii) a dentist who is legally authorized to practice dentistry by the state and who is acting within the scope of his or her license; or

(iii) a podiatrist, but only with respect to functions which he or she is legally authorized by the state to perform.

(B) patients are admitted to the hospital only by members of the medical staff who have been granted admitting privileges;

(C) a physician is on duty or on-call at all times;

(D) specific colored condition alert wrist bands that have been standardized for all hospitals licensed under Health and Safety Code, Chapter 241, are used as follows:

(i) red wrist bands for allergies;

(ii) yellow wrist bands for fall risks; and

(iii) purple wrist bands for do not resuscitate status;

(E) the governing body shall consider the addition of the following optional condition alert wrist bands. This consideration must be documented in the minutes of the meeting of the governing body in which the discussion was held:

(i) green wrist bands for latex allergy; and

(ii) pink wrist bands for restricted extremity; and

(F) the governing body shall adopt, implement, and enforce a policy and procedure regarding the removal of personal wrist bands and bracelets as well as a patient's right to refuse to wear condition alert wrist bands.

(7) Services. The governing body shall be responsible for all services furnished in the hospital, whether furnished directly or under contract. The governing body shall ensure that services are provided in a safe and effective manner that permits the hospital to comply with all applicable rules and standards.

(8) Nurse Staffing. The governing body shall adopt, implement and enforce a written nurse staffing policy to ensure that an adequate number and skill mix of nurses are available to meet the level of patient care needed. The governing body policy shall require that hospital administration adopt, implement and enforce a nurse staffing plan and policies that:

(A) require significant consideration be given to the nurse staffing plan recommended by the hospital's nurse staffing committee and the committee's evaluation of any existing plan;

(B) are based on the needs of each patient care unit and shift and on evidence relating to patient care needs;

(C) ensure that all nursing assignments consider client safety, and are commensurate with the nurse's educational preparation, experience, knowledge, and physical and emotional ability;

(D) require use of the official nurse services staffing plan as a component in setting the nurse staffing budget;

(E) encourage nurses to provide input to the nurse staffing committee relating to nurse staffing concerns;

(F) protect from retaliation nurses who provide input to the nurse staffing committee; and

(G) comply with subsection (o) of this section.

(g) Infection control. The hospital shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There shall be an active program for the prevention, control, and surveillance of infections and communicable diseases.

(1) Organization and policies. A person shall be designated as infection control professional. The hospital shall ensure that policies governing prevention, control and surveillance of infections and communicable diseases are developed, implemented and enforced.

(A) There shall be a system for identifying, reporting, investigating, and controlling health care associated infections and communicable diseases between patients and personnel.

(B) The infection control professional shall maintain a log of all reportable diseases and health care associated infections designated as epidemiologically significant according to the hospital's infection control policies.

(C) A written policy shall be adopted, implemented and enforced for reporting all reportable diseases to the local health authority and the Infectious Disease Surveillance and Epidemiology Branch, Department of State Health Services, Mail Code 2822, P. O. Box 149347, Austin, Texas 78714-9347, in accordance with Chapter 97 of this title (relating to Communicable Diseases), and Health and Safety Code, §§98.103, 98.104, and 98.1045 (relating to Reportable Infections, Alternative for Reportable Surgical Site Infections, and Reporting of Preventable Adverse Events).

(D) The infection control program shall include active participation by the pharmacist.

(2) Responsibilities of the chief executive officer (CEO), medical staff, and chief nursing officer (CNO). The CEO, the medical staff, and the CNO shall be responsible for the following.

(A) The hospital-wide quality assessment and performance improvement program and training programs shall address problems identified by the infection control professional.

(B) Successful corrective action plans in affected problem areas shall be implemented.

(3) Universal precautions. The hospital shall adopt, implement, and enforce a written policy to monitor compliance of the hospital and its personnel and medical staff with universal precautions in accordance with HSC Chapter 85, Acquired Immune Deficiency Syndrome and Human Immunodeficiency Virus Infection.

(h) Laboratory services. The hospital shall maintain directly, or have available adequate laboratory services to meet the needs of its patients.

(1) Hospital laboratory services. A hospital that provides laboratory services shall comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988), in accordance with the requirements specified in 42 Code of Federal Regulations (CFR), §§493.1 - 493.1780. CLIA 1988 applies to all hospitals with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(2) Contracted laboratory services. The hospital shall ensure that all laboratory services provided to its patients through a contractual agreement are performed in a facility

certified in the appropriate specialties and subspecialties of service in accordance with the requirements specified in 42 CFR Part 493 to comply with CLIA 1988.

(3) Adequacy of laboratory services. The hospital shall ensure the following.

(A) Emergency laboratory services shall be available 24 hours a day.

(B) A written description of services provided shall be available to the medical staff.

(C) The laboratory shall make provision for proper receipt and reporting of tissue specimens.

(D) The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.

(E) When blood and blood components are stored, there shall be written procedures readily available containing directions on how to maintain them within permissible temperatures and including instructions to be followed in the event of a power failure or other disruption of refrigeration. A label or tray with the recipient's first and last names and identification number, donor unit number and interpretation of compatibility, if performed, shall be attached securely to the blood container.

(F) The hospital shall establish a mechanism for ensuring that the patient's physician or other licensed health care professional is made aware of critical value lab results, as established by the medical staff, before or after the patient is discharged.

(4) Chemical hygiene. A hospital that provides laboratory services shall adopt, implement, and enforce written policies and procedures to manage, minimize, or eliminate the risks to laboratory personnel of exposure to potentially hazardous chemicals in the laboratory which may occur during the normal course of job performance.

(i) Linen and laundry services. The hospital shall provide sufficient clean linen to ensure the comfort of the patient.

(1) For purposes of this subsection, contaminated linen is linen which has been soiled with blood or other potentially infectious materials or may contain sharps. Other potentially infectious materials means:

(A) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(B) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(C) Human Immunodeficiency Virus (HIV)-containing cell or tissue cultures, organ cultures, and HIV or Hepatitis B Virus (HBV)-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

(2) The hospital, whether it operates its own laundry or uses commercial service, shall ensure the following.

(A) Employees of a hospital involved in transporting, processing, or otherwise handling clean or soiled linen shall be given initial and follow-up in-service training to ensure a safe product for patients and to safeguard employees in their work.

(B) Clean linen shall be handled, transported, and stored by methods that will ensure its cleanliness.

(C) All contaminated linen shall be placed and transported in bags or containers labeled or color-coded.

(D) Employees who have contact with contaminated linen shall wear gloves and other appropriate personal protective equipment.

(E) Contaminated linen shall be handled as little as possible and with a minimum of agitation. Contaminated linen shall not be sorted or rinsed in patient care areas.

(F) All contaminated linen shall be bagged or put into carts at the location where it was used.

(i) Bags containing contaminated linen shall be closed prior to transport to the laundry.

(ii) Whenever contaminated linen is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the linen shall be deposited and transported in bags that prevent leakage of fluids to the exterior.

(iii) All linen placed in chutes shall be bagged.

(iv) If chutes are not used to convey linen to a central receiving or sorting room, then adequate space shall be allocated on the various nursing units for holding the bagged contaminated linen.

(G) Linen shall be processed as follows:

(i) If hot water is used, linen shall be washed with detergent in water with a temperature of at least 71 degrees Centigrade (160 degrees Fahrenheit) for 25 minutes. Hot water requirements specified in Table 5 of §133.169(e) of this title (relating to Tables) shall be met.

(ii) If low-temperature (less than or equal to 70 degrees Centigrade) (158 degrees Fahrenheit) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration shall be used.

(iii) Commercial dry cleaning of fabrics soiled with blood also renders these items free of the risk of pathogen transmission.

(H) Flammable liquids shall not be used to process laundry, but may be used for equipment maintenance.

(j) Medical record services. The hospital shall have a medical record service that has administrative responsibility for medical records. A medical record shall be maintained for every individual who presents to the hospital for evaluation or treatment.

(1) The organization of the medical record service shall be appropriate to the scope and complexity of the services performed. The hospital shall employ or contract with adequate personnel to ensure prompt completion, filing, and retrieval of records.

(2) The hospital shall have a system of coding and indexing medical records. The system shall allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with HSC, Chapter 241, Subchapter G (Disclosure of Health Care Information).

(4) The medical record shall contain information to justify admission and continued hospitalization, support the diagnosis, reflect significant changes in the patient's condition, and describe the patient's progress and response to medications and services. Medical records shall be accurately written, promptly completed, properly filed and retained, and accessible.

(5) Medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.

(6) All orders (except verbal orders) must be dated, timed, and authenticated the next time the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders provides care to the patient, assesses the patient, or documents information in the patient's medical record.

(7) All verbal orders must be dated, timed, and authenticated within 48 hours by the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders.

(A) Use of signature stamps by physicians and other licensed practitioners credentialed by the medical staff may be allowed in hospitals when the signature stamp is authorized by the individual whose signature the stamp represents. The administrative offices of the hospital shall have on file a signed statement to the effect that he or she is the only one who has the stamp and uses it. The use of a signature stamp by any other person is prohibited.

(B) A list of computer codes and written signatures shall be readily available and shall be maintained under adequate safeguards.

(C) Signatures by facsimile shall be acceptable. If received on a thermal machine, the facsimile document shall be copied onto regular paper.

(8) Medical records (reports and printouts) shall be retained by the hospital in their original or legally reproduced form for a period of at least ten years. A legally reproduced form is a medical record retained in hard copy, microform (microfilm or microfiche), or other electronic medium. Films, scans, and other image records shall be retained for a period of at least five years. For retention purposes, medical records that shall be preserved for ten years include:

(A) identification data;

(B) the medical history of the patient;

(C) evidence of a physical examination, including a health history, performed no more than 30 days prior to admission or within 24 hours after admission. The medical history and physical examination shall be placed in the patient's medical record within 24 hours after admission.

(D) an updated medical record entry documenting an examination for any changes in the patient's condition when the medical history and physical examination are completed within 30 days before admission. This updated examination shall be completed and documented in the patient's medical record within 24 hours after admission.

(E) admitting diagnosis;

(F) diagnostic and therapeutic orders;

(G) properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state laws if applicable, to require written patient consent;

(H) clinical observations, including the results of therapy and treatment, all orders, nursing notes, medication records, vital signs, and other information necessary to monitor the patient's condition;

(I) reports of procedures, tests, and their results, including laboratory, pathology, and radiology reports;

(J) results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

(K) discharge summary with outcome of hospitalization, disposition of care, and provisions for follow-up care; and

(L) final diagnosis with completion of medical records within 30 calendar days following discharge.

(9) If a patient was less than 18 years of age at the time he was last treated, the hospital may authorize the disposal of those medical records relating to the patient on or after the date of his 20th birthday or on or after the 10th anniversary of the date on which he was last treated, whichever date is later.

(10) The hospital shall not destroy medical records that relate to any matter that is involved in litigation if the hospital knows the litigation has not been finally resolved.

(11) The hospital shall provide written notice to a patient, or a patient's legally authorized representative, that the hospital may authorize the disposal of medical records relating to the patient on or after the periods specified in this section. The notice shall be provided to the patient or the patient's legally authorized representative not later than the date on which the patient who is or will be the subject of a medical record is treated, except in an emergency treatment situation. In an emergency treatment situation, the notice shall be provided to the patient or the patient's legally authorized representative as soon as is reasonably practicable following the emergency treatment situation.

(12) If a licensed hospital should close, the hospital shall notify the department at the time of closure the disposition of the medical records, including the location of where the medical records will be stored and the identity and telephone number of the custodian of the records.

(k) Medical staff.

(1) The medical staff shall be composed of physicians and may also be composed of podiatrists, dentists and other practitioners appointed by the governing body.

(A) The medical staff shall periodically conduct appraisals of its members according to medical staff bylaws.

(B) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidate.

(2) The medical staff shall be well-organized and accountable to the governing body for the quality of the medical care provided to patients.

(A) The medical staff shall be organized in a manner approved by the governing body.

(B) If the medical staff has an executive committee, a majority of the members of the committee shall be doctors of medicine or osteopathy.

(C) Records of medical staff meetings shall be maintained.

(D) The responsibility for organization and conduct of the medical staff shall be assigned only to an individual physician.

(E) Each medical staff member shall sign a statement signifying they will abide by medical staff and hospital policies.

(3) The medical staff shall adopt, implement, and enforce bylaws, rules, and regulations to carry out its responsibilities. The bylaws shall:

(A) be approved by the governing body;

(B) include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, consultant);

(C) describe the organization of the medical staff;

(D) describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;

(E) include criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges; and

(F) include a requirement that a physical examination and medical history be done no more than 30 days before or 24 hours after an admission for each patient by a physician or other qualified practitioner who has been granted these privileges by the medical staff. The medical history and physical examination shall be placed in the patient's medical record within 24 hours after admission. When the medical history and physical examination are completed within the 30 days before admission, an updated examination for any changes in the patient's condition must be completed and documented in the patient's medical record within 24 hours after admission.

(l) Mental health services.

(1) Mental health services unit. A hospital may not admit patients to a mental health services unit unless the unit is approved by the department as meeting the requirements of §133.163(q) of this title.

(2) Admission criteria. A hospital providing mental health services shall have written admission criteria that are applied uniformly to all patients who are admitted to the service.

(A) The hospital's admission criteria shall include procedures to prevent the admission of minors for a condition which is not generally recognized as responsive to treatment in an inpatient setting for mental health services.

(i) The following conditions are not generally recognized as responsive to treatment in a hospital unless the minor to be admitted is qualified because of other disabilities, such as:

(I) cognitive disabilities due to intellectual disability; or

(II) learning disabilities.

(ii) A minor may be qualified for admission based on other disabilities which would be responsive to mental health services.

(B) The medical record shall contain evidence that admission consent was given by the patient, the patient's legal guardian, or the managing conservator, if applicable.

(C) The hospital shall have a preadmission examination procedure under which each patient's condition and medical history are reviewed by a member of the medical staff to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment.

(D) A voluntarily admitted patient shall sign an admission consent form prior to admission to a mental health unit which includes verification that the patient has been informed of the services to be provided and the estimated charges.

(3) Compliance. A hospital providing mental health services shall comply with the following rules administered by the department. The rules are:

(A) Chapter 411, Subchapter J of this title (relating to Standards of Care and Treatment in Psychiatric Hospitals);

(B) Chapter 404, Subchapter E of this title (relating to Rights of Persons Receiving Mental Health Services);

(C) Chapter 405, Subchapter E of this title (relating to Electroconvulsive Therapy (ECT));

(D) Chapter 414, Subchapter I of this title (relating to Consent to Treatment with Psychoactive Medication--Mental Health Services); and

(E) Chapter 415, Subchapter F of this title (relating to Interventions in Mental Health Programs).

(m) Mobile, transportable, and relocatable units. The hospital shall adopt, implement and enforce procedures which address the potential emergency needs for those inpatients who are taken to mobile units on the hospital's premises for diagnostic procedures or treatment.

(n) Nuclear medicine services. If the hospital provides nuclear medicine services, these services shall meet the needs of the patients in accordance with acceptable standards of practice and be licensed in accordance with §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material).

(1) Policies and procedures. Policies and procedures shall be adopted, implemented, and enforced which will describe the services nuclear medicine provides in the hospital and how employee and patient safety will be maintained.

(2) Organization and staffing. The organization of the nuclear medicine services shall be appropriate to the scope and complexity of the services offered.

(A) There shall be a medical director or clinical director who is a physician qualified in nuclear medicine.

(B) The qualifications, training, functions, and responsibilities of nuclear medicine personnel shall be specified by the medical director or clinical director and approved by the medical staff.

(3) Delivery of services. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice and in accordance with §289.256 of this title.

(A) In-house preparation of radiopharmaceuticals shall be by, or under, the direct supervision of an appropriately trained licensed pharmacist or physician.

(B) There shall be proper storage and disposal of radioactive materials.

(C) If clinical laboratory tests are performed by the nuclear medicine services staff, the nuclear medicine staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR Part 493.

(D) Nuclear medicine workers shall be provided personnel monitoring dosimeters to measure their radiation exposure. Exposure reports and documentation shall be available for review.

(4) Equipment and supplies. Equipment and supplies shall be appropriate for the types of nuclear medicine services offered and shall be maintained for safe and efficient performance. The equipment shall be inspected, tested, and calibrated at least annually by qualified personnel.

(5) Records. The hospital shall maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(A) The physician approved by the medical staff to interpret diagnostic procedures shall sign and date the interpretations of these tests.

(B) The hospital shall maintain records of the receipt and disposition of radiopharmaceuticals until disposal is authorized by the department's Radiation Safety Licensing Branch in accordance with §289.256 of this title.

(C) Nuclear medicine services shall be ordered only by an individual whose scope of state licensure and whose defined staff privileges allow such referrals.

(o) Nursing services. The hospital shall have an organized nursing service that provides 24-hour nursing services as needed.

(1) Organization. The hospital shall have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care.

(A) Nursing services shall be under the administrative authority of a chief nursing officer (CNO) who shall be an RN and comply with one of the following:

(i) possess a master's degree in nursing;

(ii) possess a master's degree in health care administration or business administration;

(iii) possess a master's degree in a health-related field obtained through a curriculum that included courses in administration and management; or

(iv) be progressing under a written plan to obtain the nursing administration qualifications associated with a master's degree in nursing. The plan shall:

(I) describe efforts to obtain the knowledge associated with graduate education and to increase administrative and management skills and experience;

(II) include courses related to leadership, administration, management, performance improvement and theoretical approaches to delivering nursing care; and

(III) provide a time-line for accomplishing skills.

(B) The CNO in hospitals with 100 or fewer licensed beds and located in counties with a population of less than 50,000, or in hospitals that have been certified by the Centers for Medicare and Medicaid Services as critical access hospitals in accordance with the

Code of Federal Regulations, Title 42, Volume 3, Part 485, Subpart F, §485.606(b), shall be exempted from the requirements in subparagraph (A)(i) - (iv) of this paragraph.

(C) The CNO shall be responsible for the operation of the services, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(D) The CNO shall report directly to the individual who has authority to represent the hospital and who is responsible for the operation of the hospital according to the policies and procedures of the hospital's governing board.

(E) The CNO shall participate with leadership from the governing body, medical staff, and clinical areas, in planning, promoting and conducting performance improvement activities.

(2) Staffing and delivery of care.

(A) The nursing services shall adopt, implement and enforce a procedure to verify that hospital nursing personnel for whom licensure is required have valid and current licensure.

(B) There shall be adequate numbers of RNs, licensed vocational nurses (LVNs), and other personnel to provide nursing care to all patients as needed.

(C) There shall be supervisory and staff personnel for each department or nursing unit to provide, when needed, the immediate availability of an RN to provide care for any patient.

(D) An RN shall be on duty in each building of a licensed hospital that contains at least one nursing unit where patients are present. The RN shall supervise and evaluate the nursing care for each patient and assign the nursing care to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(E) The nursing staff shall develop and keep current a nursing plan of care for each patient which addresses the patient's needs.

(F) The hospital shall establish a nurse staffing committee as a standing committee of the hospital. The committee shall be established in accordance with Health and Safety Code (HSC), §§161.031 - 161.033, to be responsible for soliciting and receiving input from nurses on the development, ongoing monitoring, and evaluation of the staffing plan. As provided by HSC, §161.032, the hospital's records and review relating to evaluation of these outcomes and indicators are confidential and not subject to disclosure under Government Code, Chapter 552 and not subject to disclosure, discovery, subpoena or other means of legal compulsion for their release. As used in this subsection, "committee" or "staffing committee" means a nurse staffing committee established under this subparagraph.

(i) The committee shall be composed of:

(I) at least 60% registered nurses who are involved in direct patient care at least 50% of their work time and selected by their peers who provide direct care during at least 50% of their work time;

(II) at least one representative from either infection control, quality assessment and performance improvement or risk management;

(III) members who are representative of the types of nursing services provided at the hospital; and

(IV) the chief nursing officer of the hospital who is a voting member.

(ii) Participation on the committee by a hospital employee as a committee member shall be part of the employee's work time and the hospital shall compensate that member for that time accordingly. The hospital shall relieve the committee member of other work duties during committee meetings.

(iii) The committee shall meet at least quarterly.

(iv) The responsibilities of the committee shall be to:

(I) develop and recommend to the hospital's governing body a nurse staffing plan that meets the requirements of subparagraph (G) of this paragraph;

(II) review, assess and respond to staffing concerns expressed to the committee;

(III) identify the nurse-sensitive outcome measures the committee will use to evaluate the effectiveness of the official nurse services staffing plan;

(IV) evaluate, at least semiannually, the effectiveness of the official nurse services staffing plan and variations between the plan and the actual staffing; and

(V) submit to the hospital's governing body, at least semiannually, a report on nurse staffing and patient care outcomes, including the committee's evaluation of the effectiveness of the official nurse services staffing plan and aggregate variations between the staffing plan and actual staffing.

(G) The hospital shall adopt, implement and enforce a written official nurse services staffing plan. As used in this subsection, "patient care unit" means a unit or area of a hospital in which registered nurses provide patient care.

(i) The official nurse services staffing plan and policies shall:

(I) require significant consideration to be given to the nurse staffing plan recommended by the hospital's nurse staffing committee and the committee's evaluation of any existing plan;

(II) be based on the needs of each patient care unit and shift and on evidence relating to patient care needs;

(III) require use of the official nurse services staffing plan as a component in setting the nurse staffing budget;

(IV) encourage nurses to provide input to the nurse staffing committee relating to nurse staffing concerns;

(V) protect from retaliation nurses who provide input to the nurse staffing committee; and

(VI) comply with subsection (o) of this section.

(ii) The plan shall:

(I) set minimum staffing levels for patient care units that are:

(-a-) based on multiple nurse and patient considerations including:

(-1-) patient characteristics and number of patients for whom care is being provided, including number of admissions, discharges and transfers on a unit;

(-2-) intensity of patient care being provided and variability of patient care across a nursing unit;

(-3-) scope of services provided;

(-4-) context within which care is provided, including architecture and geography of the environment, and the availability of technology; and

(-5-) nursing staff characteristics, including staff consistency and tenure, preparation and experience, and the number and competencies of clinical and non-clinical support staff the nurse must collaborate with or supervise.

(-b-) determined by the nursing assessment and in accordance with evidence-based safe nursing standards; and

(-c-) recalculated at least annually, or as necessary;

(II) include a method for adjusting the staffing plan shift to shift for each patient care unit based on factors, such as, the intensity of patient care to provide staffing flexibility to meet patient needs;

(III) include a contingency plan when patient care needs unexpectedly exceed direct patient care staff resources;

(IV) include how on-call time will be used;

(V) reflect current standards established by private accreditation organizations, governmental entities, national nursing professional associations, and other health professional organizations and should be developed based upon a review of the codes of ethics developed by the nursing profession through national nursing organizations;

(VI) include a mechanism for evaluating the effectiveness of the official nurse services staffing plan based on patient needs, nursing sensitive quality indicators, nurse satisfaction measures collected by the hospital and evidence based nurse staffing standards. At least one from each of the following three types of outcomes shall be correlated to the adequacy of staffing:

(-a-) nurse-sensitive patient outcomes selected by the nurse staffing committee, such as, patient falls, adverse drug events, injuries to patients, skin breakdown, pneumonia, infection rates, upper gastrointestinal bleeding, shock, cardiac arrest, length of stay, or patient readmissions;

(-b-) operational outcomes, such as, work-related injury or illness, vacancy and turnover rates, nursing care hours per patient day, on-call use, or overtime rates; and

(-c-) substantiated patient complaints related to staffing levels;

(VII) incorporate a process that facilitates the timely and effective identification of concerns about the adequacy of the staffing plan by the nurse staffing committee established pursuant to subparagraph (F) of this paragraph. This process shall include:

(-a-) a prohibition on retaliation for reporting concerns;

(-b-) a requirement that nurses report concerns timely through appropriate channels within the hospital;

(-c-) orientation of nurses on how to report concerns and to whom;

(-d-) encouraging nurses to provide input to the committee relating to nurse staffing concerns;

(-e-) review, assessment, and response by the committee to staffing concerns expressed to the committee;

(-f-) a process for providing feedback during the committee meeting on how concerns are addressed by the committee established under subparagraph (F) of this paragraph; and

(-g-) use of the nurse safe harbor peer review process pursuant to Occupations Code, §303.005;

(VIII) include policies and procedures that require:

(-a-) orientation of nurses and other personnel who provide nursing care to all patient care units to which they are assigned on either a temporary or permanent basis;

(-b-) that the orientation of nurses and other personnel and the competency to perform nursing services is documented in accordance with hospital policy;

(-c-) that nursing assignments be congruent with documented competency; and

(IX) be used by the hospital as a component in setting the nurse staffing budget and guiding the hospital in assigning nurses hospital wide.

(iii) The hospital shall make readily available to nurses on each patient care unit at the beginning of each shift the official nurse services staffing plan levels and current staffing levels for that unit and that shift.

(iv) There shall be a semiannual evaluation by the staffing committee of the effectiveness of the official nurse services staffing plan and variations between the staffing plan and actual staffing. The evaluation shall consider the outcomes and nursing-sensitive indicators as set out in clause (ii)(VI) of this subparagraph, patient needs, nurse satisfaction measures collected by the hospital, and evidence based nurse staffing standards. This evaluation shall be documented in the minutes of the committee established under subparagraph (F) of this paragraph and presented to the hospital's governing body. Hospitals may determine whether this evaluation is done on a unit or facility level basis. To assist the committee with the semiannual evaluation, the hospital shall report to the committee the variations between the staffing plan and actual staffing. This report of variations shall be confidential and not subject to disclosure under Government Code, Chapter 552 and not subject to disclosure, discovery, subpoena or other means of legal compulsion for their release.

(v) The staffing plan shall be retained for a period of two years.

(H) Nonemployee licensed nurses who are working in the hospital shall adhere to the policies and procedures of the hospital. The CNO shall provide for the adequate orientation, supervision, and evaluation of the clinical activities of nonemployee nursing personnel which occur within the responsibility of the nursing services.

(I) The hospital shall annually report to the department on:

(i) whether the hospital's governing body has adopted a nurse staffing policy;

(ii) whether the hospital has established a nurse staffing committee that meets the membership requirements of subparagraph (F) of this paragraph;

(iii) whether the nurse staffing committee has evaluated the hospital's official nurse services staffing plan and has reported the results of the evaluation to the hospital's governing body; and

(iv) the nurse-sensitive outcome measures the committee adopted for use in evaluating the hospital's official nurse services staffing plan.

(3) Mandatory overtime. The hospital shall adopt, implement and enforce policies on use of mandatory overtime.

(A) As used in this subsection:

(i) "on-call time" means time spent by a nurse who is not working but who is compensated for availability; and

(ii) "mandatory overtime" means a requirement that a nurse work hours or days that are in addition to the hours or days scheduled, regardless of the length of a scheduled shift or the number of scheduled shifts each week. Mandatory overtime does not include prescheduled on-call time or time immediately before or after a scheduled shift necessary to document or communicate patient status to ensure patient safety.

(B) A hospital may not require a nurse to work mandatory overtime, and a nurse may refuse to work mandatory overtime.

(C) This section does not prohibit a nurse from volunteering to work overtime.

(D) A hospital may not use on-call time as a substitute for mandatory overtime.

(E) The prohibitions on mandatory overtime do not apply if:

(i) a health care disaster, such as a natural or other type of disaster that increases the need for health care personnel, unexpectedly affects the county in which the nurse is employed or affects a contiguous county;

(ii) a federal, state, or county declaration of emergency is in effect in the county in which the nurse is employed or is in effect in a contiguous county;

(iii) there is an emergency or unforeseen event of a kind that:

(I) does not regularly occur;

(II) increases the need for health care personnel at the hospital to provide safe patient care; and

(III) could not prudently be anticipated by the hospital; or

(iv) the nurse is actively engaged in an ongoing medical or surgical procedure and the continued presence of the nurse through the completion of the procedure is necessary to ensure the health and safety of the patient. The nurse staffing committee shall ensure that scheduling a nurse for a procedure that could be anticipated to require the nurse to stay beyond the end of his or her scheduled shift does not constitute mandatory overtime.

(F) If a hospital determines that an exception exists under subparagraph (E) of this paragraph, the hospital shall, to the extent possible, make and document a good faith effort to meet the staffing need through voluntary overtime, including calling per diems and agency nurses, assigning floats, or requesting an additional day of work from off-duty employees.

(G) A hospital may not suspend, terminate, or otherwise discipline or discriminate against a nurse who refuses to work mandatory overtime.

(4) Drugs and biologicals. Drugs and biologicals shall be prepared and administered in accordance with federal and state laws, the orders of the individuals granted privileges by the medical staff, and accepted standards of practice.

(A) All drugs and biologicals shall be administered by, or under supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing rules, and in accordance with the approved medical staff policies and procedures.

(B) All orders for drugs and biologicals shall be in writing, dated, timed, and signed by the individual responsible for the care of the patient as specified under subsection (f)(6)(A) of this section. When telephone or verbal orders must be used, they shall be:

(i) accepted only by personnel who are authorized to do so by the medical staff policies and procedures, consistent with federal and state laws;

(ii) dated, timed, and authenticated within 48 hours by the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges which are consistent with the written orders; and

(iii) used infrequently.

(C) There shall be a hospital procedure for immediately reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs to the attending physician and, if appropriate, to the hospital-wide quality assessment and performance improvement program.

(5) Blood transfusions.

(A) Transfusions shall be prescribed in accordance with hospital policy and administered in accordance with a written protocol for the administration of blood and blood components and the use of infusion devices and ancillary equipment.

(B) Personnel administering blood transfusions and intravenous medications shall have special training for this duty according to written, adopted, implemented and enforced hospital policy.

(C) Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.

(D) The patient must be observed during the transfusion and for an appropriate time thereafter for suspected adverse reactions.

(E) Pretransfusion and posttransfusion vital signs shall be recorded.

(F) When warming of blood is indicated, this shall be accomplished during its passage through the transfusion set. The warming system shall be equipped with a visible thermometer and may have an audible warning system. Blood shall not be warmed above 42 degrees Celsius.

(G) Drugs or medications, including those intended for intravenous use, shall not be added to blood or blood components. A 0.9% sodium chloride injection, United States Pharmacopeia, may be added to blood or blood components. Other solutions intended for intravenous use may be used in an administration set or added to blood or blood components under either of the following conditions:

(i) they have been approved for this use by the Federal Drug Administration; or

(ii) there is documentation available to show that addition to the component involved is safe and efficacious.

(H) There shall be a system for detection, reporting and evaluation of suspected complications of transfusion. Any adverse event experienced by a patient in association with a transfusion is to be regarded as a suspected transfusion complication. In the event of a suspected transfusion complication, the personnel attending the patient shall notify immediately a responsible physician and the transfusion service and document the complication in the patient's medical record. All suspected transfusion complications shall be evaluated promptly according to an established procedure.

(I) Following the transfusion, the blood transfusion record or a copy shall be made a part of the patient's medical record.

(6) Reporting and peer review of a vocational or registered nurse. A hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with the Occupations Code §§301.401 - 301.403, 301.405 and Chapter 303 (relating to Grounds for Reporting Nurse, Duty of Nurse to Report, Duty of Peer Review Committee to Report, Duty of Person Employing Nurse to Report, and Nursing Peer Review respectively), and with the rules adopted by the Board of Nurse Examiners in 22 TAC §217.16 (relating to Minor Incidents), §217.19 (relating to Incident-Based Nursing Peer Review and Whistleblower Protections), and §217.20 (relating to Safe Harbor Peer Review for Nurses and Whistleblower Protections).

(7) Policies and procedures related to workplace safety.

(A) The hospital shall adopt, implement and enforce policies and procedures related to the work environment for nurses which:

(i) improve workplace safety and reduce the risk of injury, occupational illness, and violence; and

(ii) increase the use of ergonomic principles and ergonomically designed devices to reduce injury and fatigue.

(B) The policies and procedures adopted under subparagraph (A) of this paragraph, at a minimum, must include:

(i) evaluating new products and technology that incorporate ergonomic principles;

(ii) educating nurses in the application of ergonomic practices;

(iii) conducting workplace audits to identify areas of risk of injury, occupational illness, or violence and recommending ways to reduce those risks;

(iv) controlling access to those areas identified as having a high risk of violence; and

(v) promptly reporting crimes committed against nurses to appropriate law enforcement agencies.

(8) Safe patient handling and movement practices.

(A) The hospital shall adopt, implement and enforce policies and procedures to identify, assess, and develop strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient.

(B) The policies and procedures shall establish a process that, at a minimum, includes the following:

(i) analysis of the risk of injury to both patients and nurses posed by the patient handling needs of the patient populations served by the hospital and the physical environment in which patient handling and movement occurs;

(ii) education of nurses in the identification, assessment, and control of risks of injury to patients and nurses during patient handling;

(iii) evaluation of alternative ways to reduce risks associated with patient handling, including evaluation of equipment and the environment;

(iv) restriction, to the extent feasible with existing equipment and aids, of manual patient handling or movement of all or most of a patient's weight to emergency, life-threatening, or otherwise exceptional circumstances;

(v) collaboration with and annual report to the nurse staffing committee;

(vi) procedures for nurses to refuse to perform or be involved in patient handling or movement that the nurse believes in good faith will expose a patient or a nurse to an unacceptable risk of injury;

(vii) submission of an annual report to the governing body on activities related to the identification, assessment, and development of strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient; and

(viii) development of architectural plans for constructing or remodeling a hospital or a unit of a hospital in which patient handling and movement occurs, with consideration of the feasibility of incorporating patient handling equipment or the physical space and construction design needed to incorporate that equipment at a later date.

(p) Outpatient services. If the hospital provides outpatient services, the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Organization. Outpatient services shall be appropriately organized and integrated with inpatient services.

(2) Personnel.

(A) The hospital shall assign an individual to be responsible for outpatient services.

(B) The hospital shall have appropriate physicians on staff and other professional and nonprofessional personnel available.

(q) Pharmacy services. The hospital shall provide pharmaceutical services that meet the needs of the patients.

(1) Compliance. The hospital shall provide a pharmacy which is licensed, as required, by the Texas State Board of Pharmacy. Pharmacy services shall comply with all applicable statutes and rules.

(2) Organization. The hospital shall have a pharmacy directed by a licensed pharmacist.

(3) Medical staff. The medical staff shall be responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical services.

(4) Pharmacy management and administration. The pharmacy or drug storage area shall be administered in accordance with accepted professional principles.

(A) Standards of practice as defined by state law shall be followed regarding the provision of pharmacy services.

(B) The pharmaceutical services shall have an adequate number of personnel to ensure quality pharmaceutical services including emergency services.

(i) The staff shall be sufficient in number and training to respond to the pharmaceutical needs of the patient population being served. There shall be an arrangement for emergency services.

(ii) Employees shall provide pharmaceutical services within the scope of their license and education.

(C) Drugs and biologicals shall be properly stored to ensure ventilation, light, security, and temperature controls.

(D) Records shall have sufficient detail to follow the flow of drugs from entry through dispensation.

(E) There shall be adequate controls over all drugs and medications including the floor stock. Drug storage areas shall be approved by the pharmacist, and floor stock lists shall be established.

(F) Inspections of drug storage areas shall be conducted throughout the hospital under pharmacist supervision.

(G) There shall be a drug recall procedure.

(H) A full-time, part-time, or consulting pharmacist shall be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(i) Direction of pharmaceutical services may not require on-premises supervision but may be accomplished through regularly scheduled visits in accordance with state law.

(ii) A job description or other written agreement shall clearly define the responsibilities of the pharmacist.

(I) Current and accurate records shall be kept of the receipt and disposition of all scheduled drugs.

(i) There shall be a record system in place that provides the information on controlled substances in a readily retrievable manner which is separate from the patient record.

(ii) Records shall trace the movement of scheduled drugs throughout the services, documenting utilization or wastage.

(iii) The pharmacist shall be responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled with written orders.

(5) Delivery of services. In order to provide patient safety, drugs and biologicals shall be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state laws.

(A) All compounding, packaging, and dispensing of drugs and biologicals shall be under the supervision of a pharmacist and performed consistent with federal and state laws.

(B) All drugs and biologicals shall be kept in a secure area, and locked when appropriate.

(i) A policy shall be adopted, implemented, and enforced to ensure the safeguarding, transferring, and availability of keys to the locked storage area.

(ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be kept locked within a secure area.

(C) Outdated, mislabeled, or otherwise unusable drugs and biologicals shall not be available for patient use.

(D) When a pharmacist is not available, drugs and biologicals shall be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with federal and state laws.

(i) There shall be a current list of individuals identified by name and qualifications who are designated to remove drugs from the pharmacy.

(ii) Only amounts sufficient for immediate therapeutic needs shall be removed.

(E) Drugs and biologicals not specifically prescribed as to time or number of doses shall automatically be stopped after a reasonable time that is predetermined by the medical staff.

(i) Stop order policies and procedures shall be consistent with those of the nursing staff and the medical staff rules and regulations.

(ii) A protocol shall be established by the medical staff for the implementation of the stop order policy, in order that drugs shall be reviewed and renewed, or automatically stopped.

(iii) A system shall be in place to determine compliance with the stop order policy.

(F) Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assessment and performance improvement program. There shall be a mechanism in place for capturing, reviewing, and tracking medication errors and adverse drug reactions.

(G) Abuses and losses of controlled substances shall be reported, in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical services, and to the chief executive officer, as appropriate.

(H) Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be immediately available to the professional staff.

(i) A pharmacist shall be readily accessible by telephone or other means to discuss drug therapy, interactions, side effects, dosage, assist in drug selection, and assist in the identification of drug induced problems.

(ii) There shall be staff development programs on drug therapy available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

(I) A formulary system shall be established by the medical staff to ensure quality pharmaceuticals at reasonable costs.

(r) Quality assessment and performance improvement. The governing body shall ensure that there is an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement (QAPI) program to evaluate the provision of patient care.

(1) Program scope. The hospital-wide QAPI program shall reflect the complexity of the hospital's organization and services and have a written plan of implementation. The program must include an ongoing program that shows measurable improvements in the indicators for which there is evidence that they will improve health outcomes, and identify and reduce medical errors.

(A) All hospital departments and services, including services furnished under contract or arrangement shall be evaluated.

(B) Health care associated infections shall be evaluated.

(C) Medication therapy shall be evaluated.

(D) All medical and surgical services performed in the hospital shall be evaluated as they relate to appropriateness of diagnosis and treatment.

(E) The program must measure, analyze and track quality indicators, including adverse patients' events, and other aspects of performance that assess processes of care, hospital services and operations.

(F) Data collected must be used to monitor the effectiveness and safety of service and quality of care, and to identify opportunities for changes that will lead to improvement.

(G) Priorities must be established for performance improvement activities that focus on high-risk, high-volume, or problem-prone areas, taking into consideration the incidence, prevalence and severity of problems in those areas, and how health outcomes and quality of care may be affected.

(H) Performance improvement activities which affect patient safety, including analysis of medical errors and adverse patient events, must be established, and preventive actions implemented.

(I) Success of actions implemented as a result of performance improvement activities must be measured, and ongoing performance must be tracked to ensure improvements are sustained.

(2) Responsibility and accountability. The hospital's governing body, medical staff and administrative staff are responsible and accountable for ensuring that:

(A) an ongoing program for quality improvement is defined, implemented and maintained, and that program requirements are met;

(B) an ongoing program for patient safety, including reduction of medical errors, is defined, implemented and maintained;

(C) the hospital-wide QAPI efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated; and

(D) adequate resources are allocated for measuring, assessing, improving and sustaining the hospital's resources, and for reducing risk to patients.

(3) Medically-related patient care services. The hospital shall have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients. The hospital also shall have an effective, ongoing discharge planning program that facilitates the provision of follow-up care.

(A) Discharge planning shall be completed prior to discharge.

(B) Patients, along with necessary medical information, shall be transferred or referred to appropriate facilities, agencies, or outpatient services, as needed for follow-up or ancillary care.

(C) Screening and evaluation before patient discharge from hospital. In accordance with 42 Code of Federal Regulations (CFR), Part 483, Subpart C (relating to Requirements for Long Term Care Facilities) and the rules of the Department of Aging and Disability Services (DADS) set forth in 40 TAC Chapter 17 (relating to Preadmission Screening and Resident Review (PASRR)), all patients who are being considered for discharge from the hospital to a nursing facility shall be screened, and if appropriate, evaluated, prior to discharge by the hospital and admission to the nursing facility to determine whether the patient may have a mental illness, intellectual disability or developmental disability. If the screening indicates that the patient has a mental illness, intellectual disability or developmental disability, the hospital shall contact and arrange for the local mental health authority designated pursuant to Health and Safety Code, §533.035, to conduct prior to hospital discharge an evaluation of the patient in accordance with the applicable provisions of the PASRR rules. The purpose of PASRR is:

(i) to ensure that placement of the patient in a nursing facility is necessary;

(ii) to identify alternate placement options when applicable; and

(iii) to identify specialized services that may benefit the person with a diagnosis of mental illness, intellectual disability, or developmental disability.

(4) Implementation. The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(s) Radiology services. The hospital shall maintain, or have available, diagnostic radiologic services according to needs of the patients. All radiology equipment, including X-ray equipment, mammography equipment and laser equipment, shall be licensed and registered as required under Chapter 289 of this title (relating to Radiation Control). If therapeutic services are also provided, the services, as well as the diagnostic services, shall meet professionally approved standards for safety and personnel qualifications as required in §§289.227, 289.229, 289.230 and 289.231 of this title (relating to Registration Regulations). In a special hospital, portable X-ray equipment may be acceptable as a minimum requirement.

(1) Policies and procedures. Policies and procedures shall be adopted, implemented and enforced which will describe the radiology services provided in the hospital and how employee and patient safety will be maintained.

(2) Safety for patients and personnel. The radiology services, particularly ionizing radiology procedures, shall minimize hazards to patients and personnel.

(A) Proper safety precautions shall be maintained against radiation hazards. This includes adequate radiation shielding, safety procedures and equipment maintenance and testing.

(B) Inspection of equipment shall be made by or under the supervision of a licensed medical physicist in accordance with §289.227(o) of this title (relating to Use of Radiation Machines in the Healing Arts). Defective equipment shall be promptly repaired or replaced.

(C) Radiation workers shall be provided personnel monitoring dosimeters to measure the amount of radiation exposure they receive. Exposure reports and documentation shall be available for review.

(D) Radiology services shall be provided only on the order of individuals granted privileges by the medical staff.

(3) Personnel.

(A) A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services and shall interpret only those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of

this section a radiologist is a physician who is qualified by education and experience in radiology in accordance with medical staff bylaws.

(B) Only personnel designated as qualified by the medical staff shall use the radiology equipment and administer procedures.

(4) Records. Records of radiology services shall be maintained. The radiologist or other individuals who have been granted privileges to perform radiology services shall sign reports of his or her interpretations.

(t) Renal dialysis services.

(1) Hospitals may provide inpatient dialysis services without an additional license under HSC Chapter 251. Hospitals providing outpatient dialysis services shall be licensed under HSC Chapter 251.

(2) Hospitals may provide outpatient dialysis services when the governor or the president of the United States declares a disaster in this state or another state. The hospital may provide outpatient dialysis only during the term of the disaster declaration.

(3) Equipment.

(A) Maintenance and repair. All equipment used by a facility, including backup equipment, shall be operated within manufacturer's specifications, and maintained free of defects which could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.

(i) Staff shall be able to identify malfunctioning equipment and report such equipment to the appropriate staff for immediate repair.

(ii) Medical equipment that malfunctions must be clearly labeled and immediately removed from service until the malfunction is identified and corrected.

(iii) Written evidence of all maintenance and repairs shall be maintained.

(iv) After repairs or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning to service. This testing must be documented.

(v) A facility shall comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC), §360i(b), concerning reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.

(B) Preventive maintenance. A facility shall develop, implement and enforce a written preventive maintenance program to ensure patient care related equipment used

in a facility receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. The preventive maintenance may be provided by facility staff or by contract.

(C) Backup machine. At least one complete dialysis machine shall be available on site as backup for every ten dialysis machines in use. At least one of these backup machines must be completely operational during hours of treatment. Machines not in use during a patient shift may be counted as backup except at the time of an initial or an expansion survey.

(D) Pediatric patients. If pediatric patients are treated, a facility shall use equipment and supplies, to include blood pressure cuffs, dialyzers, and blood tubing, appropriate for this special population.

(E) Emergency equipment and supplies. A facility shall have emergency equipment and supplies immediately accessible in the treatment area.

(i) At a minimum, the emergency equipment and supplies shall include the following:

(I) oxygen;

(II) mechanical ventilatory assistance equipment, to include airways, manual breathing bag, and mask;

(III) suction equipment;

(IV) supplies specified by the medical director;

(V) electrocardiograph; and

(VI) automated external defibrillator or defibrillator.

(ii) If pediatric patients are treated, the facility shall have the appropriate type and size emergency equipment and supplies listed in clause (i) of this subparagraph for this special population.

(iii) A facility shall establish, implement, and enforce a policy for the periodic testing and maintenance of the emergency equipment. Staff shall properly maintain and test the emergency equipment and supplies and document the testing and maintenance.

(F) Transducer protector. A transducer protector shall be replaced when wetted during a dialysis treatment and shall be used for one treatment only.

(4) Water treatment and dialysate concentrates.

(A) Compliance required. A facility shall meet the requirements of this section. A facility may follow more stringent requirements than the minimum standards required by this section.

(i) The facility administrator and medical director shall each demonstrate responsibility for the water treatment and dialysate supply systems to protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminants that may be found in improperly prepared dialysate, to ensure that the dialysate is correctly formulated and meets the requirements of all applicable quality standards.

(ii) The facility administrator and medical director must assure that policies and procedures related to water treatment and dialysate are understandable and accessible to the operator(s) and that the training program includes quality testing, risks and hazards of improperly prepared concentrate and bacterial issues.

(iii) The facility administrator and medical director must be informed prior to any alteration of, or any device being added to, the water system.

(B) Water treatment. These requirements apply to water intended for use in the delivery of hemodialysis, including the preparation of concentrates from powder at a dialysis facility and dialysate.

(i) The design for the water treatment system in a facility shall be based on considerations of the source water for the facility and designed by a water quality professional with education, training, or experience in dialysis system design.

(ii) When a public water system supply is not used by a facility, the source water shall be tested by the facility at monthly intervals in the same manner as a public water system as described in 30 TAC §290.104 (relating to Summary of Maximum Contaminant Levels, Maximum Residual Disinfectant Levels, Treatment Techniques, and Action Levels), and §290.109 (relating to Microbial Contaminants) as adopted by the Texas Commission on Environmental Quality (TCEQ).

(iii) The physical space in which the water treatment system is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing, and repair of the mixing equipment and for performing the mixing procedure.

(iv) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality described in §4.2.1 (concerning Water Bacteriology) and §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI). All documents published by the AAMI as referenced in this section

may be obtained by writing the following address: 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201.

(v) Written policies and procedures for the operation of the water treatment system must be developed and implemented. Parameters for the operation of each component of the water treatment system must be developed in writing and known to the operator. Each major water system component shall be labeled in a manner that identifies the device; describes its function, how performance is verified and actions to take in the event performance is not within an acceptable range.

(vi) The materials of any components of water treatment systems (including piping, storage, filters and distribution systems) that contact the purified water shall not interact chemically or physically so as to affect the purity or quality of the product water adversely. Such components shall be fabricated from unreactive materials (e.g. plastics) or appropriate stainless steel. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, or aluminum, is prohibited.

(vii) Chemicals infused into the water such as iodine, acid, flocculants, and complexing agents shall be shown to be nondialyzable or shall be adequately removed from product water. Monitors or specific test procedures to verify removal of additives shall be provided and documented.

(viii) Each water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of two carbon tanks in series. If the source water is from a private supply which does not use chlorine/chloramine, the water treatment system shall include reverse osmosis membranes or deionization tanks and a minimum of one carbon tank.

(I) Reverse osmosis membranes. Reverse osmosis membranes, if used, shall meet the standards in §4.3.7 (concerning Reverse Osmosis) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(II) Deionization systems.

(-a-) Deionization systems, if used, shall be monitored continuously to produce water of one megohm-centimeter (cm) or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25 degrees Celsius. An audible and visual alarm shall be activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use.

(-b-) Patients shall not be dialyzed on deionized water with a resistivity less than 1.0 megohm-cm measured at the output of the deionizer.

(-c-) A minimum of two deionization (DI) tanks in series shall be used with resistivity monitors including audible and visual alarms placed pre and post the final DI tank in the system. The alarms must be audible in the patient care area.

(-d-) Feed water for deionization systems shall be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.

(-e-) If a deionization system is the last process in a water treatment system, it shall be followed by an ultrafilter or other bacteria and endotoxin reducing device.

(III) Carbon tanks.

(-a-) The carbon tanks must contain acid washed carbon, 30-mesh or smaller with a minimum iodine number of 900.

(-b-) A minimum of two carbon adsorption beds shall be installed in a series configuration.

(-c-) The total empty bed contact time (EBCT) shall be at least ten minutes, with the final tank providing at least five minutes EBCT. Carbon adsorption systems used to prepare water for portable dialysis systems are exempt from the requirement for the second carbon and a ten minute EBCT if removal of chloramines to below 0.1 milligram (mg)/1 is verified before each treatment.

(-d-) A means shall be provided to sample the product water immediately prior to the final bed(s). Water from this port(s) must be tested for chlorine/chloramine levels immediately prior to each patient shift.

(-e-) All samples for chlorine/chloramine testing must be drawn when the water treatment system has been operating for at least 15 minutes.

(-f-) Tests for total chlorine, which include both free and combined forms of chlorine, may be used as a single analysis with the maximum allowable concentration of 0.1 mg/liter (L). Test results of greater than 0.5 parts per million (ppm) for chlorine or 0.1 ppm for chloramine from the port between the initial tank(s) and final tank(s) shall require testing to be performed at the final exit and replacement of the initial tank(s).

(-g-) In a system without a holding tank, if test results at the exit of the final tank(s) are greater than the parameters for chlorine or chloramine described in this subclause, dialysis treatment shall be immediately terminated to protect patients from exposure to chlorine/chloramine and the medical director shall be notified. In systems with holding tanks, if the holding tank tests <0.1 mg/L for total chlorine, the reverse osmosis (RO) may be turned off and the product water in the holding tank may be used to finish treatments in process. The medical director shall be notified.

(-h-) If means other than granulated carbon are used to remove chlorine/chloramine, the facility's governing body must approve such use in writing after review of the safety of the intended method for use in hemodialysis applications. If such

methods include the use of additives, there must be evidence the product water does not contain unsafe levels of these additives.

(ix) Water softeners, if used, shall be tested at the end of the treatment day to verify their capacity to treat a sufficient volume of water to supply the facility for the entire treatment day and shall be fitted with a mechanism to prevent water containing the high concentrations of sodium chloride used during regeneration from entering the product water line during regeneration.

(x) If used, the face(s) of timer(s) used to control any component of the water treatment or dialysate delivery system shall be visible to the operator at all times. Written evidence that timers are checked for operation and accuracy each day of operation must be maintained.

(xi) Filter housings, if used during disinfectant procedures, shall include a means to clear the lower portion of the housing of the disinfecting agents. Filter housings shall be opaque.

(xii) Ultrafilters, or other bacterial reducing filters, if used, shall be fitted with pressure gauges on the inlet and outlet water lines to monitor the pressure drop across the membrane. Ultrafilters shall be included in routine disinfection procedures.

(xiii) If used, storage tanks shall have a conical or bowl shaped base and shall drain from the lowest point of the base. Storage tanks shall have a tight-fitting lid and be vented through a hydrophobic 0.2 micron air filter. Means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

(xiv) Ultraviolet (UV) lights, if used, shall be monitored at the frequency recommended by the manufacturer. A log sheet shall be used to record monitoring.

(xv) Water treatment system piping shall be labeled to indicate the contents of the pipe and direction of flow.

(xvi) The water treatment system must be continuously monitored during patient treatment and be guarded by audible and visual alarms which can be seen and heard in the dialysis treatment area should water quality drop below specific parameters. Quality monitor sensing cells shall be located as the last component of the water treatment system and at the beginning of the distribution system. No water treatment components that could affect the quality of the product water as measured by this device shall be located after the sensing cell.

(xvii) When deionization tanks do not follow a reverse osmosis system, parameters for the rejection rate of the membranes must assure that the lowest rate accepted would provide product water in compliance with §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition published by the AAMI.

(xviii) A facility shall maintain written logs of the operation of the water treatment system for each treatment day. The log book shall include each component's operating parameter and the action taken when a component is not within the facility's set parameters.

(xix) Microbiological testing of product water shall be conducted.

(I) Frequency. Microbiological testing shall be conducted monthly and following any repair or change to the water treatment system. For a newly installed water distribution system, or when a change has been made to an existing system, weekly testing shall be conducted for one month to verify that bacteria and endotoxin levels are consistently within the allowed limits.

(II) Sample sites. At a minimum, sample sites chosen for the testing shall include the beginning of the distribution piping, at any site of dialysate mixing, and the end of the distribution piping.

(III) Technique. Samples shall be collected immediately before sanitization/disinfection of the water treatment system and dialysis machines. Water testing results shall be routinely trended and reviewed by the medical director in order to determine if results seem questionable or if there is an opportunity for improvement. The medical director shall determine if there is a need for retesting. Repeated results of "no growth" shall be validated via an outside laboratory. A calibrated loop may not be used in microbiological testing of water samples. Colonies shall be counted using a magnifying device.

(IV) Expected results. Product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use, shall contain a total viable microbial count less than 200 colony forming units (CFU)/millimeter (ml) and an endotoxin concentration less than 2 endotoxin units (EU)/ml. The action level for the total viable microbial count in the product water shall be 50 CFU/ml and the action level for the endotoxin concentration shall be 1 EU/ml.

(V) Required action for unacceptable results. If the action levels described at subclause (IV) of this clause are observed in the product water, corrective measures shall be taken promptly to reduce the levels into an acceptable range.

(VI) Records. All bacteria and endotoxin results shall be recorded on a log sheet in order to identify trends that may indicate the need for corrective action.

(xx) If ozone generators are used to disinfect any portion of the water or dialysate delivery system, testing based on the manufacturer's direction shall be used to measure the ozone concentration each time disinfection is performed, to include testing for safe levels of residual ozone at the end of the disinfection cycle. Testing for ozone in the ambient air shall be conducted on a periodic basis as recommended by the manufacturer. Records of all testing must be maintained in a log.

(xxi) If used, hot water disinfection systems shall be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Temperature of the water shall be recorded at a point furthest from the water heater, where the lowest water temperature is likely to occur. The water temperature shall be measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection shall be maintained.

(xxii) After chemical disinfection, means shall be provided to restore the equipment and the system in which it is installed to a safe condition relative to residual disinfectant prior to the product water being used for dialysis applications.

(xxiii) Samples of product water must be submitted for chemical analysis every six months and must demonstrate that the quality of the product water used to prepare dialysate or concentrates from powder, meets §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(I) Samples for chemical analysis shall be collected at the end of the water treatment components and at the most distal point in each water distribution loop, if applicable. All other outlets from the distribution loops shall be inspected to ensure that the outlets are fabricated from compatible materials. Appropriate containers and pH adjustments shall be used to ensure accurate determinations. New facilities or facilities that add or change the configuration of the water distribution system must draw samples at the most distal point for each water distribution loop, if applicable, on a one time basis.

(II) Additional chemical analysis shall be submitted if substantial changes are made to the water treatment system or if the percent rejection of a reverse osmosis system decreased 5.0% or more from the percent rejection measured at the time the water sample for the preceding chemical analysis was taken.

(xxiv) Facility records must include all test results and evidence that the medical director has reviewed the results of the water quality testing and directed corrective action when indicated.

(xxv) Only persons qualified by the education or experience may operate, repair, or replace components of the water treatment system.

(C) Dialysate.

(i) Quality control procedures shall be established to ensure ongoing conformance to policies and procedures regarding dialysate quality.

(ii) Each facility shall set all hemodialysis machines to use only one family of concentrates. When new machines are put into service or the concentrate family or concentrate manufacturer is changed, samples shall be sent to a laboratory for verification.

(iii) Prior to each patient treatment, staff shall verify the dialysate conductivity and pH of each machine with an independent device.

(iv) Bacteriological testing shall be conducted.

(I) Frequency. Responsible facility staff shall develop a schedule to ensure each hemodialysis machine is tested quarterly for bacterial growth and the presence of endotoxins. Hemodialysis machines of home patients shall be cultured monthly until results not exceeding 200 CFU/ml are obtained for three consecutive months, then quarterly samples shall be cultured.

(II) Acceptable limits. Dialysate shall contain less than 200 CFU/ml and an endotoxin concentration of less than 2 EU/ml. The action level for total viable microbial count shall be 50 CFU/ml and the action level for endotoxin concentration shall be 1 EU/ml.

(III) Action to be taken. Disinfection and retesting shall be done when bacterial or endotoxin counts exceed the action levels. Additional samples shall be collected when there is a clinical indication of a pyrogenic reaction and/or septicemia.

(v) Only a licensed nurse may use an additive to increase concentrations of specific electrolytes in the acid concentrate. Mixing procedures shall be followed as specified by the additive manufacturer. When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate shall be labeled with the name of the patient, the final concentration of the added electrolyte, the date the prescribed concentrate was made, and the name of the person who mixed the additive.

(vi) All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides used to disinfect the equipment. The use of materials that are known to cause toxicity in hemodialysis such as copper, brass, galvanized material and aluminum is prohibited.

(vii) Facility policies shall address means to protect stored acid concentrates from tampering or from degeneration due to exposure to extreme heat or cold.

(viii) Procedures to control the transfer of acid concentrates from the delivery container to the storage tank and prevent the inadvertent mixing of different concentrate formulations shall be developed, implemented and enforced. The storage tanks shall be clearly labeled.

(ix) Concentrate mixing systems shall include a purified water source, a suitable drain, and a ground fault protected electrical outlet.

(I) Operators of mixing systems shall use personal protective equipment as specified by the manufacturer during all mixing processes.

(II) The manufacturer's instructions for use of a concentrate mixing system shall be followed, including instructions for mixing the powder with the correct amount of water. The number of bags or weight of powder added shall be determined and recorded.

(III) The mixing tank shall be clearly labeled to indicate the fill and final volumes required to correctly dilute the powder.

(IV) Systems for preparing either bicarbonate or acid concentrate from powder shall be monitored according to the manufacturer's instructions.

(V) Concentrates shall not be used, or transferred to holding tanks or distribution systems, until all tests are completed.

(VI) If a facility designs its own system for mixing concentrates, procedures shall be developed and validated using an independent laboratory to ensure proper mixing.

(x) Acid concentrate mixing tanks shall be designed to allow the inside of the tank to be rinsed when changing concentrate formulas.

(I) Acid mixing systems shall be designed and maintained to prevent rust and corrosion.

(II) Acid concentrate mixing tanks shall be emptied completely and rinsed with product water before mixing another batch of concentrate to prevent cross contamination between different batches.

(III) Acid concentrate mixing equipment shall be disinfected as specified by the equipment manufacturer or in the case where no specifications are given, as defined by facility policy.

(IV) Records of disinfection and rinsing of disinfectants to safe residual levels shall be maintained.

(xi) Bicarbonate concentrate mixing tanks shall have conical or bowl shaped bottoms and shall drain from the lowest point of the base. The tank design shall allow all internal surfaces to be disinfected and rinsed.

(I) Bicarbonate concentrate mixing tanks shall not be prefilled the night before use.

(II) If disinfectant remains in the mixing tank overnight, this solution must be completely drained, the tank rinsed and tested for residual disinfectant prior to preparing the first batch of that day of bicarbonate concentrate.

(III) Unused portions of bicarbonate concentrate shall not be mixed with fresh concentrate.

(IV) At a minimum, bicarbonate distribution systems shall be disinfected weekly. More frequent disinfection shall be done if required by the manufacturer, or if dialysate culture results are above the action level.

(V) If jugs are reused to deliver bicarbonate concentrate to individual hemodialysis machines:

(-a-) jugs shall be emptied of concentrate, rinsed and inverted to drain at the end of each treatment day;

(-b-) at a minimum, jugs shall be disinfected weekly, more frequent disinfection shall be considered by the medical director if dialysate culture results are above the action level; and

(-c-) following disinfection, jugs shall be drained, rinsed free of residual disinfectant, and inverted to dry. Testing for residual disinfectant shall be done and documented.

(xii) All mixing tanks, bulk storage tanks, dispensing tanks and containers for single hemodialysis treatments shall be labeled as to the contents.

(I) Mixing tanks. Prior to batch preparation, a label shall be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling shall remain on the mixing tank until the tank has been emptied.

(II) Bulk storage/dispensing tanks. These tanks shall be permanently labeled to identify the chemical composition or formulation of their contents.

(III) Single machine containers. At a minimum, single machine containers shall be labeled with sufficient information to differentiate the contents from other concentrate formulations used in the facility and permit positive identification by users of container contents.

(xiii) Permanent records of batches produced shall be maintained to include the concentrate formula produced, the volume of the batch, lot number(s) of powdered concentrate packages, the manufacturer of the powdered concentrate, date and time of mixing, test results, person performing mixing, and expiration date (if applicable).

(xiv) If dialysate concentrates are prepared in the facility, the manufacturers' recommendations shall be followed regarding any preventive maintenance. Records shall be maintained indicating the date, time, person performing the procedure, and the results (if applicable).

(5) Prevention requirements concerning patients.

(A) Hepatitis B vaccination.

(i) With the advice and consent of a patient's attending nephrologist, facility staff shall make the hepatitis B vaccine available to a patient who is susceptible to hepatitis B, provided that the patient has coverage or is willing to pay for vaccination.

(ii) The facility shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.

(B) Serologic screening of patients.

(i) A patient new to dialysis shall have been screened for hepatitis B surface antigen (HBsAg) within one month before or at the time of admission to the facility or have a known hepatitis B surface antibody (anti-HBs) status of at least 10 milli-international units per milliliter no more than 12 months prior to admission. The facility shall document how this screening requirement is met.

(ii) Repeated serologic screening shall be based on the antigen or antibody status of the patient.

(I) Monthly screening for HBsAg is required for patients whose previous test results are negative for HBsAg.

(II) Screening of HBsAg-positive or anti-HBs-positive patients may be performed on a less frequent basis, provided that the facility's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 2000, published by the United States Department of Health and Human Services.

(C) Isolation procedures for the HBsAg-positive patient.

(i) The facility shall treat patients positive for HBsAg in a segregated treatment area which includes a hand washing sink, a work area, patient care supplies and equipment, and sufficient space to prevent cross-contamination to other patients.

(ii) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for the HBsAg-positive patient's use only.

(iii) When a caregiver is assigned to both HBsAg-negative and HBsAg-positive patients, the HBsAg-negative patients assigned to this grouping must be Hepatitis B antibody positive. Hepatitis B antibody positive patients are to be seated at the treatment stations nearest the isolation station and be assigned to the same staff member who is caring for the HBsAg-positive patient.

(iv) If an HBsAg-positive patient is discharged, the equipment which had been reserved for that patient shall be given intermediate level disinfection prior to use for a patient testing negative for HBsAg.

(v) In the case of patients new to dialysis, if these patients are admitted for treatment before results of HBsAg or anti-HBs testing are known, these patients shall undergo treatment as if the HBsAg test results were potentially positive, except that they shall not be treated in the HBsAg isolation room, area, or machine.

(I) The facility shall treat potentially HBsAg-positive patients in a location in the treatment area which is outside of traffic patterns until the HBsAg test results are known.

(II) The dialysis machine used by this patient shall be given intermediate level disinfection prior to its use by another patient.

(III) The facility shall obtain HBsAg status results of the patient no later than three days from admission.

(u) Respiratory care services. The hospital shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) Policies and procedures shall be adopted, implemented, and enforced which describe the provision of respiratory care services in the hospital.

(2) The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.

(3) There shall be a medical director or clinical director of respiratory care services who is a physician with the knowledge, experience, and capabilities to supervise and administer the services properly. The medical director or clinical director may serve on either a full-time or part-time basis.

(4) There shall be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with the state law.

(5) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.

(6) If blood gases or other clinical laboratory tests are performed by the respiratory care services staff, the respiratory care staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR, Part 493.

(7) Services shall be provided only on, and in accordance with, the orders of a physician.

(v) Sterilization and sterile supplies.

(1) Supervision. The sterilization of all supplies and equipment shall be under the supervision of a person qualified by education, training and experience. Staff responsible for the sterilization of supplies and equipment shall participate in a documented continuing education program; new employees shall receive initial orientation and on-the-job training.

(2) Equipment and procedures.

(A) Sterilization. Every hospital shall provide equipment adequate for sterilization of supplies and equipment as needed. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of the various materials required.

(B) Written policy. Written policies and procedures for the decontamination and sterilization activities performed shall be adopted, implemented and enforced. Policies shall include the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of reusable items, as well as those for the assembly, wrapping, storage, distribution and quality control of sterile items and equipment. These written policies shall be reviewed at least every other year and approved by the infection control practitioner or committee.

(C) Separation. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and the policies and procedures for their use, shall be such as to effectively separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment. Hand washing facilities shall be provided and a separate sink shall be provided for safe disposal of liquid waste.

(D) Labeling. All containers for solutions, drugs, flammable solvents, ether, alcohol, and medicated supplies shall be clearly labeled to indicate contents. Those which are sterilized by the hospital shall be labeled so as to be identifiable both before and after sterilization. Sterilized items shall have a load control identification that indicates the sterilizer used, the cycle or load number, and the date of sterilization.

(E) Preparation for sterilization.

(i) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated and prepared in a clean, controlled environment.

(ii) All articles to be sterilized shall be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature.

(F) Packaging. All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized.

(G) External chemical indicators.

(i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process.

(ii) The indicator results shall be interpreted according to manufacturer's written instructions and indicator reaction specifications.

(iii) A log shall be maintained with the load identification, indicator results, and identification of the contents of the load.

(H) Biological indicators. Biological indicators are commercially-available microorganisms (e.g., United States Food and Drug Administration (FDA) approved strips or vials of *Bacillus* species endospores) which can be used to verify the performance of waste treatment equipment and processes (or sterilization equipment and processes).

(i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used.

(ii) Biological indicators shall be included in at least one run each week of use for steam sterilizers, at least one run each day of use for low-temperature hydrogen peroxide gas sterilizers, and every load for ethylene oxide (EO) sterilizers.

(iii) Biological indicators shall be included in every load that contains implantable objects.

(iv) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.

(v) If a test is positive, the sterilizer shall immediately be taken out of service.

(I) Implantable items shall be recalled and reprocessed if a biological indicator test (spore test) is positive.

(II) All available items shall be recalled and reprocessed if a sterilizer malfunction is found and a list of those items not retrieved in the recall shall be submitted to infection control.

(III) A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.

(I) Sterilizers.

(i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions.

(ii) EO sterilizers shall be used for processing heat and moisture sensitive items. EO sterilizers and aerators shall be used and vented according to the manufacturer's written instructions.

(iii) Flash sterilizers shall be used for emergency sterilization of clean, unwrapped instruments and porous items only.

(J) Disinfection.

(i) Written policies, approved by the infection control committee, shall be adopted, implemented and enforced for the use of chemical disinfectants.

(ii) The manufacturer's written instructions for the use of disinfectants shall be followed.

(iii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.

(iv) Disinfectant solutions shall be kept covered and used in well-ventilated areas.

(v) Chemical germicides that are registered with the United States Environmental Protection Agency as "sterilants" may be used either for sterilization or high-level disinfection.

(vi) All staff personnel using chemical disinfectants shall have received training on their use.

(K) Performance records.

(i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of five years.

(ii) Each sterilizer shall be monitored continuously during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained and shall include:

(I) the sterilizer identification;

(II) sterilization date;

(III) cycle number;

(IV) contents of each load;

(V) duration and temperature of exposure phase (if not provided on sterilizer recording charts);

(VI) identification of operator(s);

(VII) results of biological tests and dates performed;

(VIII) time-temperature recording charts from each sterilizer;

and (IX) gas concentration and relative humidity (if applicable);

(X) any other test results.

(L) Storage of sterilized items.

(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage.

(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.

(iii) The hospital shall adopt, implement and enforce a policy which describes the mechanism used to determine the shelf life of sterilized packages.

(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual adopted, implemented and enforced policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review.

(w) Surgical services. If a hospital provides surgical services, the services shall be well-organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services shall be consistent in quality with inpatient care in accordance with the complexity of services offered. A special hospital may not offer surgical services.

(1) Organization and staffing. The organization of the surgical services shall be appropriate for the scope of the services offered.

(A) The operating rooms shall be supervised by an experienced RN or physician.

(B) Licensed vocational nurses (LVNs) and surgical technologists (operating room technicians) may serve as scrub nurses or technologists under the supervision of an RN.

(C) Circulating duties in the operating room must be performed by qualified RNs. In accordance with approved medical staff polices and procedures, LVNs and surgical technologists may assist in circulatory duties under the direct supervision of a qualified RN circulator.

(D) Surgical privileges shall be delineated for all physicians, podiatrists, and dentists performing surgery in accordance with the competencies of each. The surgical services shall maintain a roster specifying the surgical privileges of each.

(E) If the facility employs surgical technologists, the facility shall adopt, implement, and enforce policies and procedures to comply with Health and Safety Code, Chapter 259 (relating to Surgical Technologists at Health Care Facilities).

(2) Delivery of service. Surgical services shall be consistent with needs and resources. Written policies governing surgical care which are designed to ensure the achievement and maintenance of high standards of medical practice and patient care shall be adopted, implemented and enforced.

(A) There shall be a complete medical history and physical examination, as required under subsection (k)(3)(F) of this section, in the medical record of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's medical record, there shall be a statement to that effect and an admission note in the record by the individual who admitted the patient.

(B) A properly executed informed consent form for the operation shall be in the patient's medical record before surgery, except in emergencies.

(C) The following equipment shall be available in the operating room suites:

(i) communication system;

(ii) cardiac monitor;

(iii) resuscitator;

(iv) defibrillator;

(v) aspirator; and

(vi) tracheotomy set.

(D) There shall be adequate provisions for immediate postoperative care.

(E) The operating room register shall be complete and up-to-date. The register shall contain, but not be limited to, the following:

- (i) patient's name and hospital identification number;
- (ii) date of operation;
- (iii) operation performed;
- (iv) operating surgeon and assistant(s);
- (v) type of anesthesia used and name of person administering it;
- (vi) time operation began and ended;
- (vii) time anesthesia began and ended;
- (viii) disposition of specimens;
- (ix) names of scrub and circulating personnel;
- (x) unusual occurrences; and
- (xi) disposition of the patient.

(F) An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and signed by the surgeon.

(x) Therapy services. If the hospital provides physical therapy, occupational therapy, audiology, or speech pathology services, the services shall be organized and staffed to ensure the health and safety of patients.

(1) Organization and staffing. The organization of the services shall be appropriate to the scope of the services offered.

(A) The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(B) Physical therapy, occupational therapy, speech therapy, or audiology services, if provided, shall be provided by staff who meet the qualifications specified by the medical staff, consistent with state law.

(2) Delivery of services. Services shall be furnished in accordance with a written plan of treatment. Services to be provided shall be consistent with applicable state laws and regulations, and in accordance with orders of the physician, podiatrist, dentist or other licensed practitioner who is authorized by the medical staff to order the services. Therapy orders shall be incorporated in the patient's medical record.

(y) Waste and waste disposal.

(1) Special waste and liquid/sewage waste management.

(A) The hospital shall comply with the requirements set forth by the department in §§1.131 - 1.137 of this title (relating to Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities) and the TCEQ requirements in 30 TAC §330.1207 (relating to Generators of Medical Waste).

(B) All sewage and liquid wastes shall be disposed of in a municipal sewerage system or a septic tank system permitted by the TCEQ in accordance with 30 TAC Chapter 285 (relating to On-Site Sewage Facilities).

(2) Waste receptacles.

(A) Waste receptacles shall be conveniently available in all toilet rooms, patient areas, staff work areas, and waiting rooms. Receptacles shall be routinely emptied of their contents at a central location(s) into closed containers.

(B) Waste receptacles shall be properly cleaned with soap and hot water, followed by treatment of inside surfaces of the receptacles with a germicidal agent.

(C) All containers for other municipal solid waste shall be leak-resistant, have tight-fitting covers, and be rodent-proof.

(D) Nonreusable containers shall be of suitable strength to minimize animal scavenging or rupture during collection operations.

§133.42. Patient Rights.

(a) Patient rights requirements for all hospitals.

(1) A hospital shall adopt, implement, and enforce a policy to ensure patients' rights. The written policy shall include:

(A) the right of the patient to the hospital's reasonable response to his or her requests and needs for treatment or service, within the hospital's capacity, its stated mission, and applicable law and regulation;

(B) the right of the patient to considerate and respectful care:

(i) the care of the patient includes consideration of the psychosocial, spiritual, and cultural variables that influence the perceptions of illness;

(ii) the care of the dying patient optimizes the comfort and dignity of the patient through:

(I) treating primary and secondary symptoms that respond to treatment as desired by the patient or surrogate decision maker;

(II) effectively managing pain; and

(III) acknowledging the psychosocial and spiritual concerns of the patient and the family regarding dying and the expression of grief by the patient and family;

(C) the right of the patient, in collaboration with his or her physician, to make decisions involving his or her health care, to include the following:

(i) the right of the patient to accept medical care or to refuse treatment to the extent permitted by law and to be informed of the medical consequences of such refusal; and

(ii) the right of the patient to formulate advance directives and to appoint a surrogate to make health care decisions on his or her behalf to the extent permitted by law. Advance directives are written instructions recognized under state law relating to the provision of health care when individuals are unable to communicate their wishes regarding medical treatment. The advance directive may be a written document authorizing an agent or surrogate to make decisions on an individual's behalf (a medical power of attorney for health care), a written or verbal statement (a living will), or some other form of instruction recognized under state law specifically addressing the provisions of health care;

(I) a hospital shall have in place a mechanism to ascertain the existence of, and, as appropriate, assist in the development of advance directives at the time of the patient's admission;

(II) the provision of care shall not be conditioned on the existence of an advance directive; and

(III) an advance directive(s) shall be in the patient's medical record and shall be reviewed periodically with the patient or surrogate decision maker if the patient has executed an advance directive;

(D) the right of the patient to the information necessary to enable him or her to make treatment decisions that reflect his or her wishes; a policy on informed decision making shall be adopted, implemented and enforced by the medical staff and governing body and shall be consistent with any legal requirements;

(E) the right of the patient to receive, at the time of admission, information about the hospital's patient rights policy(ies) and the mechanism for the initiation, review, and when possible, resolution of patient complaints concerning the quality of care;

(F) the right of the patient or the patient's designated representative to participate in the consideration of ethical issues that arise in the care of the patient. The hospital

shall have a mechanism for the consideration of ethical issues arising in the care of patients and to provide education to care givers and patients on ethical issues in health care;

(G) the right of the patient to be informed of any human experimentation or other research or educational projects affecting his or her care or treatment;

(H) the right of the patient, within the limits of law, to personal privacy and confidentiality of information;

(I) the right of the patient or the patient's legally designated representative access to the information contained in the patient's medical record, within the limits of the law; and

(J) the right of the patient's guardian, next of kin, or legally authorized responsible person to exercise, to the extent permitted by law, the rights delineated on behalf of the patient if the patient:

(i) has been adjudicated incompetent in accordance with the law;

(ii) is found by his or her physician to be medically incapable of understanding the proposed treatment or procedure;

(iii) is unable to communicate his or her wishes regarding treatment; or

(iv) is a minor.

(2) The hospital patient's bill of rights shall be prominently and conspicuously posted for display in a public area of the facility that is readily available to patients, residents, employees, and visitors.

(b) Additional patient bill of rights requirements for hospitals providing comprehensive medical rehabilitation services. A hospital that provides comprehensive medical rehabilitation services shall comply with subsection (a) of this section and with the following additional provisions applicable to patients who receive such services.

(1) The patient's bill of rights shall address the rights of minors and provide that a minor is entitled to:

(A) appropriate treatment in the least restrictive setting available;

(B) not receive unnecessary or excessive medication;

(C) an individualized treatment plan and to participate in the development of the plan;

(D) a humane treatment environment that provides reasonable protection from harm and appropriate privacy for personal needs;

(E) separation from adult patients; and

(F) regular communication between the minor patient and the patient's family.

(2) Prior to admission or acceptance for evaluation, a written copy of the patient's bill of rights in the patient's primary language, if possible, shall be given to each patient, and, as appropriate, to the patient's parent, managing conservator, or guardian.

(3) The hospital shall ensure that within 24 hours after the patient is admitted to the hospital, the rights described in this subsection are explained to the patient and, if appropriate, to the patient's parent, managing conservator, or guardian in the following manner:

(A) orally, in simple, nontechnical terms in the person's primary language, if possible; or

(B) other reasonable means calculated to communicate with a person who has an impairment of vision or hearing, if applicable.

(4) If the patient cannot comprehend the information because of illness, age, or other factors, or an emergency exists that precludes immediate presentation of the information, or the patient refused to sign the written copy of the patient's bill of rights as provided for in paragraph (5) of this subsection, the presentation of the document shall be witnessed by two members of the hospital staff, and the unsigned patient's bill of rights shall be placed in the clinical record along with a note signed by the witnesses indicating the reasons for their signatures.

(5) The hospital shall obtain a signed copy of the patient's bill of rights from each patient, or, if appropriate, from the patient's parent, managing conservator, or guardian. The signed copy shall include a statement that the patient, patient's parent, managing conservator, or guardian has read the document and understands the rights specified in the document. The signed copy shall be made a part of the patient's medical record.

(c) Additional patient bill of rights requirements for hospitals providing chemical dependency services. A hospital that provides chemical dependency services shall comply with subsection (a) of this section and with §448.701 of this title (relating to Client Bill of Rights) applicable to patients who receive such services.

(d) Additional patient bill of rights requirements for hospitals providing mental health services. A hospital that provides mental health services shall comply with subsection (a) of this section and Chapter 404, Subchapter E of this title (relating to Rights of Persons Receiving Mental Health Services) applicable to patients who receive such services.

(e) Posting requirements for patient bill of rights for hospitals providing comprehensive medical rehabilitation services, chemical dependency services, or mental health services. The hospital shall prominently and conspicuously post for display a copy of the patient's bill of rights in a public area of the hospital that is readily visible to patients, residents, employees, and visitors. The patient bill of rights posted for display shall be in English and in a second language appropriate to the demographic makeup of the community served.

§133.43. Discrimination or Retaliation Standards.

(a) Posting requirements for reporting a violation of law. In accordance with Health and Safety Code (HSC), §161.134(j) and §161.135(h), each hospital shall prominently and conspicuously post for display in a public area of the hospital that is readily visible to patients, residents, employees, and visitors a statement that nonemployees, employees and staff are protected from discrimination or retaliation for reporting a violation of law. The statement shall be in English and in a second language appropriate to the demographic makeup of the community served.

(b) Discrimination relating to employee reporting a violation of law. In accordance with HSC, §161.134(a), and §133.41(o)(2)(I)(i)(III) of this title (relating to Hospital Functions and Services), a hospital may not suspend or terminate the employment of, discipline, or otherwise discriminate against an employee for reporting in good faith to the employee's supervisor, an administrator of the hospital, a state or federal regulatory agency, a national accrediting organization or a law enforcement agency a violation of law, including a violation of the Act or this chapter. For purposes of this subsection, a report is not made in good faith if there is not a reasonable factual or legal basis for making the report.

(c) Retaliation relating to nonemployee reporting a violation of law. In accordance with HSC, §161.135(a), a hospital may not retaliate against a person who is not an employee for reporting a violation of law, including a violation of the Act or this chapter.

§133.44. Hospital Patient Transfer Policy.

(a) Definitions.

(1) Designated provider--A provider of health care services, selected by a health maintenance organization, a self-insured business corporation, a beneficial society, the Veterans Administration, CHAMPUS, a business corporation, an employee organization, a county, a public hospital, a hospital district, or any other entity to provide health care services to a patient with whom the entity has a contractual, statutory, or regulatory relationship that creates an obligation for the entity to provide the services to the patient.

(2) Mandated provider--A person who provides health care services, is selected by a county, public hospital, or hospital district, and agrees to provide health care services to eligible residents.

(b) General.

(1) The governing body of each hospital shall adopt, implement, and enforce a policy relating to patient transfers that is consistent with this section and contains each of the requirements in subsection (c) of this section. The policies shall identify hospital staff who have the authority to represent the hospital and the physician with regard to the transfer from or receipt of patients into the hospital.

(2) The transfer policy shall be adopted by the governing body of the hospital after consultation with the medical staff and shall apply to transfers between hospitals licensed under the Health and Safety Code, Chapters 241 and 577, as well as transfers to hospitals which are exempt from licensing.

(3) The policy shall govern transfers not covered by a transfer agreement.

(4) The movement of a stable patient from a hospital to another hospital is not considered to be a transfer under this section if it is the understanding and intent of both hospitals that the patient is going to the second hospital only for tests, the patient will not remain overnight at the second hospital, and the patient will return to the first hospital. This paragraph applies only when a patient remains stable during transport to and from hospitals and during testing.

(5) The hospital's transfer policy shall include a written operational plan to provide for patient transfer transportation services if the hospital does not provide its own patient transfer transportation services.

(6) If possible, each governing body, after consultation with the medical staff, shall implement its transfer policy by adopting transfer agreements with other hospitals in accordance with §133.61 of this title (relating to Hospital Patient Transfer Agreements).

(7) A public hospital or a hospital district shall accept the transfer of its eligible residents if the public hospital or hospital district has appropriate facilities, services, and staff available for providing care to the patient.

(8) The hospital's policy shall recognize and comply with the requirements of the Indigent Health Care and Treatment Act, Health and Safety Code (HSC), §§61.030-61.032 and §§61.057-61.059 (Mandated Providers) since those requirements may apply to a patient.

(9) The hospital's policy shall acknowledge contractual obligations and comply with statutory or regulatory obligations which may exist concerning a patient and a designated provider.

(10) The hospital's policy shall require that all reasonable steps are taken to secure the written informed consent of a patient, or of a person acting on a patient's behalf, when refusing a transfer or related examination and treatment. Reasonable steps include:

(A) a factual explanation of the increased medical risks to the patient reasonably expected from not being transferred, examined, or treated at the transferring hospital;

(B) a factual explanation of any increased risks to the patient from not effecting the transfer; and

(C) a factual explanation of the medical benefits reasonably expected from the provision of appropriate treatment at another hospital.

(D) The informed refusal of a patient, or of a person acting on a patient's behalf, to examination, evaluation or transfer shall be documented and signed if possible by the patient or by a person acting on the patient's behalf, dated and witnessed by the attending physician or hospital employee, and placed in the patient's medical record.

(11) The hospital's policy shall recognize the right of an individual to request a transfer into the care of a physician and a hospital of the individual's own choosing.

(12) Transfer of patients may occur routinely or as part of a regionalized plan for obtaining optimal care for patients at a more appropriate or specialized facility.

(c) Requirements for transfer of patients between hospitals.

(1) Discrimination. Except as is specifically provided in subsection (b)(8) and (9) of this section, relating, respectively, to mandated providers and designated providers, the hospital policy shall provide that the transfer of a patient may not be predicated upon arbitrary, capricious, or unreasonable discrimination based upon race, religion, national origin, age, sex, physical condition, economic status, insurance status or ability to pay.

(2) Disclosure. The hospital's policy shall recognize the right of an individual to request transfer into the care of a physician and a hospital of his own choosing; however, if a patient requests or consents to transfer for economic reasons and the patient's choice is predicated upon or influenced by representations made by the transferring physician or hospital administration regarding the availability of medical care and hospital services at a reduced cost or no cost to the patient, the physician or hospital administration shall fully disclose to the patient the eligibility requirements established by the patient's chosen physician or hospital.

(3) Patient. A patient is an individual:

(A) seeking medical treatment who may or may not be under the immediate supervision of a personal attending physician, has one or more undiagnosed or diagnosed medical conditions, and who, within reasonable medical probability, requires immediate or continuing hospital services and medical care; or

(B) admitted to the hospital as a patient.

(4) Patient evaluation. The hospital's policy shall provide that each patient who arrives at the hospital is:

(A) evaluated by a physician who is present in the hospital at the time the patient presents or is presented or evaluated by a physician on-call who is:

(i) physically able to reach the patient within 30 minutes after being informed that a patient is present at the hospital who requires immediate medical attention; or

(ii) accessible by direct, telephone, or radio communication within 30 minutes with a registered nurse, physician assistant or other qualified medical personnel as established by the governing body at the hospital under orders to assess and report the patient's condition to the physician; and

(B) personally examined and evaluated by the physician before an attempt to transfer is made; however:

(i) after receiving a report on the patient's condition from the hospital's registered nurse, physician assistant or other qualified medical personnel as established by the governing body by telephone or radio, if the physician on-call determines that an immediate transfer of the patient is medically appropriate and that the time required to conduct a personal examination and evaluation of a patient will unnecessarily delay the transfer to the detriment of the patient, the physician on-call may order the transfer by telephone or radio; and

(ii) physician orders for the transfer of a patient which are issued by telephone or radio shall be reduced to writing in the patient's medical record, signed by the registered nurse, physician assistant or other qualified medical personnel as established by the governing body receiving the order, and countersigned by the physician authorizing the transfer as soon as possible. The patient transfers resulting from physician orders issued by telephone or radio shall be subject to automatic review by the medical staff pursuant to paragraph (8) of this subsection.

(5) Hospital personnel, written protocols, standing delegation orders, eligibility and payment information. The policy of the transferring and receiving hospital shall provide that licensed nurses and other qualified personnel are available and on duty to assist with patient transfers and to provide accurate information regarding eligibility and payment practices. The policy shall provide that written protocols or standing delegation orders are in place to guide hospital personnel when a patient requires transfer to another hospital.

(6) Special requirements related to the transfer of patients who have emergency medical conditions.

(A) If a patient at a hospital has an emergency medical condition which has not been stabilized or when stabilization of the patient's vital signs is not possible because the hospital or emergency treatment area does not have the appropriate equipment or personnel to correct the underlying process (e.g. children's hospitals, thoracic surgeon on staff, or cardiopulmonary bypass capability), evaluation and treatment shall be performed and transfer shall be carried out as quickly as possible.

(B) The hospital's policy shall provide that the hospital may not transfer a patient with an emergency medical condition which has not been stabilized unless:

(i) the individual (or a legally responsible person acting on the individual's behalf), after being informed of the hospital's obligations under this section and of the risk of transfer, requests the transfer, in writing and indicates the reasons for the request, as well as that he or she is aware of the risks and benefits of the transfer;

(ii) a physician has signed a certification, which includes a summary of the risks and benefits, that, based on the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risks to the patient and, in the case of labor, to the unborn child from effecting the transfer; or

(iii) if the physician who made the determination to transfer a patient with an emergency condition is not physically present in the emergency treatment area at the time of transfer, a qualified medical person may sign a certification described in clause (ii) of this subparagraph after consultation with the physician. The physician shall countersign the physician certification within a reasonable period of time.

(C) Except as is specifically provided in subsection (b)(8) and (9) of this section, the hospital's policy shall provide that the transfer of patients who have emergency medical conditions, as determined by a physician, shall be undertaken for medical reasons only. The hospital must provide medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child.

(D) A hospital that has specialized capabilities or facilities (including, but not limited to such facilities as burn units, shock-trauma units, neonatal intensive care units, or, with respect to rural areas, regional referral centers) may not refuse to accept from a referring hospital an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual. Except as expressly permitted in clauses (i) and (ii) of this subparagraph, a hospital's policy shall provide for the receipt of patients who have an emergency medical condition from other hospitals so that upon notification from a transferring physician or a transferring hospital prior to transfer, the receiving hospital shall respond to the transferring hospital and transferring physician with the status of the transfer request within 30 minutes and either accept or refuse the transfer. The time period begins to run at the time a member of the staff of the receiving hospital receives the call initiating the request to transfer.

(i) The receiving hospital's policy may permit response to the transferring hospital and transferring physician within a period of time in excess of 30 minutes but no longer than one hour if there are extenuating circumstances for the delay. If the transfer is accepted, the reason for the delay shall be documented on the memorandum of transfer.

(ii) The response time may be extended before the expiration of the initial 30 minutes period by agreement among the transferring hospital and transferring physician and the receiving hospital and receiving physician. If the transfer is accepted, the agreed extension shall be documented in the memorandum of transfer.

(7) Physician's duties and standard of care.

(A) The policy shall provide that the transferring physician shall determine and order life support measures which are medically appropriate to stabilize the patient prior to transfer and to sustain the patient during transfer.

(B) The policy shall provide that the transferring physician shall determine and order the utilization of appropriate personnel and equipment for the transfer.

(C) The policy shall provide that in determining the use of medically appropriate life support measures, personnel, and equipment, the transferring physician shall exercise that degree of care which a reasonable and prudent physician exercising ordinary care in the same or similar locality would use for the transfer.

(D) The policy shall provide that except as allowed under paragraph (4)(B) of this subsection, prior to each patient transfer, the physician who authorizes the transfer shall personally examine and evaluate the patient to determine the patient's medical needs and to ensure that the proper transfer procedures are used.

(E) The policy shall provide that prior to transfer, the transferring physician shall ensure that a receiving hospital and physician that are appropriate to the medical needs of the patient have accepted responsibility for the patient's medical treatment and hospital care.

(8) Record review for standard of care. The hospital's policy shall provide that the hospital's medical staff review appropriate records of patients transferred from the hospital to determine that the appropriate standard of care has been met.

(9) Medical record.

(A) The hospital's policy shall provide that a copy of those portions of the patient's medical record which are available and relevant to the transfer and to the continuing care of the patient be forwarded to the receiving physician and receiving hospital with the patient. If all necessary medical records for the continued care of the patient are not available at the time the patient is transferred, the records shall be forwarded to the receiving physician and hospital as soon as possible.

(B) The medical record shall contain at a minimum:

(i) a brief description of the patient's medical history and physical examination;

(ii) a working diagnosis and recorded observations of physical assessment of the patient's condition at the time of transfer;

(iii) the reason for the transfer;

- (iv) the results of all diagnostic tests, such as laboratory tests;
- (v) pertinent X-ray films and reports; and
- (vi) any other pertinent information.

(10) Memorandum of transfer.

(A) The hospital's policy shall provide that a memorandum of transfer be completed for every patient who is transferred.

(B) The memorandum shall contain the following information:

- (i) the patient's full name, if known;
- (ii) the patient's race, religion, national origin, age, sex, physical handicap, if known;
- (iii) the patient's address and next of kin, address, and phone number if known;
- (iv) the names, telephone numbers and addresses of the transferring and receiving physicians;
- (v) the names, addresses, and telephone numbers of the transferring and receiving hospitals;
- (vi) the time and date on which the patient first presented or was presented to the transferring physician and transferring hospital;
- (vii) the time and date on which the transferring physician secured a receiving physician;
- (viii) the name, date, and time hospital administration was contacted in the receiving hospital;
- (ix) signature, time, and title of the transferring hospital administration who contacted the receiving hospital;
- (x) the certification required by paragraph (6)(B)(ii) of this subsection, if applicable (the certification may be part of the memorandum of transfer form or may be on a separate form attached to the memorandum of transfer form);
- (xi) the time and date on which the receiving physician assumed responsibility for the patient;

hospital;

- (xii) the time and date on which the patient arrived at the receiving hospital;
- (xiii) signature and date of receiving hospital administration;
- (xiv) type of vehicle and company used;
- (xv) type of equipment and personnel needed in transfers;
- (xvi) name and city of hospital to which patient was transported;
- (xvii) diagnosis by transferring physician; and
- (xviii) attachments by transferring hospital.

(C) The receipt of the memorandum of transfer shall be acknowledged in writing by the receiving hospital administration and receiving physician.

(D) A copy of the memorandum of transfer shall be retained by the transferring and receiving hospitals. The memorandum shall be filed separately from the patient's medical record and in a manner which will facilitate its inspection by the department. All memorandum of transfer forms filed separately shall be retained for five years. A copy of the memorandum of transfer may also be filed with the patient's medical record.

(d) Violations. A hospital violates the Act and this section if:

- (1) the hospital fails to comply with the requirements of this section; or
- (2) the governing body fails or refuses to:

(A) adopt a transfer policy which is consistent with this section and contains each of the requirements in subsection (c) of this section;

(B) adopt a memorandum of transfer form which meets the minimum requirements for content contained in this section; or

(C) enforce its transfer policy and the use of the memorandum of transfer.

§133.45. Miscellaneous Policies and Protocols.

(a) Determination of death and autopsy reports. The hospital shall adopt, implement, and enforce protocols to be used in determining death and for filing autopsy reports which comply with Health and Safety Code (HSC), Title 8, Subtitle A, Chapter 671 (Determination of Death and Autopsy Reports).

(b) Organ and tissue donors. The hospital shall adopt, implement, and enforce a written protocol to identify potential organ and tissue donors which is in compliance with the Texas Anatomical Gift Act, HSC, Chapter 692. The hospital shall make its protocol available to the public during the hospital's normal business hours.

(1) The hospital's protocol shall include all requirements in HSC, Chapter 692, §692.013 (Hospital Protocol).

(2) A hospital which performs organ transplants shall be a member of the Organ Procurement and Transplantation Network in accordance with 42 United States Code, §274 (Organ Procurement and Transplantation Network).

(c) All-hazard disaster preparedness.

(1) Definitions.

(A) Adult intensive care unit (ICU)--Can support critically ill/injured patients, including ventilator support.

(B) Burn or burn ICU--Either approved by the American Burn Association or self-designated. (These beds should not be included in other ICU bed counts.)

(C) Medical/surgical--Also thought of as "ward" beds.

(D) Negative pressure/isolation--Beds provided with negative airflow, providing respiratory isolation. Note: This value may represent available beds included in the counts of other types.

(E) Operating rooms--An operating room that is equipped and staffed and could be made available for patient care in a short period.

(F) Pediatric ICU--The same as adult ICU, but for patients 17 years and younger.

(G) Pediatrics--Ward medical/surgical beds for patients 17 years and younger.

(H) Physically available beds--Beds that are licensed, physically set up, and available for use. These are beds regularly maintained in the hospital for the use of patients, which furnish accommodations with supporting services (such as food, laundry, and housekeeping). These beds may or may not be staffed but are physically available.

(I) Psychiatric--Ward beds on a closed/locked psychiatric unit or ward beds where a patient will be attended by a sitter.

(J) Staffed beds--Beds that are licensed and physically available for which staff members are available to attend to the patient who occupies the bed. Staffed beds include those that are occupied and those that are vacant.

(K) Vacant/available beds--Beds that are vacant and to which patients can be transported immediately. These must include supporting space, equipment, medical material, ancillary and support services, and staff to operate under normal circumstances. These beds are licensed, physically available, and have staff on hand to attend to the patient who occupies the bed.

(2) A hospital shall adopt, implement, and enforce a written plan for all-hazard, natural or man-made, disaster preparedness for effective preparedness, mitigation, response, and recovery from disasters.

(3) The plan, which may be subject to review and approval by the department, shall be sent to the local disaster management authority.

(4) The plan shall:

(A) be developed through a joint effort of the hospital governing body, administration, medical staff, hospital personnel and emergency medical services partners;

(B) include the applicable information contained in the National Fire Protection Association 99, Standard for Health Care Facilities, 2002 edition, Chapter 12 (Health Care Emergency Management), published by the National Fire Protection Association (NFPA), and the State of Texas Emergency Management Plan. Information regarding the State of Texas Emergency Management Plan is available from the city or county emergency management coordinator. The NFPA document referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: 1 Batterymarch Park, Post Office Box 9101, Quincy, Massachusetts 02269-9101, (800) 344-3555;

(C) contain the names and contact numbers of city and county emergency management officers and the hospital water supplier;

(D) be exercised at least annually and in conjunction with state and local exercises. Hospitals participating in an exercise or responding to a real life event shall develop an after action report (AAR) within 60 days. AARs shall be retained for at least three years and be available for review by the local emergency management authority and the department;

(E) include the methodology for notifying the hospital personnel and the local disaster management authority of an event that will significantly impact hospital operations;

(F) include evidence that the hospital has communicated prospectively with the local utility and phone companies regarding the need for the hospital to be given priority for the restoration of utility and phone services and a process for testing internal and external communications systems regularly;

(G) include the use of a department approved process to update bed availability, as follows:

(i) as requested by the department during a public health emergency or state declared disaster; and

(ii) for the physically available beds and staffed beds that are vacant/available beds for the following bed types:

(I) adult ICU;

(II) burn or burn ICU;

(III) medical/surgical;

(IV) negative pressure/isolation;

(V) operating rooms;

(VI) pediatric ICU;

(VII) pediatrics; and

(VIII) psychiatric;

(iii) emergency department divert status;

(iv) for decontamination facility available; and

(v) for ventilators available;

(H) include at a minimum:

(i) a component for the reception, treatment, and disposition of casualties that can be used in the event that a disaster situation requires the hospital to accept multiple patients. This component shall include at a minimum:

(I) process, developed in conjunction with appropriate agencies, to allow essential healthcare workers and personnel to safely access their delivery care sites;

(II) procedures for the appropriate provision of personal protection equipment for and appropriate immunization of staff, volunteers, and staff families; and

(III) plan to provide food and shelter for staff and volunteers as needed throughout the duration of response;

(ii) an evacuation component that can be engaged in any emergency situation necessitating either a full or partial evacuation of the hospital. The evacuation component shall address at a minimum:

(I) activation, including who makes the decision to activate and how it is activated;

(II) when within control of the hospital, patient evacuation destination, including protocol to ensure that the patient destination is compatible to patient acuity and health care needs, plan for the order of removal of patients and planned route of movement, train and drill staff on the traffic flow and the movement of patients to a staging area, and room evacuation protocol;

(III) family/responsible party notification, including the procedure to notify patient emergency contacts of an evacuation and the patient's destination; and

(IV) transport of records and supplies, including the protocol for the transfer of patient specific medications and records to the receiving facility. These records shall include at a minimum: the patient's most recent physician's assessment, order sheet, medication administration record (MAR), and patient history with physical documentation. A weather-proof patient identification wrist band (or equivalent identification) must be intact on all patients.

(d) Voluntary paternity establishment services. A hospital that handles the birth of newborns must provide voluntary paternity establishment services in accordance with:

(1) the HSC, §192.012, Record of Acknowledgment of Paternity; and

(2) the rules of the Office of the Attorney General found at 1 TAC, Chapter 55, Subchapter J (relating to Voluntary Paternity Acknowledgment Process).

(e) Harassment and abuse. A hospital shall adopt, implement and enforce a written policy for identifying and addressing instances of alleged verbal or physical abuse or harassment of hospital employees or contracted personnel by other hospital employees or contracted personnel or by a health care provider who has clinical privileges at the hospital.

(f) Information for parents of newborn children. A hospital that provides prenatal care to a pregnant woman during gestation or at delivery of an infant, shall adopt, implement and enforce written policies to ensure compliance with HSC, Chapter 161, Subchapter T, §161.501 (relating to Parenting and Postpartum Counseling Information).

(1) The policy shall require that the woman and the father of the infant, if possible, or another adult caregiver for the infant, be provided with a resource pamphlet which includes:

(A) information on professional organizations providing counseling and assistance relating to postpartum depression and other emotional trauma associated with pregnancy and parenting;

(B) information regarding the prevention of shaken baby syndrome, as specified under HSC, §167.501(a)(1)(B)(i)-(iv);

(C) a list of diseases for which a child is required by state law to be immunized and the appropriate schedule for the administration of those immunizations; and

(D) the appropriate schedule for follow-up procedure for newborn screening.

(2) The policy shall include a requirement that it be documented in the woman's record that the information was provided and that the documentation be maintained for at least five years.

(g) Abortion. A hospital that performs abortions shall adopt, implement and enforce policies to:

(1) ensure compliance with HSC, Chapter 171, Subchapters A and B (relating to Abortion and Informed Consent);

(2) ensure compliance with Occupations Code, §164.052(a)(19) (relating to Parental Consent for Abortion).

(h) Influenza and pneumococcal vaccine for elderly persons. The hospital shall adopt, implement and enforce a policy for providing influenza and pneumococcal vaccines for elderly persons. The policy shall:

(1) establish that an elderly person, defined as 65 years of age or older, who is admitted to the hospital for a period of 24 hours or more, is informed of the availability of the influenza and pneumococcal vaccines, and, if they request the vaccine, is assessed to determine if receipt of the vaccine is in their best interest. If determined appropriate by the physician or other qualified medical personnel, the elderly person shall receive the vaccines prior to discharge from the hospital;

(2) include provisions that the influenza vaccine shall be made available in October and November, and if available, December, and pneumococcal vaccine shall be made available throughout the year;

(3) require that the person administering the vaccine ask the elderly patient if they are currently vaccinated against influenza or pneumococcal disease, assess potential contraindications, and then, if appropriate, administer the vaccine under approved hospital protocols; and

(4) address required documentation of the vaccination in the patient medical record.

(5) The department may waive requirements related to the administration of the vaccines based on established shortages of the vaccines.

§133.46. Hospital Billing.

(a) Itemized statements. A hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with the Health and Safety Code (HSC), §311.002 (Itemized Statement of Billed Services).

(b) Audits of billing. A hospital shall adopt, implement, and enforce a policy to ensure that the hospital complies with HSC, §311.0025(a) (relating to Audits of Billing).

(c) Complaint investigation procedures.

(1) A complaint submitted to the Department of State Health Services (department) relating to billing must specify the patient for whom the bill was submitted.

(2) Upon receiving a complaint warranting an investigation, the department shall send the complaint to the hospital requesting the hospital to conduct an internal investigation. Within 30 days of the hospital's receipt of the complaint, the hospital shall submit to the department:

(A) a report outlining the hospital's investigative process;

(B) the resolution or conclusions reached by the hospital with the patient, third party payor or complainant; and

(C) corrections, if any, in the hospital's policies or protocols which were made as a result of its investigative findings.

(3) In addition to the hospital's internal investigation, the department may also conduct an investigation to audit any billing and patient records of the hospital.

(4) The department shall inform in writing a complainant who identifies himself by name and address:

(A) of the receipt of the complaint;

(B) if the complainant's allegations are potential violations of the Act or this chapter warranting an investigation;

(C) whether the complaint will be investigated by the department;

(D) if the complaint was referred to the hospital for internal investigation;

(E) whether and to whom the complaint will be referred;

(F) of the results of the hospital's investigation and the hospital's resolution with the complainant; and

(G) of the department's findings if an on-site audit investigation was conducted.

(5) The department shall refer investigative reports of billing by health care professionals who have provided improper, unreasonable, or medically or clinically unnecessary treatments or billed for treatments which were not provided to the appropriate licensing agency.

§133.47. Abuse and Neglect Issues.

(a) Reporting. Incidents of abuse, neglect, exploitation, or illegal, unethical or unprofessional conduct as those terms are defined in subsections (b) and (c) of this section shall be reported to the department.

(b) Abuse or neglect of a child, and abuse, neglect or exploitation of an elderly or disabled person. The following definitions apply only to this subsection:

(1) abuse or neglect of a child, as defined in 25 Texas Administrative Code (TAC), §1.204(a) and (b) of this title (relating to Investigations of Abuse, Neglect, or Exploitation of Children or Elderly or Disabled Persons); and

(2) abuse, neglect or exploitation of an elderly or disabled person, as defined in §1.204(a) and (b) of this title.

(c) Abuse and neglect of individuals with mental illness, and illegal, unethical, and unprofessional conduct. The requirements of this subsection are in addition to the requirements of subsection (b) of this section.

(1) Definitions. The following definitions are in accordance with Health and Safety Code (HSC), §161.131 and apply only to this subsection:

(A) Abuse--

(i) Abuse (as the term is defined in 42 United States Code (USC), §10801 et seq.) is any act or failure to act by an employee of a facility rendering care or treatment which was performed, or which was failed to be performed, knowingly, recklessly, or intentionally, and which caused, or may have caused, injury or death to a individual with mental illness, and includes acts such as:

(I) the rape or sexual assault of a individual with mental illness;

(II) the striking of a individual with mental illness;

(III) the use of excessive force when placing a individual with mental illness in bodily restraints; and/or

(IV) the use of bodily or chemical restraints on a individual with mental illness which is not in compliance with federal and state laws and regulations.

(ii) In accordance with HSC, §161.132(j), abuse also includes coercive or restrictive actions that are illegal or not justified by the patient's condition and that are in response to the patient's request for discharge or refusal of medication, therapy or treatment.

(B) Illegal conduct--Illegal conduct (as the term is defined in HSC, §161.131(4)) is conduct prohibited by law.

(C) Neglect--Neglect (as the term is defined in 42 USC, §10801 et seq.) is a negligent act or omission by any individual responsible for providing services in a facility rendering care or treatment which caused or may have caused injury or death to a individual with mental illness or which placed a individual with mental illness at risk of injury or death, and includes an act or omission such as the failure to establish or carry out an appropriate individual program plan or treatment plan for a individual with mental illness, the failure to provide adequate nutrition, clothing, or health care to a individual with mental illness, or the failure to provide a safe environment for a individual with mental illness, including the failure to maintain adequate numbers of appropriately trained staff.

(D) Unethical conduct--Unethical conduct (as the term is defined in HSC, §161.131(11)) is conduct prohibited by the ethical standards adopted by state or national professional organizations for their respective professions or by rules established by the state licensing agency for the respective profession.

(E) Unprofessional conduct--Unprofessional conduct (as the term is defined in HSC, §161.131(12)) is conduct prohibited under rules adopted by the state licensing agency for the respective profession.

(2) Posting requirements. A facility shall prominently and conspicuously post for display in a public area that is readily visible to patients, residents, volunteers, employees, and visitors a statement of the duty to report abuse and neglect, or illegal, unethical or unprofessional conduct in accordance with HSC, §161.132(e). The statement shall be in English and in a second language appropriate to the demographic makeup of the community served and contain the number of the department's patient information and complaint line at (888) 973-0022.

(3) Reporting responsibility.

(A) Reporting abuse and neglect. A person, including an employee, volunteer, or other person associated with the facility who reasonably believes or who knows of information that would reasonably cause a person to believe that the physical or mental health or

welfare of a patient of the facility who is receiving mental health or chemical dependency services has been, is, or will be adversely affected by abuse or neglect (as those terms are defined in this subsection) by any person shall as soon as possible report the information supporting the belief to the department or to the appropriate state health care regulatory agency in accordance with HSC, §161.132(a).

(B) Reporting illegal, unprofessional, or unethical conduct. An employee of or other person associated with a facility including a health care professional, who reasonably believes or who knows of information that would reasonably cause a person to believe that the facility or an employee or health care professional associated with the facility, has, is, or will be engaged in conduct that is or might be illegal, unprofessional, or unethical and that relates to the operation of the facility or mental health or chemical dependency services provided in the facility shall as soon as possible report the information supporting the belief to the department or to the appropriate state health care regulatory agency in accordance with HSC, §161.132(b).

(4) Training requirements. A hospital that provides comprehensive medical rehabilitation, mental health or substance abuse services shall annually provide as a condition of continued licensure a minimum of eight hours of in-service training designed to assist employees and health care professionals associated with the facility in identifying patient abuse or neglect and illegal, unprofessional, or unethical conduct by or in the facility and establish a means for monitoring compliance with the requirement.

(d) Investigations. A complaint under this subsection will be investigated or referred by the department as follows:

(1) Allegations under subsection (b) of this section will be investigated in accordance with §1.205 of this title (relating to Reports and Investigations) and §1.206 of this title (relating to Completion of Investigation);

(2) Allegations under subsection (c) of this section will be investigated in accordance with §133.101 of this title (relating to Inspection and Investigation Procedures). Allegations concerning a health care professional's failure to report abuse and neglect or illegal, unprofessional, or unethical conduct will not be investigated by the department but will be referred to the individual's licensing board for appropriate disciplinary action.

(3) Allegations under both subsections (b) and (c) will be investigated in accordance with §§1.205 and 1.206 of this title except as noted in paragraph (2) of this subsection concerning a health care professional's failure to report.

(e) Submission of complaints. A complaint made under this section may be submitted in writing or verbally to the Patient Quality Care Unit, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756-3199, telephone, (888) 973-0022.

(f) Notification.

(1) For complaints under subsection (b) of this section, the department shall provide notification according to the following.

(A) The department shall notify the reporter, if known, in writing of the outcome of the complete investigation.

(B) The department shall notify the alleged victim, and his or her parent or guardian if a minor, in writing of the outcome of the completed investigation.

(2) For complaints under subsection (c) of this section, the department shall inform, in writing, the complainant who identifies themselves by name and address of the following:

(A) the receipt of the complaint;

(B) if the complainant's allegations are potential violations of this chapter warranting an investigation;

(C) whether the complaint will be investigated by the department;

(D) whether and to whom the complaint will be referred; and

(E) the findings of the complaint investigation.

(g) Department reporting and referral.

(1) Reporting health care professional to licensing board.

(A) In cases of abuse, neglect, or exploitation, as those terms are defined in subsection (b) of this section, by a licensed, certified, or registered health care professional, the department may forward a copy of the completed investigative report to the state agency which licenses, certifies or registers the health care professional. Any information which might reveal the identity of the reporter or any other patients or clients of the facility must be blacked out or deidentified.

(B) A health care professional who fails to report abuse and neglect or illegal, unprofessional, or unethical conduct as required by subsection (c)(3) of this section may be referred by the department to the individual's licensing board for appropriate disciplinary action.

(2) Sexual exploitation reporting requirements. In addition to the reporting requirements described in subsection (c)(3) of this section, a mental health services provider must report suspected sexual exploitation in accordance with Texas Civil Practice and Remedies Code, §81.006.

(3) Referral follow-up. The department shall request a report from each referral agency of the action taken by the agency six months after the referral.

(4) Referral of complaints. A complaint containing allegations which are not a violation of HSC, Chapter 241, or this chapter will not be investigated by the department but shall be referred to law enforcement agencies or other agencies, as appropriate.

§133.48. Patient Safety Program.

(a) General.

(1) Definitions.

(A) Medical error--The failure of a planned action to be completed as intended, the use of a wrong plan to achieve an aim, or the failure of an unplanned action that should have been completed, that results in an adverse event.

(B) Reportable event--A medical error or adverse event or occurrence which the hospital is required to report to the department, as set out in this section.

(C) Root cause analysis--An interdisciplinary review process for identifying the basic or contributing causal factors that underlie a variation in performance associated with an adverse event or reportable event. It focuses primarily on systems and processes, includes an analysis of underlying cause and effect, progresses from special causes in clinical processes to common causes in organizational processes, and identifies potential improvements in processes or systems.

(2) The hospital must develop, implement and maintain an effective, ongoing, organization-wide, data-driven Patient Safety Program (PSP).

(A) The governing body must ensure that the PSP reflects the complexity of the hospital's organization and services, including those services furnished under contract or arrangement, and focuses on the prevention and reduction of medical errors and adverse events.

(B) The PSP must be in writing, approved by the governing body and made available for review by the department. It must include the following components:

(i) the definition of medical errors, adverse events and reportable events;

(ii) the process for internal reporting of medical errors, adverse events and reportable events;

(iii) a list of events and occurrences which staff are required to report internally;

(iv) time frames for internal reporting of medical errors, adverse events and reportable events;

hospital policy;

- (v) consequences for failing to report events in accordance with
- (vi) mechanisms for preservation and collection of event data;
- (vii) the process for conducting root cause analysis;
- (viii) the process for communicating action plans; and
- (ix) the process for feedback to staff regarding the root cause analysis and action plan.

(3) The hospital must provide patient safety education and training to staff who have responsibilities related to the implementation, development, supervision or evaluation of the PSP. Training must include all PSP components as set out in paragraph (2)(B) of this subsection.

(4) The hospital must designate one or more individuals, or an interdisciplinary group, qualified by training or experience to be responsible for the management of the patient safety program. These responsibilities shall include:

- (A) coordinating all patient safety activities;
- (B) facilitating assessment and appropriate response to reported events;
- (C) monitoring root cause analysis and resulting action plans; and
- (D) serving as liaison among hospital departments and committees to ensure hospital-wide integration of the PSP.

(5) Within 45 days of becoming aware of a reportable event specified under subsection (b)(1)(A) of this section, the hospital must:

(A) complete a root cause analysis to examine the cause and effect of the event through an impartial process; and

(B) develop an action plan identifying the strategies that the hospital intends to employ to reduce the risk of similar events occurring in the future. The action plan must:

- (i) designate responsibility for implementation and oversight;
- (ii) specify time frames for implementation; and
- (iii) include a strategy for measuring the effectiveness of the actions taken.

(C) The hospital must make the root cause analysis and action plan available for on-site review by department representatives.

(6) The hospital shall submit the following to the department on the anniversary date of the license expiration:

(A) an annual events report in accordance with subsection (b)(1) of this section; and

(B) a best practices report in accordance with subsection (b)(2) of this section.

(b) Reporting requirements.

(1) Annual events report.

(A) On the renewal of the hospital's license, or annually based on the hospital's original licensing date, the hospital shall submit to the department a report that lists the number of occurrences at the hospital, including any outpatient facility owned or operated by the hospital, of each of the following events occurring during the preceding year:

(i) a medication error resulting in a patient's unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient;

(ii) a perinatal death unrelated to a congenital condition in an infant with a birth weight greater than 2,500 grams;

(iii) the suicide of a patient in a setting in which the patient received care 24 hours a day;

(iv) the abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant;

(v) the sexual assault of a patient during treatment or while the patient was on the premises of the hospital or facility;

(vi) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities;

(vii) a surgical procedure on the wrong patient or on the wrong body part of a patient;

(viii) a foreign object accidentally left in a patient during a procedure; and

(ix) a patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended.

(B) The hospital is not required to include any information other than the total number of occurrences of each of the events listed under subparagraph (A) of this paragraph.

(2) Best practices report.

(A) On the renewal of the hospital's license, or annually based on the hospital's original licensing date, the hospital shall submit to the department at least one report of the best practices and safety measures related to a reported event.

(B) The best practice report may be submitted on a form to be prescribed by the department, or the hospital may submit a copy of a report submitted to a patient safety organization.

(C) Hospitals may voluntarily report additional best practices and safety measures.

§133.49. Reporting Requirements.

A hospital shall submit reports to the department in accordance with the reporting requirements in Health and Safety Code, §§98.103, 98.104, and 98.1045 (relating to Reportable Infections, Alternative for Reportable Surgical Site Infections, and Reporting of Preventable Adverse Events).

Subchapter D. Voluntary Agreements.

§133.61. Hospital Patient Transfer Agreements.

(a) General provisions.

(1) Transfer agreements between hospitals are voluntary.

(2) Transfer agreements must comply with the transfer policies required under §133.44 of this title (relating to Hospital Patient Transfer Policy).

(3) The transfer agreement shall be submitted to the Department of State Health Services (department) for review to determine if the agreement meets the requirements of subsection (b) of this section.

(4) Multiple transfer agreements may be entered into by a hospital based upon the type or level of medical services available at other hospitals.

(b) Minimum requirements for hospital patient transfer agreements. Patient transfer agreements must include specific language consistent with the following requirements:

(1) §133.44(c)(1) of this title (relating to prohibiting discrimination);

(2) §133.44(c)(6)(A)-(B) of this title (relating to the transfer of patients with emergency medical conditions);

(3) §133.44(b)(8) of this title (relating to compliance with the Indigent Health Care and Treatment Act);

(4) §133.44(b)(11) of this title (relating to the patient's right to request transfer);

(5) §133.44(c)(7) of this title (relating to the physician's duties and standard of care); and

(6) §133.44(c)(9) and (10) of this title (relating to medical record and memorandum of transfer).

(c) Review of transfer agreements.

(1) In order that the department may review the transfer agreements for compliance with the minimum requirements, each party to the transfer agreement shall jointly submit the following documents to the department:

(A) a copy of the current or proposed agreement signed by each hospital's representative;

(B) the date of the adoption of the agreement; and

(C) the effective date of the agreement.

(2) The department may waive the submittal of the documents required under paragraph (1) of this subsection to avoid the repetitious submission of required documentation and approved agreements.

(3) If a governing body or a governing body's designee executes a transfer agreement and the entire text of that agreement consists of the entire text of an agreement that has been previously approved by the department, the governing body or the governing body's designee is not required to submit the later agreement for review. On the date the later agreement is fully executed and before the later agreement is implemented, the governing body or the governing body's designee must give adequate notice to the department that the later agreement has been executed.

(4) The department shall review the agreement within 30 calendar days after the department's receipt of the agreement to determine if the agreement is consistent with the requirements of this section.

(5) After the department's review of the agreement, if the department determines that the agreement is consistent with the requirements contained in this section, the department shall notify the hospital administration that the agreement has been approved.

(6) If the department determines that the agreement is not consistent with the requirements contained in this section, the department shall give notice to the hospital administration that the agreement is deficient and provide recommendations for correction.

(7) A transfer agreement will be considered in compliance if it is consistent with the rules that were in effect at the time the transfer agreement was executed and approved by the department.

(d) Appeals.

(1) If the department rejects a patient transfer agreement, the hospitals that are parties to the agreement may jointly request reconsideration of the department's decision.

(2) A hospital that is party to a rejected agreement shall appeal the rejection jointly with an appeal by other appealing parties or waive that hospital's opportunity to appeal.

(3) To initiate the appeal process, the party hospitals shall notify the department, in writing, that each party hospital requests formal reconsideration of the department's decision.

(4) The request must be received by the department within 20 calendar days from the receipt of the department's rejection notice by the hospital that submitted the proposed agreement for review and approval.

(5) Failure of the party hospitals to provide a written request for appeal shall be deemed a waiver of the opportunity for an internal reconsideration by the department, and the rejection shall become final.

(6) An internal review of a rejection shall consist of a review of the actions taken to-date concerning the rejection of the agreement.

(7) The review shall be conducted by a three member panel. The members shall be appointed by the commissioner of state health services. The panel members shall not have participated in the department's decision.

(A) The panel shall meet as necessary.

(B) The panel shall review all agreement submissions for which an appeal has been requested.

(C) The review shall be based primarily on the documentation provided with the request for an appeal, but the party requesting the appeal may appear before the panel, if they desire.

(D) The panel's decision is binding on the department and the hospital(s).

(e) Amendments to an agreement.

(1) The governing body of a hospital or governing body's designee may adopt proposed amendments to a transfer agreement which has been approved by the department. However, before the amendments are implemented, the governing body or the governing body's designee shall submit the proposed amendments to the department for review in the same manner as the agreement to be amended was submitted.

(2) The department shall review the amendments and shall approve or reject them in the same manner as provided for the review of the agreement to be amended.

(f) Complaints. Complaints alleging a violation of a transfer agreement shall be treated in the same manner as complaints alleging violations of the Act or this chapter.

§133.62. Cooperative Agreements.

(a) A cooperative agreement is an agreement among two or more hospitals for the allocation or sharing of health care equipment, facilities, personnel, or services, and may be established in accordance with Health and Safety Code (HSC), Chapter 314.

(b) For purposes of this section only, the term hospital is limited to a general or special hospital licensed under HSC, Chapter 241, or a private mental hospital licensed under HSC, Chapter 577.

(c) A hospital may negotiate and enter into cooperative agreements with other hospitals in the state if the likely benefits resulting from the agreement outweigh any disadvantages attributable to a reduction in competition that may result from the agreements. Acting through their boards of directors, a group of hospitals may conduct discussions or negotiations concerning cooperative agreements, provided that the discussions or negotiations do not involve price fixing or predatory pricing.

(d) Parties to a cooperative agreement may apply to the department for a certification of public advantage governing the cooperative agreement. The application must include the application fee in accordance with §133.26(e) of this title (relating to Fees), and a written copy of the cooperative agreement that describes the nature and scope of the cooperation in the agreement and any consideration passing to any party under the agreement. A copy of the application and copies of all additional related materials must be submitted to the attorney general and to the department at the same time.

Subchapter E. Waiver Provisions.

§133.81. Waiver Provisions.

(a) Request for a waiver. A hospital may submit a written request to the director for a waiver or modification of a particular provision of the Texas Hospital Licensing Act (Act) or a minimum standard in this chapter, except fire safety requirements. The written request shall specify the section(s) of the Act or this chapter for which a waiver is requested.

(b) Waiver request requirements. In requesting the waiver, the hospital must address each of the following points and provide documentation as necessary to support their position. The hospital must:

(1) provide evidence to support why the requested waiver will not adversely affect the health and safety of the hospital patients, employees, or the general public;

(2) indicate how it was determined that granting the waiver would not adversely impact the hospital's participation in the federal Medicare program or accreditation by a Centers for Medicare and Medicaid Services-approved organization;

(3) describe how not granting the waiver would impose an unreasonable hardship on the hospital in providing adequate care for patients;

(4) describe how the waiver would facilitate the creation or operation of the hospital; and

(5) explain why the waiver would be appropriate when balanced against the best interests of the individuals served or to be served by the hospital.

(c) Supporting documentation. The hospital should submit supporting documentation with the waiver request. The department may request additional written documentation from the hospital to support the waiver or modification.

(d) Written recommendation. The director shall submit a written recommendation for granting or denying the waiver to the commissioner of state health services (commissioner).

(e) Granting order. If the director recommends that the waiver or modification be granted, the commissioner may issue a written order granting the waiver or modification.

(f) Denial of order. If the director recommends that the waiver or modification be denied, the commissioner may issue a written order denying the waiver or modification.

(g) File documentation. The licensing file for the hospital maintained by the Department of State Health Services shall contain a copy of the request, any supporting documents which were provided, the written recommendation of the director, and the order. The hospital is to maintain the original order in their permanent records.

Subchapter F. Inspection and Investigation Procedures.

§133.101. Inspection and Investigation Procedures.

(a) Routine inspections. The Department of State Health Services (department) may conduct an inspection of each hospital prior to the issuance or renewal of a hospital license.

(1) A hospital is not subject to routine inspections subsequent to the issuance of the initial license while the hospital maintains:

(A) certification under Title XVIII of the Social Security Act, 42 United States Code (USC), §§1395 et seq; or

(B) accreditation by a Centers for Medicare and Medicaid Services-approved organization.

(2) The department may conduct an inspection of a hospital exempt from an annual licensing inspection under paragraph (1) of this subsection before issuing a renewal license to the hospital if the certification or accreditation body has not conducted an on-site inspection of the hospital in the preceding three years and the department determines that an inspection of the hospital by the certification or accreditation body is not scheduled within 90 days.

(b) Complaint investigations.

(1) Complaint investigations are conducted if the department finds that reasonable cause exists to believe that the hospital has violated provisions of the Act, this chapter, special license conditions, or orders of the commissioner of state health services (commissioner).

(2) Complaints received by the department concerning abuse and neglect, or illegal, unprofessional, or unethical conduct will be conducted in accordance with §133.47(d) of this title (relating to Abuse and Neglect Issues).

(3) Complaint investigations may be coordinated with the federal Centers for Medicare and Medicaid Services and its agents responsible for the inspection of hospitals to determine compliance with the conditions of participation under Title XVIII of the Social Security Act, (42 USC, §§1395 et seq), so as to avoid duplicate investigations.

(4) Complaint investigations are unannounced.

(5) Following the investigation of a complaint, the department shall notify the complainant if the complaint was substantiated and if regulatory violations were identified.

(c) Reinspection.

(1) Reinspections may be conducted by the department if a hospital applies for the reissuance of its license after the suspension or revocation of the hospital's license, the assessment of administrative or civil penalties, or the issuance of an injunction against the hospital for violations of the Act, this chapter, a special license condition, or an order of the commissioner.

(2) A reinspection may be conducted to ascertain compliance with either health or construction requirements or both.

(d) General.

(1) The department may make any inspection, survey, or investigation that it considers necessary. A representative of the department may enter the premises of a hospital at any reasonable time to make an inspection or an investigation to ensure compliance with or prevent a violation of the Act, the rules adopted under the Act, an order or special order of the commissioner, a special license provision, a court order granting injunctive relief, or other enforcement procedures. Ensuring compliance includes permitting photocopying of any records or other information by or on behalf of the department as necessary to determine or verify compliance with the statute or rules adopted under the statute, except that the department may not photocopy, reproduce, remove or dictate from any part of the root cause analysis or action plan required under §133.48 of this title (relating to Patient Safety Program).

(2) The department or a representative of the department is entitled to access to all books, records, or other documents maintained by or on behalf of the hospital to the extent necessary to enforce the Act, this chapter, an order or special order of the commissioner, a special license provision, a court order granting injunctive relief, or other enforcement procedures. The department shall maintain the confidentiality of hospital records as applicable under federal or state law.

(3) By applying for or holding a hospital license, the hospital consents to entry and inspection or investigation of the hospital by the department or a representative of the department in accordance with the Act and this chapter.

(e) Inspection and investigation protocol.

(1) The department surveyor(s) shall hold a conference with the hospital administrator or designee before beginning the on-site inspection or investigation to explain the nature, scope, and estimated time schedule of the inspection or investigation.

(2) Department surveyor(s) may conduct interviews with any person with knowledge of the facts.

(3) The department surveyor(s) shall inform the hospital administrator or designee of the preliminary findings of the inspection or investigation and shall give the person a reasonable opportunity to submit additional facts or other information to the department's authorized representative in response to those findings.

(4) Following an inspection or investigation of a hospital by the department, the department surveyor(s) shall hold an exit conference with the hospital administrator or designee and other invited staff and provide the following to the hospital administrator or designee:

(A) the specific nature of the inspection or investigation;

- (B) any alleged violations of a specific statute or rule;
- (C) identity of any records that were duplicated;
- (D) the specific nature of any finding regarding an alleged violation or deficiency;
- (E) if the deficiency is alleged, the severity of the deficiency; and
- (F) if there are no deficiencies found, a statement indicating this fact.

(5) If deficiencies are cited, the department surveyor(s) shall obtain either at the time of the exit conference or within 10 days of the hospital's receipt of the statement of deficiencies a plan of correction which is provided by the hospital and indicates the date(s) by which correction(s) will be made and any other written comments, if any, by the hospital administrator or designee concerning the inspection or investigation. Additional facts, written comments, or other information provided by the hospital in response to the findings shall be made a part of the record of the inspection or investigation for all purposes.

(6) The department surveyor(s) shall obtain the signature of the hospital administrator or designee acknowledging the receipt of the statement of deficiencies and plan of correction form.

(7) The department surveyor(s) shall inform the administrator or designee of the hospital's right to an informal administrative review when there is disagreement with the surveyor's findings and recommendations or when additional information bearing on the findings is available.

(8) If deficiencies are cited and the plan of correction is not acceptable, the department shall notify the hospital in writing and request that the plan of correction be resubmitted within 10 calendar days of the hospital's receipt of the department's written notice. Upon resubmission of an acceptable plan of correction, written notice shall be sent by the department to the hospital acknowledging same.

(9) Responses to the department may be submitted by facsimile.

(10) The hospital shall come into compliance by the completion date provided on the statement of deficiencies and plan of correction form.

(11) The department shall verify the correction of deficiencies either by mail or by an on-site inspection or investigation.

(12) Acceptance of a plan of correction does not preclude the department from taking enforcement action under §133.121 of this title (relating to Enforcement Action).

(f) Release of information by the department.

(1) Upon written request, the department shall provide information on the identity, including the signature, of each department representative conducting, reviewing, or approving the results of the inspection or investigation, and the date on which the department representative acted on the matter.

(2) Upon written request, the department shall release inspection documents in accordance with state and federal law.

§133.102. Complaint Against a Department of State Health Services Surveyor.

(a) A hospital may register a complaint against a Department of State Health Services surveyor who conducts an inspection or investigation in accordance with §133.101 of this title (relating to Inspection and Investigation Procedures).

(b) A complaint against a surveyor shall be registered with the Patient Quality Care Unit, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756-3199, telephone (512) 834-6650 or (888) 973-0022.

(1) A complaint against a surveyor which is received by telephone will be referred within two working days to the appropriate supervisor. The caller will be requested to submit the complaint in writing.

(2) When a complaint is received in writing, it will be forwarded to the appropriate supervisor within two working days. Within 10 calendar days of receipt of the complaint, the department will inform the complainant in writing that the complaint has been forwarded to the appropriate supervisor.

(3) Within 10 calendar days of the supervisor's receipt of the complaint, the supervisor will notify the complainant in writing that an investigation will be done.

(4) The supervisor will review the documentation in the survey packet and interview the surveyor identified in the complaint to obtain facts and assess the objectivity of the surveyor in the surveyor's application of this chapter during the hospital's inspection or investigation.

(5) The supervisor will review the applicable rules, personnel policies, and review the training and qualifications of the surveyor as it relates to the inspection or investigation.

(6) The supervisor will document the investigation. A report of the investigation will be placed in the hospital's file if the complaint and investigation affected the inspection process. A counseling form will be used and placed in the surveyor's personnel file if the complaint relates to personnel performance.

(7) The supervisor shall offer to meet with the complainant to resolve the issue. The surveyor identified in the complaint will participate in the discussion. The resolution meeting may be conducted at the division's office or during an on-site follow-up visit to the hospital.

(8) Changes and deletions will be made to the inspection report, if necessary.

(9) The supervisor will notify the complainant in writing of the status of the investigation within 30 calendar days of the date the supervisor received the complaint.

(10) The supervisor will forward all final documentation to the director of the Patient Quality Care Unit and notify the complainant of the results.

Subchapter G. Enforcement.

§133.121. Enforcement Action.

Enforcement action may be taken for the following reasons.

(1) Denial, suspension or revocation of a license or imposition of an administrative penalty. The department has jurisdiction to enforce violations of the Act or the rules adopted under this chapter. The department may deny, suspend, or revoke a license or impose an administrative penalty if the licensee or applicant:

(A) fails to comply with any provision of Health and Safety Code (HSC), Chapters 241 or 311;

(B) fails to comply with any provision of this chapter (25 Texas Administrative Code, Chapter 133);

(C) fails to comply with a special license condition;

(D) fails to comply with an order of the department or another enforcement procedure under HSC, Chapters 241 or 311;

(E) has a history of failure to comply with the rules adopted under this chapter relating to patient environment, health, safety, and rights;

(F) has aided, abetted or permitted the commission of an illegal act;

(G) has committed fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to the department or required to be maintained by the facility pursuant to the provisions of this chapter;

(H) fails to pay administrative penalties in accordance with HSC, Chapter 241;

(I) fails to implement plans of corrections to deficiencies cited by the department; or

(J) fails to comply with applicable requirements within a designated probation period.

(2) Denial of a license. The department has jurisdiction to enforce violations of the HSC, Chapters 241 and 311 and this chapter. The department may deny a license if the applicant:

(A) fails to provide timely and sufficient information required by the department that is directly related to the application;

(B) has had the following actions taken against the applicant within the two-year period preceding the application:

(i) decertification or cancellation of its contract under the Medicare or Medicaid program in any state;

(ii) federal Medicare or state Medicaid sanctions or penalties;

(iii) unsatisfied federal or state tax liens;

(iv) unsatisfied final judgments;

(v) eviction involving any property or space used as a hospital in any state;

(vi) unresolved state Medicaid or federal Medicare audit exceptions;

(vii) denial, suspension, or revocation of a hospital license, a private psychiatric hospital license, or a license for any health care facility in any state; or

(viii) a court injunction prohibiting ownership or operation of a facility.

(3) Emergency suspension. Following notice and opportunity for hearing, the commissioner of the department of state health services (commissioner) or a person designated by the commissioner may issue an emergency order in relation to the operation of a hospital licensed under this chapter if the commissioner or the commissioner's designee determines that the hospital is violating this chapter, a rule adopted pursuant to this chapter, a special license provision, injunctive relief, an order of the commissioner or the commissioner's designee, or another enforcement procedure permitted under this chapter and the provision, rule, license provision, injunctive relief, order, or enforcement procedure relates to the health or safety of the hospital's patients.

(A) The department shall send written notice of the hearing and shall include within the notice the time and place of the hearing. The hearing must be held within 10 days after the date of the hospital's receipt of the notice.

(B) The hearing shall be held in accordance with the department's informal hearing rules.

(C) The order shall be effective on delivery to the hospital or at a later date specified in the order.

(4) Probation. In lieu of suspending or revoking the license, the department may schedule the facility for a probation period of not less than 30 days if the facility is found in repeated noncompliance with these rules or HSC, Chapter 241, and the facility's noncompliance does not endanger the health and safety of the public.

(5) Administrative penalty. The department has jurisdiction to impose an administrative penalty against a facility licensed or regulated under this chapter for violations of the HSC, Chapters 241 and 311 and this chapter. The imposition of an administrative penalty shall be in accordance with the provisions of the HSC, §241.059 and §241.060.

(6) Licensure of persons or entities with criminal backgrounds. The department may deny a person or entity a license or suspend or revoke an existing license on the grounds that the person or entity has been convicted of a felony or misdemeanor that directly relates to the duties and responsibilities of the ownership or operation of a facility. The department shall apply the requirements of the Occupations Code, Chapter 53.

(A) The department is entitled to obtain criminal history information maintained by the Texas Department of Public Safety (Government Code, §411.122), the Federal Bureau of Investigation (Government Code, §411.087) or any other law enforcement agency to investigate the eligibility of an applicant for an initial or renewal license and to investigate the continued eligibility of a licensee.

(B) In determining whether a criminal conviction directly relates, the department shall consider the provisions of Occupations Code, §53.022 and §53.023.

(C) The following felonies and misdemeanors directly relate because these criminal offenses indicate an inability or a tendency for the person to be unable to own or operate a facility:

(i) a misdemeanor violation of HSC, Chapter 241;

(ii) a misdemeanor or felony involving moral turpitude;

(iii) a misdemeanor or felony relating to deceptive business practices;

(iv) a misdemeanor or felony of practicing any health-related profession without a required license;

(v) a misdemeanor or felony under any federal or state law relating to drugs, dangerous drugs, or controlled substances;

(vi) a misdemeanor or felony under the Texas Penal Code (TPC), Title 5, involving a patient or a client of any health care facility, a home and community support services agency or a health care professional;

(vii) a misdemeanor or felony under the TPC:

(I) Title 4 - offenses of attempting or conspiring to commit any of the offenses in this clause;

(II) Title 5 - offenses against the person;

(III) Title 7 - offenses against property;

(IV) Title 8 - offenses against public administration;

(V) Title 9 - offenses against public order and decency;

(VI) Title 10 - offenses against public health, safety and morals; or

(VII) Title 11 - offenses involving organized crime.

(viii) Offenses listed in subparagraph (C) of this paragraph are not exclusive in that the department may consider similar criminal convictions from other state, federal, foreign or military jurisdictions that demonstrate the inability of the person or entity to own or operate a facility.

(ix) A license shall be revoked on the licensee's imprisonment following a felony conviction, felony community supervision revocation, revocation of parole, or revocation of mandatory supervision.

(7) Notice. If the department proposes to deny, suspend or revoke a license, or impose an administrative penalty, the department shall send a notice of the proposed action by certified mail, return receipt requested, at the address shown in the current records of the department or the department may personally deliver the notice. The notice to deny, suspend, or revoke a license, or impose an administrative penalty, shall state the alleged facts or conduct to warrant the proposed action, provide an opportunity to demonstrate or achieve compliance, and shall state that the applicant or license holder has an opportunity for a hearing before imposition of the action.

(8) Acceptance. Within 20 days after receipt of the notice, the applicant or licensee may notify the department, in writing, of acceptance of the department's determination or request a hearing.

(9) Hearing request.

(A) A request for a hearing by the applicant or licensee shall be in writing and submitted to the department within 20 calendar days of receipt of the notice. Receipt of the notice is presumed to occur on the 30th day after the date the notice is mailed by the department to the last address known of the applicant or licensee.

(B) A hearing shall be conducted pursuant to the Administrative Procedure Act, Government Code, Chapter 2001.

(10) No response to notice. If the applicant or licensee fails to timely respond to the notice or does not request a hearing in writing within 30 days after the date of the notice, the case shall be set for a hearing.

(11) Notification of department's final decision. The department shall send the licensee or applicant a copy of the department's decision for denial, suspension or revocation of license or imposition of an administrative penalty by registered mail, which shall include the findings of fact and conclusions of law on which the department based its decision.

(12) Decision to suspend or revoke. When the department's decision to suspend or revoke a license is final, the licensee must immediately cease operation, unless a stay of such action is issued by the district court.

(13) Return of original license. Upon suspension, revocation or non-renewal of the license, the original license shall be returned to the department upon the effective date of the department's determination.

(14) Reapplication following denial or revocation.

(A) After the department's decision to deny or revoke, or the voluntary surrender of a license by a facility while enforcement action is pending, a facility may petition the department, in writing, for a license.

(B) The department may allow a reapplication for licensure if there is proof that the reasons for the original action no longer exist.

(C) The department may deny reapplication for licensure if the department determines that:

(i) the reasons for the original action continues;

(ii) the petitioner has failed to offer sufficient proof that conditions have changed; or

(iii) the petitioner has demonstrated a repeated history of failure to provide patients a safe environment or has violated patient rights.

(D) If the department allows a reapplication for licensure, the petitioner shall be required to meet the requirements as described in §133.22 of this title (relating to Application and Issuance of Initial License).

(15) Expiration of a license during suspension. A facility whose license expires during a suspension period may not reapply for license renewal until the end of the suspension period.

(16) Surrender of a license. In the event that enforcement, as defined in this subsection, is pending or reasonably imminent, the surrender of a facility license shall not deprive the department of jurisdiction in regard to enforcement against the facility.

Subchapter H. Fire Prevention and Safety Requirements.

§133.141. Fire Prevention and Protection.

(a) Fire inspections.

(1) Annual inspection. Approval of the fire protection of a hospital by the local fire department shall be a prerequisite for licensure.

(2) Purpose of inspection. The purpose of these inspections shall be to ascertain and to cause to be corrected any conditions liable to cause fire or violations of any of the provisions or intent of these rules, or of any other applicable ordinances, which affect fire safety in any way.

(3) Hazardous or dangerous conditions or materials. Whenever any of the officers, members, or inspectors of the fire department or bureau of fire prevention find in any building or upon any premises dangerous or hazardous conditions or materials, removal or remedy of dangerous conditions or materials shall be carried out in a manner specified by the head of the local fire department.

(4) Access for inspection. At all reasonable hours, the chief of the fire department, the chief of the bureau of fire prevention, or any of the fire inspectors may enter any building or premises for the purpose of making an inspection or investigation which may be deemed necessary under the provisions of these rules.

(b) Fire reporting. All occurrences of fire shall be reported to the local fire authority and shall be reported in writing to the hospital licensing director as soon as possible but not later than 10 calendar days following the occurrence.

(c) Fire protection. Fire protection shall be provided in accordance with the requirements of National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), §18.7, and §133.161(a)(1) of this title (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located), and §133.162(a)(1) and (d) of this title (relating to New Construction Requirements). When required or installed, sprinkler systems for exterior fire exposures shall comply with National Fire Protection Association 80A, Recommended Practice

for Protection of Buildings from Exterior Fire Exposures, 2001 edition. All documents published by NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, Post Office Box 9101, Quincy, MA 02269-9101 or (800) 344-3555.

(d) Smoking rules. Each hospital shall adopt, implement and enforce a smoking policy. The policy shall include the minimal provisions of NFPA 101, §18.7.4.

(e) Fire extinguishing systems. Inspection, testing, and maintenance of fire-fighting equipment shall be conducted by each hospital.

(1) Water-based fire protection systems. All fire sprinkler systems, fire pumps, fire standpipe and hose systems, water storage tanks, and valves and fire department connections shall be inspected, tested and maintained in accordance with National Fire Protection Association 25, Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems, 2002 edition.

(2) Range hood extinguishers. Fire extinguishing systems for commercial cooking equipment, such as at range hoods, shall be inspected and maintained in accordance with National Fire Protection Association 96, Standard for Ventilation Control and Fire Protection of Cooking Operations, 2001 edition.

(3) Portable fire extinguishers. Every portable fire extinguisher located in a hospital or upon hospital property shall be installed, tagged, and maintained in accordance with National Fire Protection Association 10, Standard for Portable Fire Extinguishers, 2002 edition.

(f) Fire protection and evacuation plan. A plan for the protection of patients in the event of fire and their evacuation from the building when necessary shall be formulated according to NFPA 101, §18.7. Copies of the plan shall be available to all staff.

(1) Posting requirements. An evacuation floor plan shall be prominently and conspicuously posted for display throughout the hospital in public areas that are readily visible to patients, residents, employees, and visitors.

(2) Annual training. Each hospital shall conduct an annual training program for instruction of all personnel in the location and use of fire-fighting equipment. All employees shall be instructed regarding their duties under the fire protection and evacuation plan.

(g) Fire drills. The hospital shall conduct at least 12 fire drills each year, one fire drill per shift per quarter, which shall include communication of alarms, simulation of evacuation of patients and other occupants, and use of fire-fighting equipment.

(h) Fire alarm system. Every hospital and building used for patient care shall have an approved fire alarm system. Each fire alarm system shall be installed and tested in accordance with §133.161(a)(1)(A) of this title for existing hospitals, and §133.162(d)(5)(N) of this title for new construction.

(i) System for communicating an alarm of fire. A reliable communication system shall be provided as a means of reporting a fire to the fire department. This is in addition to the automatic alarm transmission to the fire department required by NFPA 101, §18.3.4.3.2.

(j) Fire department access. As an aid to fire department services, every hospital shall provide the following.

(1) Driveways. The hospital shall maintain driveways, free from all obstructions, to main buildings for fire department apparatus use.

(2) Submission of plans. Upon request, the hospital shall submit a copy of the floor plans of the building to the local fire department officials.

(3) Outside identification. The hospital shall place proper identification on the outside of the main building showing the locations of siamese connections and standpipes as required by the local fire department services.

(k) Fire department protection. When a hospital is located outside of the service area or range of the public fire protection, arrangements shall be made to have the nearest fire department respond in case of a fire.

§133.142. General Safety.

(a) Safety committee. Each hospital shall have a multidisciplinary safety committee. The hospital chief executive officer (CEO) shall appoint the chairman and members of the safety committee.

(1) Safety officer. The CEO shall appoint a safety officer who is knowledgeable in safety practices in health care facilities. The safety officer shall be a member of the safety committee, and shall carry out the functions of the safety program.

(2) Safety committee meetings. The safety committee shall meet as required by the chairman, but not less than quarterly. Written minutes of each meeting shall be retained for at least one year.

(3) Safety activities.

(A) Incident reports. The safety committee shall establish an incident reporting system which includes a mechanism to ensure that all incidents recorded in safety committee minutes are evaluated, and documentation is provided to show follow-up and corrective actions.

(B) Safety policies and procedures. Safety policies and procedures for each department or service shall be developed, implemented and enforced.

(C) Safety training and continuing education. Safety training shall be established as part of new employee orientation and in the continuing education of all employees.

(4) Written authority. The authority of the safety committee to take action when conditions exist that are a possible threat to life, health, or building damage, shall be defined in writing and approved by the governing body.

(b) Safety manual. Each department or service shall have a safety policy and procedure manual within their own area that becomes a part of the overall facility safety manual.

(c) Emergency communication system. An emergency communication system shall be provided in each facility. The system shall be self-sufficient and capable of operating without reliance on the building's service or emergency power supply. Such system shall have the capability of communicating with the available community or state emergency networks, including police and fire departments.

§133.143. Handling and Storage of Gases, Anesthetics, and Flammable Liquids.

(a) Flammable germicides. If flammable germicides, including alcohol-based products, are used for preoperative surgical skin preparation, the facility must:

(1) use only self-contained, single-use, pre-measured applicators to apply the surgical skin preparations;

(2) follow all manufacturer product safety warnings and guidelines;

(3) develop, implement and enforce written policies and procedures outlining the safety precautions required related to the use of the products, which, at a minimum, must include minimum drying times, prevention and management of product pooling, parameters related to draping and the use of ignition sources, staff responsibilities related to ensuring safe use of the product, and documentation requirements sufficient to evaluate compliance with the written policies and procedures;

(4) ensure that all staff working in the surgical environment where flammable surgical skin preparation products are in use have received training on product safety and the facility policies and procedures related to the use of the product;

(5) develop, implement and enforce an interdisciplinary team process for the investigation and analysis of all surgical suite fires and alleged violations of the policies; and

(6) report all occurrences of surgical suite fires to the department in care of the Facility Licensing Group within two business days, and complete an investigation of the occurrence and develop and implement a corrective action plan within 30 days.

(b) Flammable and nonflammable gases and liquids. Flammability of liquids and gases shall be determined by National Fire Protection Association 329, Handling Releases of

Flammable and Combustible Liquids and Gases, 1999 edition. All documents published by National Fire Protection Association (NFPA) as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101 or (800) 344-3555.

(1) Nonflammable gases (examples include, but are not limited to, oxygen and nitrous oxide) shall be stored and distributed in accordance with Chapter 5 of the National Fire Protection Association 99, Standard for Health Care Facilities, 2002 edition (NFPA 99).

(A) Medical gases and liquefied medical gases shall be handled in accordance with the requirements of NFPA 99, Chapter 9.

(B) Oxygen shall be administered in accordance with NFPA 99, §9.6.

(2) Piped flammable gas systems intended for use in laboratories and piping systems for fuel gases shall comply with requirements of NFPA 99, §11.11.

(3) Flammable gases shall be stored in accordance with NFPA 99, §11.10.

(4) Flammable and combustible liquids used in laboratories shall be handled and stored in accordance with NFPA 99, §11.7, and National Fire Protection Association 101, Life Safety Code, 2003 edition, §18.3.2.2.

(5) Other flammable agents shall be stored in accordance with NFPA 99, Chapter 7.

(c) Gasoline and gasoline powered equipment. No motor vehicles including gasoline powered standby generators or any amount of gasoline shall be located within the hospital building. Other devices which may cause or communicate fire, and which are not necessary for patient treatment or care, shall not be stored within the hospital building. All such devices and materials when necessary shall be used within the building only with precautions ensuring a reasonable degree of safety from fire.

(d) Gas fired appliances. The installation, use and maintenance of gas fired appliances and gas piping installations shall comply with the National Fire Protection Association 54, National Fuel Gas Code, 2002 edition. The use of portable gas heaters and unvented open flame heaters is specifically prohibited.

Subchapter I. Physical Plant and Construction Requirements.

§133.161. Requirements for Buildings in Which Existing Licensed Hospitals Are Located.

(a) Compliance. All buildings in which existing hospitals licensed by the Department of State Health Services (department) are located shall comply with this subsection.

(1) Minimum fire safety and construction requirements.

(A) Existing licensed hospitals shall meet the requirements for health care occupancies contained in the 1967, 1973, 1981, 1985, 1991, 1997, 2000, or 2003 editions of the National Fire Protection Association 101, Life Safety Code, (NFPA 101), the Hospital Licensing Standards/Rules (1969, 1985, or 1998 editions as amended), and the hospital licensing rules under which the buildings or sections of buildings were constructed. All documents published by NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101 or (800) 344-3555.

(B) Existing hospitals or portions of existing hospitals constructed prior to the adoption of any of the editions of NFPA 101, the Hospital Licensing Standards, and the hospital licensing rules listed in subparagraph (A) of this paragraph, shall comply with this section and Chapter 19, NFPA 101, 2003 edition.

(C) Compliance with the requirements of Chapter 4 of the National Fire Protection Association 101A, Alternative Approaches to Life Safety, 2001 edition, (relating to Fire Safety Evaluation System for Health Care Occupancies) will be acceptable in lieu of complying with the requirements of Chapter 19, NFPA 101, 2003 edition.

(2) Remodeling of existing facilities. All requirements listed in this chapter relating to new construction are applicable to renovations, additions and alterations unless stated otherwise.

(A) Alteration or installation of new equipment. Any alteration or any installation of new equipment shall be accomplished as nearly as practicable with the requirements for new construction, except that when existing conditions make changes impractical to accomplish, minor deviations from functional requirements may be permitted if the intent of the requirements is met and if the care and safety of patients will not be jeopardized.

(B) Installation, alteration, or extension approval. No new system of mechanical, electrical, plumbing, fire protection, or piped medical gas system may be installed or any such existing system may be replaced, materially altered or extended in an existing building licensed as a hospital, until complete plans and specifications for the replacement, installation, alteration, or extension have been submitted to the department, reviewed and approved in accordance with §133.167 of this title (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records).

(C) Minor remodeling or alterations. All remodeling or alterations which do not involve alterations to load bearing members or partitions, change functional operation, affect fire safety (e.g. modifications to the fire, smoke, and corridor walls), add or subtract beds or services for which the hospital is licensed, and do not involve changes listed in subparagraph (B) of this paragraph, shall be submitted for approval without submitting contract documents. Such approval shall be requested in writing with a brief description of the proposed changes in accordance with §133.167(f)(3) of this title.

(D) Major remodeling or alterations. Plans shall be submitted in accordance with §133.167 of this title for all major remodeling or alterations. All remodeling or alterations which involve alterations to load bearing members or partitions, change functional operation, affect fire safety (e.g. modifications to the fire, smoke, and corridor walls), or add beds or services over those for which the hospital is licensed are considered as major remodeling and alterations.

(E) Phasing of construction in existing facilities.

(i) Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction will minimize disruptions of existing functions.

(ii) Access, exit access, and fire protection shall be maintained so that the safety of the occupants will not be jeopardized during construction.

(iii) A noncombustible or limited combustible dust and vapor barrier shall be provided to separate areas undergoing demolition and construction from occupied areas. When a fire retardant plastic material is used for temporary daily usage, it shall be removed at the end of each day.

(iv) The air inside the construction area shall be protected by mechanical filtration that recirculates inside the space or is exhausted directly to the exterior.

(v) The area shall be properly ventilated and maintained. The area under construction shall have a negative air pressure differential to the adjoining areas and shall continue to operate as long as construction dust and odors are present.

(vi) Temporary sound barriers shall be provided where intense prolonged construction noises will disturb patients or staff in the occupied portions of the building.

(F) Nonconforming conditions. When doing renovation work, if it is found to be infeasible to correct all of the nonconforming conditions in the existing hospital in accordance with these rules, a conditional approval may be granted by the department if the operation of the hospital, necessary access by the handicapped, and safety of the patients are not jeopardized by the nonconforming condition.

(b) Previously licensed hospitals. Buildings which have been licensed previously as hospitals but have been vacated or used for purposes other than as hospitals and which are not in compliance with the 1967, 1973, 1981, 1985, 1991, 1997, 2000, or 2003 editions of the NFPA 101, the Hospital Licensing Standards/Rules (1969, 1985, or 1998 editions as amended), and hospital licensing rules under which the building or sections of buildings were constructed shall comply with the requirements of §133.162 of this title (relating to New Construction Requirements), §133.163 of this title (relating to Spatial Requirements for New Construction), §133.165 of this title (relating to Building with Multiple Occupancies), §133.167 of this title, and §133.168 of this title (relating to Construction, Inspections, and Approval of Project).

§133.162. New Construction Requirements.

(a) Hospital location. Any proposed new hospital shall be easily accessible to the community and to service vehicles such as delivery trucks, ambulances, and fire protection apparatus. No building may be converted for use as a hospital which, because of its location, physical condition, state of repair, or arrangement of facilities, would be hazardous to the health and safety of the patients.

(1) Hazardous locations.

(A) Underground and above ground hazards. New hospitals or additions to existing hospitals shall not be constructed within 150 feet of easement boundaries or setbacks of hazardous underground locations including but not limited to liquid butane or propane, liquid petroleum or natural gas transmission lines, high pressure lines, and not within the easement of high voltage electrical lines.

(B) Fire hazards. New hospitals and additions to existing hospitals shall not be built within 300 feet of above ground or underground storage tanks containing liquid petroleum or other flammable liquids used in connection with a bulk plant, marine terminal, aircraft refueling, bottling plant of a liquefied petroleum gas installation, or near other hazardous or hazard producing plants.

(2) Undesirable locations.

(A) Nuisance producing sites. New hospitals shall not be located near nuisance producing industrial sites, feed lots, sanitary landfills, or manufacturing plants producing excessive noise or air pollution.

(B) Cemeteries. New hospitals shall not be located near a cemetery in a manner that allows direct view of the cemetery from patient windows.

(C) Flood plains.

(i) New construction. Construction of a new hospital is prohibited in a designated 100-year flood plain.

(ii) Previously licensed hospital. An existing building or a portion of an existing building located in a designated 100-year flood plain which was previously licensed as a hospital but has been vacated or used for purposes other than a hospital, will not be licensed as a hospital.

(iii) Existing hospital. Access and required functional hospital components shall be constructed above the designated flood plain in a new addition to an existing hospital located in a designated 100-year flood plain.

(D) Airports. Construction of new hospitals shall be avoided in close proximity to airports. When hospitals are proposed to be located near airports, recommendations of the Texas Aviation Authority and the Federal Aviation Authority shall apply. A hospital may not be constructed within a rectangular area formed by lines perpendicular to and two miles (10,560 feet) from each end of any runway and by lines parallel to and one-half mile (2,640 feet) from each side of any runway.

(b) Environmental considerations. Development of a hospital site and hospital construction shall be governed by state and local regulations and requirements with respect to the effect of noise and traffic on the community and the environmental impact on air and water.

(c) Hospital site.

(1) Paved roads and walkways. Paved roads shall be provided within the lot lines to provide access from public roads to the main entrance, emergency entrance, entrances serving community activities, and to service entrances, including loading and unloading docks for delivery trucks.

(A) Emergency entrance. Hospitals having an organized emergency services department shall have the emergency entrance well-marked to facilitate entry from the public roads or streets serving the site.

(B) Access to emergency department. Access to the emergency entrance shall not conflict with other vehicular traffic or pedestrian traffic and shall be located so as not to be compromised by floods.

(C) Pedestrian traffic. Finished surface walkways shall be provided for pedestrians.

(2) Parking. Off-street parking shall be available for visitors, employees, and staff. Parking structures directly accessible from a hospital shall be separated with two-hour fire rated noncombustible construction. When used as required means of egress for hospital occupants, parking structures shall comply with National Fire Protection Association 88A, Standard for Parking Structures, 2002 edition. This requirement does not apply to freestanding parking structures. All documents published by National Fire Protection Association (NFPA) as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101 or (800) 344-3555.

(A) Number of parking places. In the absence of a formal parking study, one parking space shall be provided for each day shift employee plus one space for each patient bed. This ratio may be reduced in an area convenient to a public transportation system or to public parking facilities on the basis of a formal parking study. Parking facilities shall be increased accordingly when the size of existing facilities is increased.

(B) Additional parking. Additional parking shall be required to accommodate medical staff, outpatient and other services when such services are provided.

(C) Emergency and delivery parking. Separate parking facilities shall be provided for ambulances and delivery vehicles.

(d) Building design and construction requirements. Every building and every portion thereof shall be designed and constructed to sustain all dead and live loads in accordance with accepted engineering practices and standards and the local governing building codes. Where there is no local governing building code, the hospital shall be constructed in accordance with the International Building Code, 2003 edition, published by the International Code Council, 5203 Leesburg Pike, Falls Church, VA 22041, telephone (800) 786-4452.

(1) General architectural requirements. All new construction, including conversion of an existing building to a hospital, and establishing a separately licensed hospital in a building with an existing licensed hospital, shall comply with Chapter 18 of the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), and Subchapters H and I of this chapter (relating to Fire Prevention and Safety Requirements, and Physical Plant and Construction Requirements, respectively). Construction documents shall be submitted to the department in accordance with §133.167 of this title (relating to Preparation, Submittal, Review and Approval of Plans, and Retention of Records).

(A) Physical environment. A physical environment that protects the health and safety of patients, personnel, and the public shall be provided in each hospital. The physical premises of the hospital and those areas of the hospital's physical structure that are used by the patients (including all stairwells, corridors, and passageways) shall meet the local building and fire safety codes and Subchapters H and I of this chapter.

(B) Construction type. A hospital may occupy an entire building or a portion of a building, provided the hospital portion of the building is separated from the rest of the building in accordance with subparagraph (C) of this paragraph and the entire building or the hospital portion of the building complies with new construction requirements (type of construction permitted for hospitals by NFPA 101, §18.1.6.2), and the entire building is protected with a fire sprinkler system conforming with requirements of National Fire Protection Association 13, Standard for the Installation of Sprinkler Systems, 2002 Edition (NFPA 13).

(C) Separate buildings. Portions of a building divided horizontally with two-hour fire rated walls which are continuous (without offsets) from the foundation to above the roof shall be considered as a separate building. Communicating openings in the two-hour wall shall be limited to public spaces such as lobbies and corridors. All such openings shall be protected with self-closing one and one-half hour, Class B fire door assemblies.

(D) Design for the handicapped. Special considerations benefiting handicapped staff, visitors, and patients shall be provided. Each hospital shall comply with the Americans with Disabilities Act (ADA) of 1990, Public Law 101-336, 42 United States Code, Chapter 126, and Title 36 Code of Federal Regulations, Part 1191, Appendix A, Accessibility Guidelines for Buildings and Facilities, or Title 16 TAC, Chapter 68, Texas Accessibility Standards (TAS), April 1, 1994 edition, issued by the Texas Department of Licensing and Regulation, under the Texas Architectural Barriers Act, Texas Government Code, Chapter 469.

(E) Patient safety. In developing construction documents for submission to the department in accordance with §133.167 of this title, the owner shall comply with the requirements of Health and Safety Code, Chapter 256, Safe Patient Handling and Movement Practices. Section 256.002(b)(8) requires a hospital's governing body to consider the feasibility of incorporating patient handling equipment or the physical space and construction design needed to incorporate that equipment at a later date.

(F) Other regulations. The more stringent standard, code or requirement shall apply when a difference in requirements for construction exists.

(G) Exceeding minimum requirements. Nothing in this subchapter shall be construed to prohibit a better type of building construction, more exits, or otherwise safer conditions than the minimum requirements specified in this subchapter.

(H) Equivalency. Nothing in this subchapter is intended to prevent the use of systems, methods, or devices of equivalent or superior quality, strength, fire resistance, effectiveness, durability, and safety to those prescribed by this subchapter, providing technical documentation which demonstrates equivalency is submitted to the department for approval.

(I) Freestanding buildings (not for patient use). Separate freestanding buildings for nonpatient use such as the heating plant, boiler plant, laundry, repair workshops, or general storage may be of unprotected noncombustible construction, protected noncombustible construction, or fire-resistive construction and be designed in accordance with other occupancy classifications requirements listed in NFPA 101.

(J) Freestanding buildings (for patient use other than sleeping). Buildings containing areas for patient use which do not contain patient sleeping areas and in which care or treatment is rendered to ambulatory inpatients who are capable of judgment and appropriate physical action for self-preservation under emergency conditions, may be classified as business or ambulatory care occupancies as listed in NFPA 101, Chapters 20 and 38, respectively, instead of hospital occupancy.

(K) Energy conservation. In new construction and in major alterations and additions to existing buildings and in new buildings, electrical and mechanical components shall be selected for efficient utilization of energy. Hospital construction shall be in accordance with the provisions of the Texas Building Energy Performance Standards, Health and Safety Code, Chapter 388.

(L) Heliports. Heliports located on hospital buildings or land used or intended to be used for landing and take off of helicopters shall comply with National Fire Protection Association 418, Standard for Heliports, and 2001 edition.

(2) General detail and finish requirements. Details and finishes in new construction projects, including additions and alterations, shall be in compliance with this paragraph, with NFPA 101, Chapter 18, with local building codes, and with any specific detail

and finish requirements for the particular unit as contained in §133.163 of this title (relating to Spatial Requirements for New Construction).

(A) General detail requirements.

(i) Fire safety. Fire safety features, including compartmentation, means of egress, automatic extinguishing systems, inspections, smoking regulations, and other details relating to fire prevention and fire protection shall comply with §133.161 of this title (relating to Requirements for Buildings in Which Existing Licensed Hospitals Are Located), and NFPA 101, Chapter 18 requirements for hospitals. The Fire Safety Evaluation System for Health Care Occupancies contained in the National Fire Protection Association 101A, Alternative Approaches to Life Safety, 2001 edition, Chapter 3, shall not be used in new building construction, renovations or additions to existing hospitals.

(ii) Access to exits. Corridors providing access to all patient, diagnostic, treatment, and sleeping rooms and exits shall be at least eight feet in clear and unobstructed width (except as allowed by NFPA 101, §18.2.3.4, Exceptions 1 and 2), not less than seven feet six inches in height, and constructed in accordance with requirements listed in NFPA 101, §18.3.6.

(iii) Corridors in other occupancies. Public corridors in outpatient, administrative, and service areas which are designed to other than hospital requirements and are the required means of egress from the hospital shall be not less than five feet in width.

(iv) Encroachment into the means of egress. Items such as drinking fountains, telephone booths or stations, and vending machines shall be so located as to not project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum. Portable equipment shall not be stored so as to project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum.

(v) Doors in means of egress. All door leaves in the means of egress shall be not less than 44 inches wide or as otherwise permitted for hospitals by NFPA 101, §18.2.3.6.

(vi) Sliding doors. Horizontal sliding doors serving an occupant load of fewer than 10 shall be permitted. The area served by the door has no high hazard contents. The door is readily operable from either side without special knowledge or effort. The force required to operate the door in the direction of door travel is not more than 30 pounds per foot to set the door in motion and is not more than 15 pounds per foot to close the door or open in the minimum required width. The door assembly complies with any required fire protection rating, and, where rated, is self-closing or automatic closing. The sliding doors opening to the egress corridor doors shall have a latch or other mechanism that ensures that the doors will not rebound into a partially open position if forcefully closed. The sliding doors may have breakaway provisions and shall be installed to resist passage of smoke. The latching sliding panel shall have a minimum clear opening of 41.5 inches in the fully open position. The fixed panels may have recessed tracks.

(vii) Control doors. Designs that include cross-corridor control doors should be avoided. When unavoidable, cross-corridor control doors shall consist of two 44-inch wide leaves which swing in a direction opposite from the other, or of the double acting type. Each door leaf shall be provided with a view window.

(viii) Emergency access. Rooms containing bathtubs, showers, and water closets, intended for patient use shall be provided with at least one door having hardware which will permit access from the outside in any emergency. Door leaf width of such doors shall not be less than 36 inches.

(ix) Obstruction of corridors. All doors which swing towards the corridor must be recessed. Corridor doors to rooms not subject to occupancy (any room that you can walk into and close the door behind you is considered occupiable) may swing into the corridor, provided that such doors comply with the requirements of NFPA 101, §7.2.1.4.4.

(x) Stair landing. Doors shall not open immediately onto a stair without a landing. The landing shall be 44 inches deep or have a depth at least equal to the door width, whichever is greater.

(xi) Doors to rooms subject to occupancy. All doors to rooms subject to occupancy shall be of the swing type except that horizontal sliding doors complying with the requirements of NFPA 101, §18.2.2.2.9 are permitted. Door leaves to rooms subject to occupancy shall not be less than 36 inches wide.

(xii) Operable windows and exterior doors. Windows that can be opened without tools or keys and outer doors without automatic closing devices shall be provided with insect screens.

(xiii) Glazing. Glass doors, lights, sidelights, borrowed lights, and windows located within 12 inches of a door jamb or with a bottom-frame height of less than 18 inches and a top-frame height of more than 36 inches above the finished floor which may be broken accidentally by pedestrian traffic shall be glazed with safety glass or plastic glazing material that will resist breaking and will not create dangerous cutting edges when broken. Similar materials shall be used for wall openings in activity areas such as recreation and exercise rooms, unless otherwise required for fire safety. Safety glass, tempered or plastic glazing materials shall be used for shower doors and bath enclosures, interior windows and doors. Plastic and similar materials used for glazing shall comply with the flame spread ratings of NFPA 101, §18.3.3.

(xiv) Fire doors. All fire doors shall be listed by an independent testing laboratory and shall meet the construction requirements for fire doors in National Fire Protection Association 80, Standard for Fire Doors and Fire Windows, 1999 edition. Reference to a labeled door shall be construed to include labeled frame and hardware.

(xv) Grab bars. Grab bars shall be provided at patient toilets, showers and tubs. The bars shall be one and one-half inches in diameter, shall have either one and one-fourth or one and one-half inches clearance to walls, and shall have sufficient strength

and anchorage to sustain a concentrated vertical or horizontal load of 250 pounds. Grab bars are not permitted at bathing and toilet fixtures in mental health and chemical dependency units unless designed and installed to eliminate the possibility of patients harming themselves. Grab bars intended for use by the disabled shall also comply with ADA requirements.

(xvi) Soap dishes. Soap dishes shall be provided at all showers and bathtubs.

(xvii) Hand washing facilities. Location and arrangement of fittings for hand washing facilities shall permit their proper use and operation. Hand washing fixtures with hands-free operable controls shall be provided within each workroom, examination, and treatment room. Hands-free includes blade-type handles, and foot, knee, or sensor operated controls. Particular care shall be given to the clearances required for blade-type operating handles. Lavatories and hand washing facilities shall be securely anchored to withstand an applied vertical load of not less than 250 pounds on the front of the fixture. In addition to the specific areas noted, hand washing facilities shall be provided and conveniently located for staff use throughout the hospital where patient care contact occurs and services are provided.

(xviii) Soap dispensers. A liquid or foam soap dispenser shall be located at each hand washing facility.

(xix) Alcohol-based hand rubs. Alcohol-based hand rubs (ABHRs) are considered flammable. When used, the ABHRs shall meet the following requirements:

(I) The dispensers may be installed in a corridor so long as the corridor width is six feet or greater. The dispensers shall be installed at least four feet apart.

(II) The maximum individual dispenser fluid capacity is 1.2 liters for dispensers in rooms, corridors, and areas open to corridors, and 2.0 liters for dispensers in suites of rooms.

(III) The dispensers shall not be installed over or directly adjacent to electrical outlets and switches.

(IV) Dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

(V) Each smoke compartment may contain a maximum aggregate of 10 gallons of ABHR solution in dispensers and a maximum of five gallons in storage.

(xx) Hand drying. Provisions for hand drying shall be included at all hand washing facilities except scrub sinks. There shall be hot air dryers or individual paper or cloth units enclosed in such a way as to provide protection against dust or soil and ensure single-unit dispensing.

(xxi) Mirrors. Mirrors shall not be installed at hand washing fixtures where asepsis control and sanitation requirements would be lessened by hair combing. Mirrors may be installed in patient rooms, patient toilet rooms, lockers, and public toilet rooms.

(xxii) Ceiling heights. The minimum ceiling height shall be seven feet six inches with the following exceptions.

(I) Boiler rooms. Boiler rooms shall have ceiling clearances not less than two feet six inches above the main boiler header and connecting piping.

(II) Rooms with ceiling-mounted equipment. Rooms containing ceiling-mounted equipment shall have the ceiling height clearance increased to accommodate the equipment or fixtures.

(III) Overhead clearance. Suspended tracks, rails, pipes, signs, lights, door closers, exit signs, and other fixtures that protrude into the path of normal traffic shall not be less than six feet eight inches above the finished floor.

(xxiii) Areas producing impact noises. Recreation rooms, exercise rooms, and similar spaces where impact noises may be generated shall not be located directly over patient bed area or operating rooms unless special provisions are made to minimize noise.

(xxiv) Noise reduction. Noise reduction criteria in accordance with the Table 1 in §133.169(a) of this title (relating to Tables) shall apply to partitions, floor, and ceiling construction in patient areas.

(xxv) Rooms with heat-producing equipment. Rooms containing heat-producing equipment such as heater rooms, laundries, etc. shall be insulated and ventilated to prevent any occupied floor surface above from exceeding a temperature differential of 10 degrees Fahrenheit above the ambient room temperature.

(xxvi) Chutes. Linen and refuse chutes shall comply with the requirements of National Fire Protection Association 82, Standard on Incinerators, Waste and Linen Handling Systems and Equipment, 2004 edition, and NFPA 101, §18.5.4.

(xxvii) Thresholds and expansion joint covers. Thresholds and expansion joint covers shall be flush or not more than one-half inch above the floor surface to facilitate the use of wheelchairs and carts. Expansion and seismic joints shall be constructed to restrict the passage of smoke and fire and shall be listed by a nationally recognized testing laboratory.

(xxviii) Housekeeping room.

(I) In addition to the housekeeping room(s) required in certain departments, sufficient housekeeping rooms shall be provided throughout the hospital as required to maintain a clean and sanitary environment.

(II) Each housekeeping room shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

(B) General finish requirements.

(i) Cubicle curtains and draperies.

(I) Cubicle curtains, draperies and other hanging fabrics shall be noncombustible or flame retardant and shall pass both the small scale and the large-scale tests of National Fire Protection Association 701, Standard Methods of Fire Tests for Flame-Resistant Textiles and Films, 1999 edition. Copies of laboratory test reports for installed materials shall be submitted to the department at the time of the final construction inspection.

(II) Cubicle curtains shall be provided to assure patient privacy.

(ii) Flame spread, smoke development and noxious gases. Flame spread and smoke developed limitations of interior finishes shall comply with Table 2 of §133.169(b) of this title and NFPA 101, §10.2. The use of materials known to produce large or concentrated amounts of noxious or toxic gases shall not be used in exit accesses or in patient areas. Copies of laboratory test reports for installed materials tested in accordance with National Fire Protection Association 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 edition, and National Fire Protection Association 258, Standard Research Test Method for Determining Smoke Generation of Solid Materials, 2001 edition, shall be provided.

(iii) Floor finishes. Flooring shall be easy to clean and have wear resistance appropriate for the location involved. Floors that are subject to traffic while wet (such as shower and bath areas, kitchens, and similar work areas) shall have a nonslip surface. In all areas frequently subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. The following are acceptable floor finishes:

(I) painted concrete;

(II) vinyl and vinyl composition tiles and sheets;

(III) monolithic or seamless flooring. Where required, seamless flooring shall be impervious to water, coved and installed integral with the base, tightly sealed to the wall, and without voids that can harbor insects or retain dirt particles. The base shall not be less than six inches in height. Welded joint flooring is acceptable;

(IV) ceramic and quarry tile;

(V) wood floors. Wood floors subject to frequent cleaning methods shall be avoided. When wood floors are used, the floor shall be tightly sealed, without voids and the joints shall be impervious to water;

(VI) carpet flooring. Carpeting installed in intensive care units, nurseries, patient rooms and similar patient care areas shall be treated to prevent bacterial and fungal growth;

(VII) terrazzo; and

(VIII) poured in place floors.

(iv) Wall finishes. Wall finishes shall be smooth, washable, moisture resistant, and cleanable by standard housekeeping practices. Wall finishes shall comply with requirements contained in Table 2 of §133.169(b) of this title, and NFPA 101, §18.3.3.

(I) Wall finishes shall be water-resistant in the immediate area of plumbing fixtures.

(II) Wall finishes subject to frequent wet cleaning methods shall be impervious to water, tightly sealed and without voids.

(v) Floor, wall and ceiling penetrations. Floor, wall and ceiling penetrations by pipes, ducts, and conduits or any direct openings shall be tightly sealed to minimize entry of dirt particles, rodents and insects. Joints of structural elements shall be similarly sealed.

(vi) Ceiling types. Ceilings which are a part of a rated roof/ceiling assembly or a floor/ceiling assembly shall be constructed of listed components and installed in accordance with the listing. Three types of ceilings that are required in various areas of the hospital are:

(I) Ordinary ceilings. Ceilings such as acoustical tiles installed in a metal grid which are dry cleanable with equipment used in daily housekeeping activities such as dusters and vacuum cleaners.

(II) Washable ceilings. Ceilings that are made of washable, smooth, moisture impervious materials such as painted lay-in gypsum wallboard or vinyl faced acoustic tile in a metal grid.

(III) Monolithic ceilings. Ceilings which are monolithic from wall to wall (painted solid gypsum wallboard), smooth and without fissures, open joints, or crevices and with a washable and moisture impervious finish.

(vii) Special construction. Special conditions may require special wall and ceiling construction for security in areas such as storage of controlled substances and areas where patients are likely to attempt suicide or escape.

(viii) Flammable anesthetizing locations. Flammable anesthetic locations in which flammable anesthetic agents are stored or administered shall comply with

Annex E of the National Fire Protection Association 99, Standard for Health Care Facilities, 2002 edition (NFPA 99).

(ix) Materials finishes. Materials known to produce noxious gases when burned shall not be used for mattresses, upholstery, and wall finishes.

(x) Signage. A sign shall be posted at the entrance to each toilet/restroom to identify the facility for public, staff or patient use. Signs are not required for patient room bathrooms.

(3) General mechanical requirements. This paragraph contains common requirements for mechanical systems; steam and hot and cold water systems; air conditioning, heating and ventilating systems; plumbing fixtures; piping systems; and thermal and acoustical insulation. The hospital shall comply with the requirements of this paragraph and any specific mechanical requirements for the particular unit of the hospital in accordance with §133.163 of this title.

(A) Equipment location. When mechanical equipment is exposed to weather, it shall be protected by weatherproof construction or weather protected.

(B) Vibration isolation. Mechanical equipment shall be mounted on vibration isolators as required to prevent unacceptable structure-borne vibration. Ducts, pipes, etc. connected to mechanical equipment which is a source of vibration shall be isolated from the equipment with vibration isolators.

(C) Performance and acceptance. Prior to completion and acceptance of the facility, all mechanical systems shall be tested, balanced, and operated to demonstrate to the design engineer or his representative that the installation and performance of these systems conform to the requirements of the plans and specifications.

(i) Material lists. Upon completion of the contract, the owner shall be provided with parts lists and procurement information with numbers and description for each piece of equipment.

(ii) Instructions. Upon completion of the contract, the owner shall be provided with instructions in the operational use of systems and equipment as required.

(D) Heating, ventilating and air conditioning (HVAC) systems. All HVAC systems shall comply with and shall be installed in accordance with the requirements of National Fire Protection Association 90A, Standard for the Installation of Air Conditioning and Ventilating Systems, 2002 edition, (NFPA 90A), NFPA 99, Chapter 6, the requirements contained in this subparagraph, and the specific requirements for a particular unit in accordance with §133.163 of this title.

(i) General ventilation requirements. All rooms and areas in the hospital listed in Table 3 of §133.169(c) of this title shall have provision for positive ventilation. Fans serving exhaust systems shall be located at the discharge end and shall be conveniently

accessible for service. Exhaust systems may be combined, unless otherwise noted, for efficient use of recovery devices required for energy conservation. The ventilation rates shown in Table 3 of §133.169(c) of this title shall be used only as minimum requirements since they do not preclude the use of higher rates that may be appropriate. Supply air to the building and exhaust air from the building shall be regulated to provide a positive pressure within the building with respect to the exterior.

(I) Cost reduction methods. To reduce utility costs, facility design may utilize energy conserving procedures including recovery devices, variable air volume, load shedding, systems shutdown or reduction of ventilation rates (when specifically permitted) in certain areas when unoccupied. In no case shall patient care be jeopardized.

(II) Economizer cycle. Mechanical systems shall be arranged to take advantage of outside air conditions by using an economizer cycle when appropriate to reduce heating and cooling systems loads. Innovative design that provides for additional energy conservation while meeting the intent of this section for acceptable patient care may be presented to the department for consideration.

(III) Outside air intake locations. Outside air intakes shall be located at least 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, or areas which may collect vehicular exhaust or other noxious fumes. (Prevailing winds and proximity to other structures may require more stringent requirements). Plumbing and vacuum vents that terminate five feet above the level of the top of the air intake may be located as close as 10 feet.

(IV) Low air intake location limit. The bottom of outside air intakes serving central systems shall be located as high as practical but at least six feet above ground level, or if installed above the roof, three feet above the roof level.

(V) Contaminated air exhaust outlets. Exhaust outlets from areas (kitchen hoods, etc.) that exhaust contaminated air shall be above the roof and be arranged to exhaust upward unless the air has been treated by an appropriate means where sidewall exhaust will be allowed. Ethylene oxide sterilizers shall be terminated above the roof and be arranged to exhaust upward.

(VI) Directional air flow. Ventilation systems shall be designed and balanced to provide directional flow as shown in Table 3 of §133.169(c) of this title. For reductions and shutdown of ventilation systems when a room is unoccupied, the provisions in Note 4 of Table 3 of §133.169(c) of this title shall be followed.

(VII) Areas requiring fully ducted systems. Fully ducted supply, return and exhaust air for HVAC systems shall be provided for all critical care areas, sensitive care areas, all patient care areas, all areas requiring a sterile regimen, storage rooms, food preparation areas, and where required for fire safety purposes. Combination systems, utilizing both ducts and plenums for movement of air in these areas shall not be permitted.

(VIII) Ventilation start-up requirements. Air handling systems shall not be started or operated without the filters installed in place. This includes the 90% and 99.97% efficiency filters where required. Ducts shall be cleaned thoroughly and throughout by a certified air duct cleaning contractor when the air handling systems have been operating without the required filters in place. When ducts are determined to be dirty or dusty, the department will require a written report assuring cleanliness of duct and clean air quality.

(IX) Humidifier location. When duct humidifiers are located upstream of the final filters, they shall be located at least 15 feet from the filters. Ductwork with duct-mounted humidifiers shall be provided with a means of removing water accumulation. An adjustable high-limit humidistat shall be located downstream of the humidifier to reduce the potential of condensation inside the duct. All duct take-offs should be sufficiently downstream of the humidifier to ensure complete moisture absorption. Reservoir-type water spray or evaporative pan humidifiers shall not be used.

(ii) Filtration requirements. All central air handling systems serving patient care areas, including nursing unit corridors, shall be equipped with filters having efficiencies equal to, or greater than, those specified in Table 4 of §133.169(d) of this title. Filter efficiencies shall be average efficiencies tested in accordance with American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), Inc., Standard 52.2, 1999 edition, Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size. All joints between filter segments, and between filter segments and the enclosing ductwork, shall have gaskets and seals to provide a positive seal against air leakage. Air handlers serving more than one room shall be considered as central air handlers. All documents published by ASHRAE as referenced in this section may be obtained by writing or calling the ASHRAE, Inc. at the following address or telephone number: ASHRAE, Inc., 1791 Tullie Circle, N. E., Atlanta, GA 30329; telephone (404) 636-8400.

(I) Filtration requirements for air handling units serving single rooms requiring asepsis control. Dedicated air handlers serving only one room where asepsis control is required, such as, but not limited to, operating rooms, delivery rooms, special procedure rooms, and nurseries shall be equipped with filters having efficiencies equal to, or greater than, those specified for patient care areas in Table 4 of §133.169(d) of this title.

(II) Filtration requirements for air handling units serving other single rooms. Dedicated air handlers serving all other single rooms shall be equipped with nominal filters installed at the return air system.

(III) Location of multiple filters. Where two filter beds are required by Table 4 of §133.169(d) of this title, filter bed number one shall be located upstream of the air conditioning equipment, and filter bed number two shall be downstream of the supply air blowers and cooling and heating coils.

(IV) Location of single filters. Where only one filter bed is required by Table 4 of §133.169(d) of this title, it shall be located upstream of the supply fan. Filter frames shall be durable and constructed to provide an airtight fit with the enclosing ductwork.

(V) Pressure monitoring devices. A manometer or draft gauge shall be installed across each filter bed having a required efficiency of 75% or more including hoods requiring high efficiency particulate air (HEPA) filters.

(iii) Thermal and acoustical insulation for air handling systems. Asbestos insulation shall not be used.

(I) Thermal duct insulation. Air ducts and casings with outside surface temperature below ambient dew point or temperature above 80 degrees Fahrenheit shall be provided with thermal insulation.

(II) Insulation in air plenums and ducts. Linings in air ducts and equipment shall meet the Erosion Test Method described in Underwriters Laboratories (UL), Inc., Standard Number 181 (relating to Factory-Made Duct Materials and Air Duct Connectors), April 4, 1996 edition. This document may be obtained from the Underwriters Laboratories, Inc., 333 Pfingsten Road, Northbrook, IL 60062-2096.

(III) Insulation flame spread and smoke developed ratings. Interior and exterior insulation, including finishes and adhesives on the exterior surfaces of ducts and equipment, shall have a flame spread rating of 25 or less and a smoke developed rating of 50 or less as required by NFPA 90A, Chapters 4 and 5.

(IV) Linings and acoustical traps. Duct lining and acoustical traps exposed to air movement shall not be used in ducts serving critical care areas. This requirement shall not apply to mixing boxes and acoustical traps that have approved nonabrasive coverings over such linings.

(V) Frangible insulation. Insulation of soft and spray-on types shall not be used where it is subject to air currents or mechanical erosion or where loose particles may create a maintenance problem.

(VI) Existing duct linings. Internal linings shall not be used in ducts, terminal boxes, or other air system components supplying operating rooms, delivery rooms, birthing rooms, labor rooms, recovery rooms, nurseries, trauma rooms, isolation rooms, and intensive care units unless terminal filters of at least 90% efficiency are installed downstream of linings.

(iv) Ventilation for anesthetizing locations. Ventilation for anesthetizing locations, as defined in NFPA 99, §3.3, shall comply with NFPA 99, §13.4.1.2, and any specific ventilation requirements for the particular unit in accordance with §133.163 of this title.

(I) Smoke removal systems for windowless anesthetizing locations. Smoke removal systems shall be provided in all windowless anesthetizing locations in accordance with NFPA 99, §6.4.1.2.

(II) Smoke removal systems for surgical suites. Smoke removal systems shall be provided in all surgical suites in accordance with NFPA 99, §6.4.1.3.

(III) Smoke exhaust grilles. Exhaust grilles for smoke evacuation systems shall be ceiling-mounted or wall-mounted within 12 inches of the ceiling.

(v) Location of return and exhaust air devices. The bottoms of wall-mounted return and exhaust air openings shall be at least four inches above the floor. Return air openings located less than six inches above the floor shall be provided with nominal filters. All exhaust air openings and return air openings located higher than six inches but less than seven feet above the floor shall be protected with grilles or screens having openings through which a one-half inch sphere will not pass.

(vi) Ray protection. Ducts which penetrate construction intended for X-ray or other ray protection shall not impair the effectiveness of the protection.

(vii) Fire damper requirements. Fire dampers shall be located and installed in all ducts at the point of penetration of a required two-hour or higher fire rated wall or floor in accordance with the requirements of NFPA 101, §18.5.2.

(viii) Smoke damper requirements. Smoke dampers shall be located and installed in accordance with the requirements of NFPA 101, §18.3.7.3, and NFPA 90A, Chapter 5.

(I) Fail-safe installation. Smoke dampers shall close on activation of the fire alarm system by smoke detectors installed and located as required by National Fire Protection Association 72, National Fire Alarm Code, 2002 edition (NFPA 72), Chapter 8; NFPA 90A, Chapter 6; and NFPA 101, §18.3.7; the fire sprinkler system; and upon loss of power. Smoke dampers shall not close by fan shutdown alone unless it is a part of an engineered smoke removal system.

(II) Interconnection of air handling fans and smoke dampers. Air handling fans and smoke damper controls may be interconnected so that closing of smoke dampers will not damage the ducts.

(III) Frangible devices. Use of frangible devices for shutting smoke dampers is not permitted.

(ix) Acceptable damper assemblies. Only fire damper and smoke damper assemblies integral with sleeves and listed for the intended purpose shall be acceptable.

(x) Duct access doors. Unobstructed access to duct openings in accordance with NFPA 90A, §4.3.4, shall be provided in ducts within reach and sight of every fire damper, smoke damper and smoke detector. Each opening shall be protected by an internally insulated door which shall be labeled externally to indicate the fire protection device located within.

(xi) Restarting controls. Controls for restarting fans may be installed for convenient fire department use to assist in evacuation of smoke after a fire is controlled, provided that provisions are made to avoid possible damage to the system because of closed dampers. To accomplish this, smoke dampers shall be equipped with remote control devices.

(xii) Make-up air. If air supply requirements in Table 3 of §133.169(c) of this title do not provide sufficient air for use by exhaust hoods and safety cabinets, filtered make-up air shall be ducted to maintain the required air flow direction in that room. Make-up systems for hoods shall be arranged to minimize short circuiting of air and to avoid reduction in air velocity at the point of contaminant capture.

(4) General piping systems and plumbing fixture requirements. All piping systems and plumbing fixtures shall be designed and installed in accordance with the requirements of the National Standard Plumbing Code Illustrated published by the National Association of Plumbing-Heating-Cooling Contractors (PHCC), 2003 edition, and this paragraph. The National Standard Plumbing Code may be obtained by writing or calling the PHCC at the following address or telephone number: Plumbing-Heating-Cooling Contractors, P. O. Box 6808, Falls Church, VA 22046; telephone (800) 533-7694.

(A) Piping systems.

(i) Water supply systems. Water service pipe to point of entrance to the building shall be brass pipe, copper tube (not less than type M when buried directly), copper pipe, cast iron water pipe, galvanized steel pipe, or approved plastic pipe. Domestic water distribution system piping within buildings shall be brass pipe, copper pipe, copper tube, or galvanized steel pipe. Piping systems shall be designed to supply water at sufficient pressure to operate all fixtures and equipment during maximum demand.

(I) Valves. Each water service main, branch main, riser, and branch to a group of fixtures shall be equipped with accessible and readily identifiable shutoff valves. Stop valves shall be provided at each fixture.

(II) Backflow preventers. Backflow preventers (vacuum breakers) shall be installed on hose bibbs, laboratory sinks, janitor sinks, bedpan-flushing attachments, autopsy tables, and on all other fixtures to which hoses or tubing can be attached.

(III) Flushing valves. Flush valves installed on plumbing fixtures shall be of a quiet operating type, equipped with silencers.

(IV) Capacity of water heating equipment. Water heating equipment shall have sufficient capacity to supply water for clinical, dietary and laundry use at the temperatures and amounts specified in Table 5 of §133.169(e) of this title.

(V) Water temperature measurements. Water temperatures shall be measured at hot water point of use or at the inlet to processing equipment.

(VI) Water storage tanks. Domestic water storage tank(s) shall be fabricated of corrosion-resistant metal or lined with noncorrosive material. When potable water storage tanks (hot and cold) are used, the water shall be used and replenished. Water shall not be stored in tanks for future use unless the water is tested weekly for contaminants/bacteria.

(VII) Hot water distribution. Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times.

(VIII) Emergency water supply. Emergency potable water storage facilities shall be provided. The storage capacity shall not be less than 500 gallons or 12 gallons per licensed patient bed, whichever is greater. Capacity of hot water storage tanks may be included as part of the required emergency water capacity when valves and piping systems are arranged to make this water available at all times. When bottle water is used in lieu of water storage facilities, the hospital shall maintain and ensure the required amount of bottled water supply on hand at all times, maintain an inventory record which reflects the rotation and replacement of expired bottled water, and have adequate storage space on site that is readily accessible by staff in the event of an emergency. The hospital shall ensure the continued availability and delivery of bottled water until the emergency situation has concluded.

(IX) Purified water supply system. Purified water distribution system piping shall be task specific and include, but not necessarily be limited to, Polypropylene (PP), Polyvinylidene fluoride (PVDF) or Polyvinyl Chloride (PVC) pipe. Final installed purified water system piping assemblies shall be UL approved and fully comply with applicable American Society for Testing and Materials (ASTM) Fire Resistant/Smoke Density requirements. The applicable documents are available from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959.

(X) Dead-end piping. Dead-end piping (risers with no flow, branches with no fixture) shall not be installed. In any renovation work, dead-end piping shall be removed. Empty risers, mains and branches installed for future use are permitted.

(ii) Fire sprinkler systems. Fire sprinkler systems shall be provided in hospitals as required by NFPA 101, §18.3.5. All fire sprinkler systems shall be designed, installed, and maintained in accordance with the requirements of NFPA 13, and shall be certified as required by §133.168(c)(1)(C) of this title (relating to Construction, Inspections, and Approval of Project).

(iii) Nonflammable medical gas and clinical vacuum systems. Nonflammable medical gas and clinical vacuum system installations shall be designed, installed and certified in accordance with the requirements of NFPA 99, §5.1 for Level I systems and the requirements of this clause.

(I) Outlets. Nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 6 of §133.169(f) of this title.

(II) Installer qualifications. All installations of the medical gas piping systems shall be done only by, or under the direct supervision of a holder of a master plumber license or a journeyman plumber license with a medical gas piping installation endorsement issued by the Texas State Board of Plumbing Examiners.

(III) Installer tests. Prior to closing of walls, the installer shall perform an initial pressure test, a blowdown test, a secondary pressure test, a cross-connection test, and a purge of the piping system as required by NFPA 99.

(IV) Qualifications for conducting verification tests and inspections. Verification testing shall be performed and inspected by a party, other than the installer, installing contractor, or material vendor. Testing shall be conducted by a registered medical gas system verifier and technically competent and experienced in the field of medical gas and vacuum pipeline testing and meeting the requirements of the American Society of Safety Engineers (ASSE) Personnel Standard 6030, Professional Qualifications Standard for Medical Gas Systems. The document published by ASSE Personnel Standard 6030, Professional Qualifications Standard for Medical Gas Systems as referenced in this rule may be obtained by writing or calling The American Society of Safety Engineers (ASSE) at ASSE International Office, 901 Canterbury, Suite A, Westlake, Ohio 44145, telephone (440) 885-3040.

(V) Verification tests. Upon completion of the installer inspections and tests and after closing of walls, verification tests of the medical gas piping systems, the warning system, and the gas supply source shall be conducted. The verification tests shall include a cross-connection test, valve test, flow test, piping purge test, piping purity test, final tie-in test, operational pressure tests, and medical gas concentration test.

(VI) Verification test requirements. Verification tests of the medical gas piping system and the warning system shall be performed on all new piped medical gas systems, additions, renovations, or repaired portions of an existing system. All systems that are breached and components that are added, renovated, or replaced shall be inspected and appropriately tested. The breached portions of the systems subject to inspection and testing shall be all of the new and existing components in the immediate zone or area located upstream of the point or area of intrusion and downstream to the end of the system or a properly installed isolation valve.

(VII) Warning system verification tests. Verification tests of piped medical gas systems shall include tests of the source alarms and monitoring safeguards, master alarm systems, and the area alarm systems.

(VIII) Source equipment verification tests. Source equipment verification tests shall include medical gas supply sources (bulk and manifold) and the compressed air source systems (compressors, dryers, filters, and regulators).

(IX) Hospital responsibility. Before new piped medical gas systems, additions, renovations, or repaired portions of an existing system are put into use, the hospital shall be responsible for ensuring that the gas delivered at the outlet is the gas shown on the outlet label and that the proper connecting fittings are checked against their labels.

(X) Written certification. Upon successful completion of all verification tests, written certification for affected piped medical gas systems and piped medical vacuum systems including the supply sources and warning systems shall be provided by a party technically competent and experienced in the field of medical gas pipeline testing stating that the provisions of NFPA 99 have been adhered to and systems integrity has been achieved. The written certification shall be submitted directly to the hospital and the installer. A copy shall be forwarded to the department by the hospital.

(XI) Documentation of medical gas and clinical vacuum outlets. Documentation of the installed, modified, extended or repaired medical gas piping system shall be submitted to the department by the same party certifying the piped medical gas systems. The number and type of medical gas outlets (oxygen, vacuum, medical air, nitrogen, nitrous oxide, etc.) shall be documented and arranged tabularly by room numbers and room types.

(iv) Medical gas storage facilities. Main storage of medical gases may be outside or inside the hospital in accordance with NFPA 99, §5.1. Provision shall be made for additional separate storage of reserve gas cylinders necessary to complete at least one day's procedures.

(v) Multiple gas outlets on one medical gas outlet. Y-connections, "twinning", or other similar devices shall not be used on any medical gas outlet.

(vi) Waste anesthetic gas disposal (WAGD) systems. Each space routinely used for administering inhalation anesthesia shall be provided with a WAGD system as required by NFPA 99, §5.1.3.7.

(vii) Steam and hot water systems.

(I) Boilers. Boilers shall have the capacity, based upon the net ratings as published in The I-B-R Ratings Book for Boilers, Baseboard Radiation and Finned Tube (commercial) by the Hydronics Institute Division of GAMA, to supply the normal requirements of all systems and equipment. The number and arrangement of boilers shall be such that, when one boiler breaks down or routine maintenance requires that one boiler be temporarily taken out of service, the capacity of the remaining boiler(s) shall be sufficient to provide hot water service for clinical, dietary, and patient use, steam for sterilization and dietary purposes, and heating for operating, delivery, emergency, labor, recovery, intensive care, nursery, treatment, and general patient rooms. However, reserve capacity for space heating of noncritical care areas (e.g. general patient rooms and administrative areas) is not required in geographical areas where a design dry bulb temperature equals 25 degrees Fahrenheit or higher as based on the 99% design value shown in the Handbook of Fundamentals, 2005 edition, published by ASHRAE, Inc. The document published by the Hydronics Institute Division of GAMA as referenced in this rule may be obtained by writing or calling the Hydronics Institute Division of GAMA at 35 Russo Place, P. O. Box 218, Berkeley Heights, N.J. 07922, telephone (908) 464-8200.

(II) Boiler accessories. Boiler feed pumps, heating circulating pumps, condensate return pumps, and fuel oil pumps shall be connected and installed to provide normal and standby service.

(III) Valves. Supply and return mains and risers of cooling, heating, and process steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return ends except that vacuum condensate returns need not be valved at each piece of equipment.

(IV) Hot water distribution systems. Hot water distribution systems for patient care areas shall be under constant recirculation to provide continuous hot water at each hot water outlet. Nonrecirculated fixtures branch piping shall not exceed 25 feet in length. Water temperature is measured at the point of use or inlet to the equipment. Tankless water system may be used at point of use.

(V) Domestic hot water system. The domestic hot water system shall make provisions to limit the amount of Legionella bacteria and opportunistic waterborne pathogens.

(viii) Drainage systems.

(I) Above ground piping. Soil stacks, drains, vents, waste lines, and leaders installed above ground within buildings shall be drain-waste-vent (DWV) weight or heavier and shall be: copper pipe, copper tube, cast iron pipe, or galvanized iron pipe.

(II) Underground piping. All underground building drains shall be: cast iron soil pipe, hard temper copper tube (DWV or heavier), acrylonitrile-butodiene-styrene (ABS) plastic pipe (DWV Schedule 40 or heavier), polyvinyl chloride (PVC) plastic pipe (DWV Schedule 40 or heavier), or extra strength vitrified clay pipe (VCP) with compression joints or couplings with at least 12 inches of earth cover.

(III) Drains for chemical wastes. Separate drainage systems for chemical wastes (acids and other corrosive materials) shall be provided. Materials acceptable for chemical waste drainage systems shall include chemically resistant glass pipe, high silicone content cast iron pipe, VCP, plastic pipe, or plastic lined pipe.

(ix) Thermal insulation for piping systems and equipment. Insulation shall be provided for the following:

- (I) boilers, smoke breeching, and stacks;
- (II) steam supply and condensate return piping;
- (III) hot water piping and all hot water heaters, generators, converters, and storage tanks;

(IV) chilled water, refrigerant, other process piping, equipment operating with fluid temperatures below ambient dew point, and water supply and drainage piping on which condensation may occur. Insulation on cold surfaces shall include an exterior vapor barrier;

(V) other piping, ducts, and equipment as necessary to maintain the efficiency of the system.

(x) Pipe and equipment insulation rating. Flame spread shall not exceed 25 and smoke development rating shall not exceed 150 for pipe insulation as determined by an independent testing laboratory in accordance with National Fire Protection Association 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 edition. Smoke development rating for pipe insulation located in environmental air areas shall not exceed 50.

(xi) Asbestos insulation. Asbestos insulation shall not be used.

(B) Plumbing fixtures. Plumbing fixtures shall be made of nonabsorptive acid-resistant materials and shall comply with the recommendations of the National Standard Plumbing Code and this paragraph.

(i) Sink and lavatory controls. All fixtures used by medical and nursing staff and all lavatories used by patients and food handlers shall be trimmed with valves which can be operated without the use of hands. Blade handles used for this purpose shall not be less than four inches in length. Single lever or wrist blade devices may be used.

(ii) Clinical sink traps. Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

(iii) Sinks for disposal of plaster of paris. Sinks used for the disposal of plaster of paris shall have a plaster trap.

(iv) Back-flow or siphoning. All plumbing fixtures and equipment shall be designed and installed to prevent the back-flow or back-siphonage of any material into the water supply. The over-the-rim type water inlet shall be used wherever possible. Vacuum-breaking devices shall be properly installed when an over-the-rim type water inlet cannot be utilized.

(v) Drinking fountain. Each drinking fountain shall be designed so that the water issues at an angle from the vertical, the end of the water orifice is above the rim of the bowl, and a guard is located over the orifice to protect it from lip contamination.

(vi) Sterilizing equipment. All sterilizing equipment shall be designed and installed to prevent not only the contamination of the water supply but also the entrance of contaminating materials into the sterilizing units.

(vii) Hose attachment. No hose shall be affixed to any faucet if the end of the hose can become submerged in contaminated liquid unless the faucet is equipped with an approved, properly installed vacuum breaker.

(viii) Bedpan washers and sterilizers. Bedpan washers and sterilizers shall be designed and installed so that both hot and cold water inlets shall be protected against back- siphonage at maximum water level.

(ix) Flood level rim clearance. The water supply spout for lavatories and sinks required in patient care areas shall be mounted so that its discharge point is a minimum of five inches above the rim of the fixture.

(x) Scrub sink controls. Scrub sinks and lavatories used for scrubbing in procedure rooms shall be trimmed with foot, knee, or ultrasonic controls. Single lever wrist blades are not acceptable at scrub sinks.

(xi) Floor drains or floor sinks. Where floor drains or floor sinks are installed, they shall be of a type that can be easily cleaned by removal of the cover. Removable stainless steel mesh shall be provided in addition to grilled drain cover to prevent entry of large particles of waste which might cause stoppages.

(xii) Under-counter piping. Under-counter piping and above floor drains shall be arranged (raised) so as not to interfere with cleaning of floor below the equipment.

(xiii) Ice machines. All ice-making machines used for human consumption shall be of the self-dispensing type. Copper tubing shall be provided for supply connections to ice machines.

(xiv) Food disposal units. A food disposal unit shall only be permitted in the dietary department (§133.163(e) of this title).

(5) General electrical requirements. This paragraph contains common electrical requirements. The hospital shall comply with the requirements of this paragraph and with any specific electrical requirements for the particular unit of the hospital in accordance with §133.163 of this title.

(A) Electrical installations. All new electrical material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of the National Fire Protection Association 70, National Electrical Code, 1999 edition (NFPA 70), and NFPA 99 and as necessary to provide a complete electrical system. Electrical systems and components shall be listed by nationally recognized listing agencies as complying with available standards and shall be installed in accordance with the listings and manufacturers' instructions.

(i) All fixtures, switches, sockets, and other pieces of apparatus shall be maintained in a safe and working condition.

(ii) Extension cords and cables shall not be used for permanent wiring.

(iii) All electrical heating devices shall be equipped with a pilot light to indicate when the device is in service, unless equipped with a temperature limiting device integral with the heater.

(iv) All equipment, fixtures, and appliances shall be properly grounded in accordance with NFPA 70.

(v) Under-counter receptacles and conduits shall be arranged (raised) to not interfere with cleaning of floor below the equipment.

(B) Installation testing and certification.

(i) Installation testing. The electrical installations, including alarm, nurses calling system and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional.

(ii) Grounding system testing. The grounding system shall be tested as described in NFPA 99, 4.3.3, for patient care areas in new or renovated work. The testing shall be performed by a qualified electrician or their qualified electrical testing agent. The electrical contractor shall provide a letter stating that the grounding system has been tested in accordance with NFPA 99, the testing device use complies with NFPA 99, and whether the grounding system passed the test. The letter shall be signed by the qualified electrical contractor, or their designated qualified electrical testing agent, certifying that the system has been tested and the results of the test are indicated.

(C) Electrical safeguards. Shielded isolation transformers, voltage regulators, filters, surge suppressors, and other safeguards shall be provided as required where power line disturbances are likely to affect fire alarm components, data processing, equipment used for treatment, and automated laboratory diagnostic equipment.

(D) Services and switchboards. Electrical service and switchboards serving the required hospital components shall be installed above the designated 100-year flood plain. Main switchboards shall be located in separate rooms, separated from adjacent areas with one-hour fire rated enclosures containing only electrical switchgear and distribution panels and shall be accessible to authorized persons only. These rooms shall be ventilated to provide an environment free of corrosive or explosive fumes and gases, or any flammable and combustible materials. Switchboards shall be located convenient for use and readily accessible for maintenance as required by NFPA 70, Article 384. Overload protective devices shall operate properly in ambient temperatures.

(E) Panelboards. Panelboards serving normal lighting and appliance circuits shall be located on the same floor as the circuits they serve. Panelboards serving critical branch emergency circuits shall be located on each floor that has major users (operating rooms,

delivery suites, intensive care, etc.) and may also serve the floor above and the floor below. Panelboards serving life safety branch circuits may serve three floors, the floor where the panelboard is located, and the floors above and below.

(F) Wiring. All conductors for controls, equipment, lighting and power operating at 100 volts or higher shall be installed in accordance with the requirements of NFPA 70, Article 517. All surface mounted wiring operating at less than 100 volts shall be protected from mechanical injury with metal raceways to a height of seven feet above the floor. Conduits and cables shall be supported in accordance with NFPA 70, Article 300.

(G) Lighting.

(i) Lighting intensity for staff and patient needs shall comply with guidelines for health care facilities set forth in the Illuminating Engineering Society of North America (IESNA) Handbook, 2000 edition, published by the IESNA, 120 Wall Street, Floor 17, New York, New York 10005.

(I) Consideration should be given to controlling intensity and wavelength to prevent harm to the patient's eyes (i.e., retina damage to premature infants and cataracts due to ultraviolet light).

(II) Approaches to buildings and parking lots, shall be illuminated. All rooms including storerooms, electrical and mechanical equipment rooms, and all attics shall have sufficient artificial lighting so that all parts of these spaces shall be clearly visible.

(III) Consideration should be given to the special needs of the elderly. Excessive contrast in lighting levels that makes effective sight adaptation difficult shall be minimized.

(ii) Means of egress and exit sign lighting intensity shall comply with NFPA 101, §§7.8 - 7.10.

(iii) Electric lamps which may be subject to breakage or which are installed in fixtures in confined locations when near woodwork, paper, clothing, or other combustible materials, shall be protected by wire guards, or plastic shields.

(iv) Ceiling-mounted surgical and examination light fixtures shall be suspended from rigid support structures mounted above the ceiling.

(H) Receptacles. Only listed hospital grade single-grounding or duplex-grounding receptacles shall be used in all patient care areas. This does not apply to special purpose receptacles.

(i) Installations of multiple-ganged receptacles shall not be permitted in patient care areas.

(ii) Electrical outlets powered from the critical branch shall be provided in all patient care, procedure and treatment locations in accordance with NFPA 99, §4.4.2.2.3. At least one receptacle at each patient treatment or procedure location shall be powered from the normal power panel.

(iii) Replacement of malfunctioning receptacles and installation of new receptacles powered from the critical branch in existing facilities shall be accomplished with receptacles of the same distinct color as the existing receptacles.

(iv) In locations where mobile X-ray or other equipment requiring special electrical configuration is used, the additional receptacles shall be distinctively marked for the special use.

(v) Each receptacle shall be grounded to the reference grounding point by means of a green insulated copper equipment grounding conductor.

(vi) All critical care area receptacles shall be identified. The face plate for the receptacle(s) shall have a nonremovable label or be engraved indicating the panel and circuit number.

(I) Equipment.

(i) Equipment required for safe operation of the hospital shall be powered from the equipment system in accordance with the requirements contained in NFPA 99, §4.4.2.2.3.

(ii) Boiler accessories including feed pumps, heat-circulating pumps, condensate return pumps, fuel oil pumps, and waste heat boilers shall be connected and installed to provide both normal and standby service.

(iii) Laser equipment shall be installed according to manufacturer recommendations and shall be registered with the Radiation Branch, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.

(J) Ground fault circuit interrupters (GFCI). GFCI receptacles shall be provided for all general use receptacles located within three feet of a wash basin or sink. When GFCI receptacles are used, they shall be connected to not affect other devices connected to the circuit in the event of a trip. Receptacles connected to the critical branch that may be used for equipment that should not be interrupted do not have to be GFCI protected. Receptacles in wet locations, as defined by NFPA 70, §§517.20 and 517.21, shall be GFCI protected regardless of the branch of the electrical system serving the receptacle.

(K) Grounding requirements. In areas such as critical care units and special nurseries where a patient may be treated with an internal probe or catheter connected to the heart, the ground system shall comply with applicable sections of NFPA 99 and NFPA 70.

(L) Nurses calling systems. Three different types of nurses calling systems are required to be installed in a hospital: a nurses regular calling system; a nurses emergency calling system; and a staff emergency assistance calling system. The hospital shall comply with the requirements of this subparagraph in addition to any specific requirements for nurses calling systems for the particular unit of the hospital in accordance with §133.163 and Table 7 of §133.169(g) of this title. Where required in this subparagraph, a distinct visible signal is provided when a colored dome light lamp, or particular combination of colored lamps is used for only one type of call. Different flash rates do not meet this requirement.

(i) A nurses regular calling system is intended for routine communication between each patient and the nursing staff. Activation of the system at a patient's regular calling station will sound a repeating (every 20 seconds or less) distinct audible signal at the nurse station, indicate type and location of call on the system monitor, and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. The audible signal shall be canceled and two-way voice communication between the patient room and the nursing staff shall be established at the unit's nursing station when the call is answered by the nursing staff. The visible signal(s) in the corridor shall be canceled upon termination of the call. Calls shall activate visible signals in accordance with Table 7 of §133.169(g) of this title. An alarm shall activate at the nurses station when the call cable is unplugged.

(ii) A nurses emergency calling system shall be installed in all toilets used by patients to summon nursing staff in an emergency. Activation of the system shall sound a repeating (every 5 seconds or less) a distinct audible signal at the nurse station, indicate type and location of call on the system monitor, and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. The visible and audible signals shall be cancelable only at the patient calling station. Calls shall activate visible signals in accordance with Table 7 of §133.169(g) of this title. When conveniently located and accessible from both the bathing and toilet fixtures, one emergency call station may serve one bathroom. A nurses emergency call system shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord extending to within six inches of the floor will satisfy this requirement.

(iii) A staff emergency assistance calling system (code blue) is intended to be used by staff to summon additional help in an emergency. In open suites, an emergency assistant call system device shall be located at the head of each bed and in each individual room. The emergency assistance calling device can be shared between two beds if conveniently located. Activation of the system will sound a distinct audible signal at the nursing unit's nurses station or at a staffed control station of a suite, department or unit, indicate type and location of call on the system monitor and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. Calls shall activate audible and visible signals in accordance with Table 7 of §133.169(g) of this title. A visible system shall clearly define the alarm location to a continuously staffed back up area (other than the nurse station or an administrative center) from which assistance can be summoned. Alternatively, back up may be provided via automatic annunciation from the staff emergency assistance calling system through wireless phones or

paggers. The system shall have voice communication capability so that the type of emergency or help required may be specified between the point of alarm and the unit's nurse station.

(M) Emergency electric service. A type I essential electrical system shall be provided in each hospital in accordance with requirements of NFPA 99; NFPA 101, and National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 2002 edition.

(i) When the emergency and standby power systems require a fuel source with tank, the fuel storage capacity tank shall have enough fuel for a period of 24 hours.

(ii) When a vapor liquefied petroleum gas (LPG) systems (natural gas) system is used, the 24-hour fuel capacity on-site is not required. The vapor withdrawal LPG system shall require a dedicated fuel supply.

(iii) When the emergency generator(s) and electrical transformer(s) are located within the same area, they shall be located at least 10 feet apart.

(N) Fire alarm system. A fire alarm system which complies with NFPA 101, §18.3.4, and with NFPA 72, Chapter 6 requirements, shall be provided in each facility. The required fire alarm system components are as follows:

(i) A fire alarm control panel (FACP) shall be installed at a continuously attended (24 hour) location. A remote fire alarm annunciator listed for fire alarm service and installed at a continuously attended location and is capable of indicating both visual and audible alarm, trouble and supervisory signals in accordance with the requirements of NFPA 72 may be substituted for the FACP.

(ii) Manual fire alarm pull stations shall be installed in accordance with NFPA 101, §18.3.4.

(iii) Smoke detectors for door release service shall be installed on the ceiling at each door opening in the smoke partition in accordance with NFPA 72, §6.15.6, where the doors are held open with electromagnetic devices conforming with NFPA 101, §18.2.2.6.

(iv) Ceiling-mounted smoke detector(s) shall be installed in room containing the FACP when this room is not attended continuously by staff as required by NFPA 72, §4.4.5.

(v) Smoke detectors shall be installed in air ducts in accordance with NFPA 72, §5.14.4.2 and §5.14.5 and NFPA 90A, §6.4.2.

(vi) Smoke detectors shall be installed in return air ducts in accordance with requirements of NFPA 72 §5.14.4.2.2 and §5.14.5 and NFPA 90A, §6.4.2.2.

(vii) Fire sprinkler system water flow switches shall be installed in accordance with requirements of NFPA 101, §9.6.2; NFPA 13, §6.9; and NFPA 72, §8.5.3.3.3.4.

(viii) Sprinkler system valve supervisory switches shall be installed in accordance with the requirements of NFPA 72, §6.8.5.5.

(ix) Audible alarm indicating devices shall be installed in accordance with the requirements of NFPA 101, §18.3.4, and NFPA 72, §7.4.

(x) Visual fire alarm indicating devices which comply with the requirements of paragraph (1)(D) of this subsection and NFPA 72, §7.5, shall be provided.

(xi) Devices for transmitting alarm for alerting the local fire brigade or municipal fire department of fire or other emergency shall be provided. The devices shall be listed for the fire alarm service by a nationally recognized laboratory, and be installed in accordance with such listing and the requirements of NFPA 72.

(xii) A smoke detection system for spaces open to corridor(s) shall be provided when required by NFPA 101, §18.3.6.1.

(xiii) A fire alarm signal notification which complies with NFPA 101, §9.6.3, shall be provided to alert occupants of fire or other emergency.

(xiv) Wiring for fire alarm detection circuits and fire alarm notification circuits shall comply with requirements of NFPA 70, Article 760.

(xv) A smoke detection system for elevator recall shall be located in elevator lobbies, elevator machine rooms and at the top of elevator hoist ways as required by NFPA 72, §6.15.3.10.

(I) The elevator recall smoke detection system in new construction shall comply with requirements of American Society of Mechanical Engineers/American National Standards Institute (ASME/ANSI) A17.1, Safety Code for Elevators and Escalators, 2000 edition. The publications of the ASME/ANSI referenced in this section may be obtained by writing ASME/ANSI, United Engineering Center, 345 East 47th Street, New York, N.Y. 10017.

(II) The elevator recall smoke detection system in existing hospitals shall comply with requirements of ASME/ANSI A17.3, Safety Code for Existing Elevators and Escalators, 2002 edition.

(xvi) Smoke detectors for initiating smoke removal from windowless anesthetizing areas shall be provided in accordance with NFPA 99, §6.4.1.2.

(xvii) Smoke detectors for initiating smoke removal from surgical suites shall be provided in accordance with NFPA 99, §6.4.1.3.

(xviii) A smoke detection system for initiating smoke removal from atriums shall be located above the highest floor level of the atrium and at return intakes from the atrium in accordance with National Fire Protection Association 92B, Guide for Smoke Management Systems in Malls, Atria, and Large Areas, 2000 edition.

(xix) Smoke detector(s) for shutdown of air handling units shall be provided. The detectors shall be installed in accordance with NFPA 90A, §6.4.3.

(O) Telecommunications and information systems. Telecommunications and information systems central equipment shall be installed in a separate location designed for the intended purpose. Special air conditioning and voltage regulation shall be provided as recommended by the manufacturer.

(P) Lightning protection systems. When installed, lightning protection systems shall comply with National Fire Protection Association 780, Standard for the Installation of Lightning Protection Systems, 2000 edition.

§133.163. Spatial Requirements for New Construction.

(a) Administration and public suite.

(1) Architectural requirements. The following rooms or areas shall be provided.

(A) Primary entrance. An entrance at grade level shall be accessible and protected from inclement weather with a drive under canopy for loading and unloading passengers.

(B) Lobby. A main lobby shall be located at the primary entrance and shall include a reception and information counter or desk, waiting space(s), public toilet facilities, public telephones, drinking fountain(s), and storage room or alcove for wheelchairs.

(C) Admissions area. An admissions area shall include a waiting area, work counters or desk, private interview spaces, and storage room or alcove for wheelchairs. The waiting area and wheelchair storage may be shared with similar areas located in the main lobby. The admission area may be omitted if exclusive bedside registration is used.

(D) General or individual office(s). Office space shall be provided for business transactions, medical and financial records, and administrative and professional staffs.

(E) Multipurpose room(s). Room(s) shall be provided for conferences, meetings, and health education purposes including provisions for showing visual aids.

(F) Storage. Storage for office equipment and supplies shall be provided. The construction protection for the storage room or area shall be in accordance with the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), §18.3.2. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, 1

Batterymarch Park, Quincy, Massachusetts 02269-9101, (800) 344-3555; the NFPA website address is <http://catalog.nfpa.org>.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title (relating to New Construction Requirements).

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(b) Cart cleaning and sanitizing unit.

(1) Architectural requirements.

(A) Cart cleaning, sanitizing and storage facilities shall be provided for carts serving central services, dietary services, and linen services.

(B) Cart facilities may be provided for each service or be centrally located.

(C) Hand washing fixtures shall be provided in cart cleaning, sanitizing and storage areas.

(2) Details and finishes. When interior cart cleaning facilities are provided, details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Flooring in the cart cleaning and sanitizing unit shall be of the seamless type, or ceramic or quarry tile as required by §133.162(d)(2)(B)(iii)(III) or (IV) of this title.

(B) Ceilings in the cart cleaning and sanitizing unit shall be the monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) Hand washing fixtures shall be provided with hot and cold water. Hot and cold water fixtures shall be provided in cart cleaning and sanitizing locations regardless of whether or not they are interior or exterior.

(B) Where floor drains or floor sinks are installed, they shall be of a type that can be easily cleaned by removal of the cover. Removable stainless steel mesh shall be provided in addition to a gridded drain cover to prevent entry of large particles of waste which might cause stoppages. Floor drains and floor sinks shall be located to avoid conditions where removal of covers for cleaning is difficult.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(c) Central sterile supply suite.

(1) Architectural requirements.

(A) General. When obstetrical or surgical services are provided, the following rooms or areas shall be provided.

(i) Decontamination room. This room shall be physically separated from all other areas of the suite. The room shall include work counters or tables, flush type utility sink, equipment for initial disinfection, and hand washing facilities with hands-free operable controls. Materials shall be transferred from the decontamination room to the clean assembly room by way of pass-through doors, windows or washer equipment. The dirty side of the decontamination room may be combined with a soiled utility room if all functions for each space are provided within the room.

(ii) Clean and assembly room. The room shall include counters or tables, equipment for sterilizing and hand washing facilities with hands-free operable controls. Clean and soiled work areas shall be physically separated.

(iii) Breakdown storage room. A storage room for breakdown of supplies shall be provided. The storage room shall have adequate areas and counters for breakdown of prepackaged supplies.

(iv) Sterile and clean supply room. A sterile and clean supply room shall be provided. Storage of sterile and clean supplies shall not occur within the breakdown room.

(v) Equipment storage. An equipment storage room shall be provided.

(vi) Cart storage room. The storage room for distribution carts shall be adjacent to clean and sterile storage and close to main distribution points.

(vii) Multipurpose room. The equipment storage and cart storage room can be combined into a multipurpose room.

(B) Service areas. The central supply suite shall provide the following.

(i) Office space. Office space for director of central services.

(ii) Staff toilets. Facilities may be outside the unit but must be convenient for staff use and shall contain hand washing fixtures with hands-free operable controls.

(iii) Locker room. When provided, the locker room for staff shall include lockers, toilets, lavatories, showers, and male and female dressing rooms or cubicles. A central changing locker room may be shared and made available within the immediate area of the central sterile supply suite.

(iv) Housekeeping room. A housekeeping room shall be provided and contain a floor receptor or service sink and storage space for housekeeping supplies and equipment. The housekeeping room shall be located on the decontamination/soiled side of the central sterile supply suite.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details. Mirrors shall not be installed at hand washing fixtures in clean and sterile supply areas.

(B) Finishes.

(i) Flooring used in the decontamination room and the clean assembly room shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in the decontamination room, clean assembly room, and supply storage room shall be the monolithic type in accordance with §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The sterile supply room and the clean and assembly room shall include provisions for ventilation, humidity, and temperature control.

(B) When provided, installations of ethylene oxide (EO) sterilizers shall comply with the requirements of 30 TAC, §106.417 (relating to Ethylene Oxide Sterilizers), administered by the Texas Commission on Environmental Quality (TCEQ), and the following requirements.

(i) All source areas shall be exhausted, including the sterilizer equipment room, service and aeration areas, over sterilizer door, and the aerator. If the EO cylinders are not located in a well-ventilated unoccupied equipment space, an exhaust hood shall

be provided over the cylinders. The relief valve shall be terminated in a well-ventilated, unoccupied equipment space, or outside the building.

(ii) General airflow shall be away from sterilizer operators and towards the sterilizers.

(iii) A dedicated exhaust fan and an exhaust duct system shall be provided for EO sterilizers. The exhaust outlet to the atmosphere shall be located on the highest roof, directed upward, and not less than 25 feet from any air intake. A legible warning sign shall be provided to identify the exhaust stack on the roof.

(iv) An audible and visual alarm located in sterilizer work area and a 24-hour staffed location shall be activated upon loss of airflow in the exhaust system.

(C) Filtration requirements for air handling units serving the central sterile supply suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title (relating to Tables).

(D) Duct linings exposed to air movement shall not be used in ducts serving the central sterile supply suite unless terminal filters of at least 90% efficiency are installed downstream of linings. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title. When medical gas systems are provided, the systems shall comply with §133.162(d)(4) of this title and this paragraph.

(A) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in sterile areas unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(B) No plumbing lines may be exposed or on walls where possible leaks would create a potential of contamination of the sterile areas.

(C) The compressed air required for the decontamination room shall not be connected to the medical air piping distribution system such as supporting breathable air for respiratory assistance needs, anesthesia machines, intermittent positive pressure breathing machine (IPPB), etc. A separate compressed air supply source shall be provided for maintenance and equipment needs for facility support use.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. Electrical circuit(s) to equipment in wet areas shall be provided with ground fault circuit interrupters (GFCIs).

(d) Critical care unit.

(1) Architectural requirements.

(A) General. When a critical care unit(s) (CCU) (also known as intensive care unit) is provided, the unit(s) may be classified as general CCU, coronary CCU (CCCU) or pediatric CCU (PCCU). Requirements for neonatal intensive care units (NCCU) are stated in subsection (u) of this section.

(i) The CCU(s) shall be a separate suite(s) operated separately from other units of the hospital. The location shall be arranged to eliminate the need for through traffic.

(ii) When elevator transport is required for critically ill patients, the size of the elevator cab, mechanisms and controls shall meet the specialized needs.

(B) CCU services and facilities. The following services and facilities shall apply to all classifications of CCUs unless otherwise noted.

(i) The patient area (whether separate rooms, cubicles, or multiple-bed space) shall have a minimum clear floor area of 200 square feet per bed exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. A minimum of 13 feet width shall be provided for the head wall for each bed.

(ii) When an open ward plan is used, at least one private room for every six ward beds shall be provided for medical isolation or psychological needs.

(iii) A minimum of one airborne infection isolation room shall be provided for each type of CCU suite. The number of airborne infection isolation rooms shall be determined based on an infection control risk assessment. Each room shall comply with requirements of subsection (t)(1)(C)(iii) and (iv) of this section. In addition, the isolation room shall comply with clause (i) of this subparagraph.

(iv) When private rooms or cubicles are provided, view panels in the door or walls of these rooms are required. Curtains or other means shall be provided to cover the viewing panels when visual privacy is required.

(v) For open ward environments in adult and pediatric units, the clearance between a bed and a wall/partition shall be a minimum of five feet. The clearance between sides of beds shall be a minimum of eight feet. The minimum distance at the foot of the bed shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space requirement at the foot of the bed may be shared between two beds. The multiple-bed CCU wards shall contain cabinets, work counters, and hand washing fixtures with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagrams A and B of §133.169(h) of this title .

(vi) Each room and ward shall be located on an exterior wall and shall have a window. In a ward, one window may serve more than one patient. The window sill height shall not exceed five feet above the floor. Patient beds shall not be located more than 50 feet from an exterior window. Patients' views to outside windows shall be direct. When partitions are used, the patient's view to the outside window(s) may be through no more than two separate clear vision panels. Windows shall be in accordance with subsection (t)(2)(A)(v) of this section.

(vii) Hand washing fixtures with hands-free operable controls shall be located in or adjacent to the nurse station, inside of each room at the entrance of the room, and at a ratio of one fixture to each three beds for an open ward layout. Hand washing fixtures shall be sized to contain splashing and conveniently distributed throughout the ward. When a combination modular swivel/fixed toilet and hand washing fixture is provided, hospital administration shall provide a letter (on hospital letterhead) indicating if the toilet is for staff convenience (bed pan washing) or for patient use.

(I) If the toilet is for patient use, an additional hand washing fixture shall be provided in each room at the entrance of the room. If the modular toilet/hand washing unit is for patient use, provision shall be made for patient privacy and odor control. The toilet room exhaust shall be in accordance with Table 3 of §133.169(c) of this title.

(II) When the modular toilet/hand washing unit is for staff use, it shall be near the entrance to the room.

(viii) The nurse station shall be located to permit direct visual observation of each patient served. Video cameras or mirrors shall not be substituted for direct visual observation. The nurse station shall have space for counters and storage. The counter height shall not exceed 42 inches. The nurse station may be combined with or include centers for reception and communication.

(ix) When individual nurse substations are provided and located at each patient room(s), they shall be located to permit direct visual observation of each patient served. The nurse substation shall have space for a counter, storage space and a recessed sitting space. The substation shall, at a minimum, be recessed one foot six inches from the egress corridor.

(x) Storage and preparation of medication may be done from a room, alcove area or from a self-contained dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks are not acceptable for hand washing.

(xi) An intravenous solution support shall be provided at each patient crib, bed or bassinets. The intravenous solution shall not be suspended directly over the patient.

(xii) Storage space shall be provided for emergency equipment in the unit.

(C) CCCU. When a CCCU is provided, the CCCU shall comply with the requirements contained in subparagraph (B) of this paragraph and the following.

(i) Each CCCU bed shall be in a separate room. Equipment for monitoring cardiac patients shall be provided by visual display both at the bed location and at the nurse station.

(ii) Each coronary patient shall have direct access to a toilet room and a hand washing fixture. Swivel type commodes may be utilized in lieu of individual toilet rooms, but provision must be made for patient privacy and odor control. The toilet room exhaust rate shall be in accordance with Table 3 of §133.169(c) of this title.

(iii) When medical, surgical, and coronary critical care services are combined in one CCU suite, at least 50% of the beds shall be located in private rooms. (Note: Medical/surgical patients may utilize open areas or private critical care rooms as needed and available but, insofar as possible, coronary patients should not be accommodated in open ward areas.)

(D) PCCU. When a PCCU is provided, the unit shall comply with the requirements contained in subparagraph (B) of this paragraph and the following.

(i) The PCCU may be an open ward, private rooms, or combination of both. When an open ward plan is used, one private room is required for each 10 beds or fraction thereof.

(ii) In a multiple-bassinet/crib (sleeping unit) room/ward the clearance between the side of the sleeping unit and a wall/partition shall be a minimum of five feet. The clearance between sides of sleeping units shall be a minimum of eight feet. The minimum distance at the foot of the bassinet shall not be less than ten feet for single load area/room or sixteen feet for double load area/room. Four feet of the passage space requirement at the foot of the bassinet may be shared between two bassinets. The fixed and moveable cabinets and shelves shall not encroach upon the bassinet/crib clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram K of §133.169(h) of this title.

(iii) A sleeping space shall be provided for parents who spend long hours with the patient. This space may be within the patient room or separate from the patient area but shall be in communication with the PCCU staff.

(iv) Hand washing fixtures with hands-free operable controls shall be provided in each room near the entrance of the room, and in open wards at a minimum ratio of one fixture to each three cribs, beds or bassinets. Hand washing fixtures shall be sized to contain splashing.

(v) A room shall be provided for private discussions and shall be located within, or convenient to, the PCCU. The multipurpose room noted in subparagraph (F)(v) of this paragraph will meet this requirement if conveniently located.

(vi) Storage space for infant formula shall be provided. This functional space may be outside the PCCU but shall be available for use at all times.

(vii) Storage cabinets or closets for toys and games shall be provided within the unit.

(viii) Storage area for cots, bed linens, and other items needed for overnight accommodation of parents shall be provided in the general location of sleeping accommodations.

(ix) An examination/treatment room with a minimum of 120 square feet of clear floor area shall be located in or near the PCCU suite. The room shall contain a hand washing fixture with hands-free operable controls, storage facilities, counter, or shelf space for writing. This requirement does not apply when all patient rooms are private rooms.

(E) Additional service spaces. The following additional service spaces shall be immediately available within each type of CCU(s). These may be shared by more than one CCU (unless otherwise noted) provided that direct access is available from each.

(i) Securable closets. Securable closets or cabinet compartments for the personal effects of nursing personnel, located in or near the nurse station, shall be provided. At a minimum, these shall be large enough for purses and billfolds. Coats may be stored in closets or cabinets on each floor or in a central staff locker area.

(ii) Charting and dictation area(s) for physicians. Space for recording, record storage and reviews shall be provided near cribs, beds or bassinets. Dictation space may be in a separate room or alcove. Suitable space shall be provided when computers are used for the clinical records.

(iii) X-ray viewing area. Each type of CCU shall be provided with an X-ray viewing area and film illuminators for handling at least four films simultaneously. When the entire CCU suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(iv) Nourishment station. The nourishment station shall contain a sink with hands-free operable controls, work counter, refrigerator, cabinets, and not be located in the medication room or the clean workroom. Space shall be included for temporary holding of unused or soiled dietary trays.

(v) Ice machine. The ice machine shall provide ice for treatment and patient use. Ice-making equipment for treatment may be in the clean workroom or the nourishment station.

(vi) Equipment storage. In addition to above, twenty square feet of equipment storage shall be provided for each patient station. These storage areas shall be out of the way of the corridor traffic.

(vii) Stretcher storage alcove. The alcove provided for stretcher or bassinet storage shall be located out of direct line of traffic.

(viii) Clean workroom. The room shall contain a work counter, a hand washing fixture with hands-free operable controls, and storage facilities for clean and sterile supplies.

(ix) Clean linen storage. There shall be a designated area for clean linen storage. This may be within a clean workroom, a separate closet, or an approved distribution system. If a closed cart system is used, storage of the cart may be in an alcove.

(x) Soiled workroom. The soiled workroom shall contain a work counter, a clinical sink with hands-free operable controls or equivalent flushing rim type fixture with hot and cold mixing faucet, separate hand washing facilities, and separate waste and soiled linen receptacles.

(xi) Soiled holding room. When provided, soiled holding rooms used only for temporary holding of soiled material may omit the clinical sink and work counter.

(xii) Housekeeping room. A housekeeping room shall be provided within or immediately adjacent to the CCU. It shall not be shared with other nursing units or departments.

(F) Other required areas/rooms. The following areas/rooms shall be provided and may be located outside the unit if conveniently accessible.

(i) Waiting space. A visitors' waiting space shall be provided with toilet facility(ies), public telephone(s), and drinking fountain(s). One waiting space may serve other CCUs.

(ii) Offices. Room(s) shall be provided for critical care medical and nursing management and administrative personnel. The offices shall be large enough to permit consulting with members of the critical care team and visitors. The offices shall be linked with the unit by telephone or an intercommunications system.

(iii) Staff lounge. A staff lounge shall include toilet facilities with a hand washing fixture with hands-free operable controls. The lounge(s) shall be located so that staff may be recalled quickly to the patient area in emergencies. One lounge may serve multiple CCUs when the lounge is adjacent to the units. Toilet facilities may be shared as long as privacy is maintained for changing areas.

(iv) On-call rooms. Physicians and other staff on 24-hour on-call work schedules shall be provided with sleeping rooms with access to a shower(s), toilet(s), and lavatory(ies). If on-call room(s) are not within the CCU served, a dedicated telephone or intercom system shall connect the on-call room(s) to the CCU(s).

(v) Multipurpose room(s). A multipurpose room for staff, patients, and patients' families for patient conferences, reports, education, and training sessions shall be provided. This room(s) must be accessible to each nursing unit.

(vi) A consultation room shall be provided, if not provided elsewhere in the unit.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) At least one door to a CCU room shall be not less than four feet wide (41.5 inches clear width) and arranged to minimize interference with movement of beds and large equipment.

(ii) Sliding doors in CCUs shall not have floor tracks at the latch side of the sliding panel, have hardware that minimizes jamming possibilities, and be in accordance with §133.162(d)(2)(A)(vi) of this title.

(iii) Glazing in viewing panels shall be safety glass, wire glass, or clear plastic.

(iv) Noise control and sound attenuation in an open ward environment shall be a design factor and meet the requirements contained in Table 1 of §133.169(a) of this title.

(v) Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over CCU(s), unless special provisions are made to minimize such noise.

(B) Finishes.

(i) Flooring used in soiled workrooms shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in the soiled workroom shall be monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Room recirculating units shall not be used.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Receptacles at each bed location in a CCU(s) shall be served by two branch circuits, one or more from the critical branch panel of the emergency electrical system and one or more from the normal system. One critical branch circuit shall serve only one bed location. All branch circuits from the normal system shall be from a single panelboard. All branch circuits from the emergency electrical system shall be from a single panelboard.

(ii) A minimum of seven hospital grade duplex outlets shall be conveniently located at the head of each bed, crib or bassinet. At least three of these duplex outlets shall be on the critical branch of the emergency electrical system.

(iii) Hospital grade receptacles in the PCCU shall be tamper-resistant or provided with GFCIs.

(B) Nurses calling systems. The nurse call system shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(e) Dietary suite.

(1) Architectural requirements.

(A) General. Construction, equipment, and installation shall comply with §§229.161-229.171 of this title (relating to Texas Food Establishments).

(B) Food service facilities. Food services shall be provided by an on-site food preparation system or an off-site food service system or a combination of the two. The following minimum functional elements shall be provided on site regardless of the type of dietary services.

(i) Dining area. Provide dining space(s) for ambulatory patients, staff, and visitors. These spaces shall be separate from the food preparation and distribution areas.

(ii) Receiving area. This receiving area shall have direct access to the outside for incoming dietary supplies or off-site food preparation service and shall be separate from the general receiving area. The receiving area shall contain a control station and an area for breakout for loading, unloading, uncrating, and weighing supplies. The entrance area to the receiving area shall be covered from the weather.

(iii) Storage spaces. Storage spaces shall be convenient to receiving area and food preparation area and shall be located to exclude traffic through the food preparation area. Regardless of the type of food services provided, the facility shall provide storage of food for emergency use for a minimum of four calendar days.

(I) Storage space(s). Storage space(s) shall be provided for bulk, refrigerated, and frozen foods.

(II) Cleaning supply storage. This room or closet shall be used to store nonfood items that might contaminate edibles. This storage area may be combined with the housekeeping room.

(iv) Food preparation area. Counter space shall be provided for food prep work, equipment, and an area to assemble trays for distribution for patient meals.

(v) Ice-making equipment. Ice-making equipment shall be provided for both drinks and food products (self-dispensing equipment) and for general use (storage-bin type equipment).

(vi) Hand washing. Hand washing fixtures with hands-free operable controls shall be conveniently located at all food preparation areas and serving areas.

(vii) Food service carts. When a cart distribution system is provided, space shall be provided for storage, loading, distribution, receiving, and sanitizing of the food service carts. The cart traffic shall be designed to eliminate any danger of cross-circulation between outgoing food carts and incoming soiled carts, and the cleaning and sanitizing process. Cart circulation shall not be through food processing areas.

(viii) Ware washing room. A ware washing room equipped with commercial type dishwasher equipment shall be located separate from the food preparation and serving areas. Space shall be provided for receiving, scraping, sorting, and stacking soiled tableware and for transferring clean tableware to the using areas. Hand washing facilities with hands-free operable controls shall be located within the soiled dish wash area. A physical separation to prevent cross-traffic between "dirty side" and "clean side" of the dish wash areas shall be provided.

(ix) Pot washing facilities. A three compartmented sink of adequate size for intended use shall be provided convenient to the food preparation area. Supplemental heat for hot water to clean pots and pans shall be by booster heater or by steam jet.

(x) Waste storage room. A food waste storage room shall be conveniently located to the food preparation and ware washing areas but not within the food preparation area. It shall have direct access to the hospital's waste collection and disposal facilities.

(xi) Sanitizing facilities. Storage areas and sanitizing facilities for garbage or refuse cans, carts, and mobile tray conveyors shall be provided. All containers for trash storage shall have tight-fitting lids.

(xii) Housekeeping room. A housekeeping room shall be provided for the exclusive use of the dietary department. Where hot water or steam is used for general cleaning, additional space within the room shall be provided for the storage of hoses and nozzles.

(xiii) Office spaces. An office shall be provided for the use of the food service manager or the dietary service manager. In smaller facilities, a designated alcove may be located in an area that is part of the food preparation area.

(xiv) Toilets and locker spaces. A toilet room(s) with a hand washing fixture(s) with hands-free operable controls shall be provided for the exclusive use of the dietary staff. Toilet room(s) shall not open directly into the food preparation areas, but must be in close proximity to them. For larger facilities, a locker room or space for lockers shall be provided for staff belongings.

(C) Additional service areas, rooms and facilities. When an on-site food preparation system is used, in addition to the items required in subparagraph (B) of this paragraph, the following service areas, rooms and facilities shall be provided.

(i) Food preparation facilities. When food preparation systems are provided, there shall be space and equipment for preparing, cooking, and baking.

(ii) Tray assembly line. A patient tray assembly and distribution area shall be located within close proximity to the food preparation and distribution areas.

(iii) Food storage. When food is prepared on site, the storage room shall be adequate to accommodate food for a seven calendar day menu cycle.

(iv) Additional storage room(s). An additional room(s) shall be provided for the storage of cooking wares, extra trays, flatware, plastic and paper products, and portable equipment.

(v) Drying storage area. Provisions shall be made for drying and storage of pots and pans from the pot washing room.

(D) Equipment. Equipment for use in the dietary suite shall meet the following requirements.

(i) Mechanical devices shall be heavy duty, suitable for the use intended, and easily cleaned. Where equipment is movable, provide heavy duty locking casters. Equipment with fixed utility connections shall not be equipped with casters.

(ii) Floor, wall, and top panels of walk-in coolers, refrigerators, and freezers shall be insulated. Coolers and refrigerators shall be capable of maintaining a

temperature down to freezing. Freezers shall be capable of maintaining a temperature of 20 degrees below 0 degrees Fahrenheit. Coolers, refrigerators, and freezers shall be thermostatically controlled to maintain desired temperature settings in increments of two degrees or less. Interior temperatures shall be indicated digitally and visible from the exterior. Controls shall include audible and visible high and low-temperature alarm. The time of alarm shall be automatically recorded.

(iii) Walk-in units may be lockable from the outside but must have a release mechanism for exit from inside at all times. The interior shall be lighted. All shelving shall be corrosion-resistant, easily cleaned, and constructed and anchored to support a loading of at least 100 pounds per linear foot.

(iv) All cooking equipment shall be equipped with automatic shutoff devices to prevent excessive heat buildup.

(E) Vending services. When vending machines are provided, a dedicated room or an alcove shall be located so that access is available at all times.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Food storage shelves shall not be less than four inches above the finished floor and the space below the bottom shelf shall be closed in and sealed tight for ease of cleaning.

(ii) Operable windows and doors not equipped with automatic closing devices shall be equipped with insect screens.

(iii) Food processing areas in the central dietary kitchen shall have ceiling heights not less than nine feet. Ceiling-mounted equipment shall be supported from rigid structures located above the finished ceiling.

(iv) Mirrors shall not be installed at hand washing fixtures in the food preparation areas.

(B) Finishes.

(i) Floors in areas used for food preparation, food assembly, soiled and clean ware cleaning shall be water-resistant and grease-proof. Floor surfaces, including tile joints, shall be resistant to food acids.

(ii) Wall bases in food preparation, food assembly, soiled and clean ware cleaning and other areas which are frequently subject to wet cleaning methods shall be made integral and coved with the floor, tightly sealed to the wall, constructed without voids that can harbor insects, retain dirt particles, and be impervious to water.

(iii) In the dietary and food preparation areas, the wall construction, finishes, and trim, including the joints between the walls and the floors, shall be free of voids, cracks, and crevices.

(iv) The ceiling in food preparation and food assembly areas shall be washable as required by §133.162(d)(2)(B)(vi)(II) of this title.

(v) The ceiling in the soiled and clean ware cleaning area shall be of the monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Exhaust hoods handling grease-laden vapors in food preparation centers shall comply with National Fire Protection Association 96, Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations, 2001 edition. All hoods over cooking ranges shall be equipped with grease filters, fire extinguishing systems, and heat-actuated fan controls. Clean out openings shall be provided every 20 feet and at any changes in direction in the horizontal exhaust duct systems serving these hoods. (Horizontal runs of ducts serving range hoods should be kept to a minimum.)

(B) When air change standards in Table 3 of §133.169(c) of this title do not provide sufficient air for proper operation of exhaust hoods (when in use), supplementary filtered make-up air shall be provided in these rooms to maintain the required airflow direction and exhaust velocity. Make-up systems for hoods shall be arranged to minimize "short circuiting" of air and to avoid reduction in air velocity at the point of contaminant capture.

(C) Air handling units serving the dietary suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) The kitchen grease traps shall be located and arranged to permit easy access without the need to enter food preparation or storage areas. Grease traps shall be of capacity required and shall be accessible from outside of the building without need to interrupt any services.

(B) Grease traps or grease interceptors shall be located outside the food preparation area and shall comply with the requirements in the National Association of Plumbing-Heating-Cooling Contractors (PHCC), National Standard Plumbing Code, 2000 edition. This publication may be obtained from the National Association of Plumbing-Heating-Cooling Contractors, 180 South Washington Street, Falls Church, VA 22046; telephone (703) 237-8100.

(C) The material used for plumbing fixtures shall be nonabsorptive and acid-resistant.

(D) Water spouts used at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and containers.

(E) Hand washing fixtures used by food handlers shall be trimmed with valves that can be operated without hands. Single lever or wrist blade devices may be used. Blade handles used for this purpose shall not be less than four inches in length.

(F) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in food preparation centers, food serving facilities and food storage areas unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(G) No plumbing lines may be exposed overhead or on walls where possible leaks would create a potential for food contamination.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) Exhaust hoods shall have an indicator light indicating that the exhaust fan is in operation.

(B) The electrical circuit(s) to equipment in wet areas shall be provided with five milliampere GFCI.

(f) Emergency suite. This subsection applies to all hospitals (general or special) included under the hospital license, including those licensed as a multiple-location hospital.

(1) Architectural requirements.

(A) Emergency treatment area.

(i) Emergency treatment room. As a minimum requirement, all hospitals shall provide at least one emergency treatment room and facilities to handle emergencies. The room(s) and facilities shall meet the following requirements.

(I) The emergency treatment room for a single patient shall have a minimum clear area of 120 square feet clear floor area exclusive of fixed and movable cabinets and shelves. The minimum clear room dimension exclusive of fixed cabinets and built-in shelves shall be 10 feet. The emergency treatment room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls.

(II) When a multiple-bed emergency treatment room is provided, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of four feet. The clearance between the sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed emergency treatment room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this subclause are illustrated in Table 8, Diagram C of §133.169(h) of this title.

(III) One hand washing fixture with hands-free operable controls shall be provided for each bed/gurney location. One hand washing fixture may serve two beds/gurneys if distributed appropriately between the two.

(IV) Storage space shall be provided within the room or suite and be under staff control for general medical-surgical emergency supplies and medications. Adequate space shall be provided for emergency equipment such as emergency treatment trays, ventilator, defibrillator, splints, cardiac monitor, etc.

(V) Locked storage space shall be provided for drugs and an area for preparation of medication with a work counter, refrigerator, and hand washing fixture with hands-free operable controls.

(VI) An alcove shall be provided for stretcher and wheelchair storage. The storage shall be located out of the line of traffic.

(VII) Patient toilet room(s) shall be provided and shall be convenient to treatment rooms, examination rooms, and holding rooms, and a hand washing fixture with hands-free operable controls.

(VIII) In a special hospital, comprehensive medical rehabilitation hospital, or pediatric and adolescent hospital, the emergency treatment room and facilities may be located anywhere in the hospital.

(ii) Additional requirements for a general hospital. Except for comprehensive medical rehabilitation hospitals and pediatric and adolescent hospitals that generally provide care that is not administered for or in expectation of compensation, a general hospital shall also meet the following requirements.

(I) Emergency entry signage. An emergency sign shall be provided at the entry from the public road(s) or street(s) serving the site. The emergency sign at the entry to the site shall be illuminated and connected to the emergency essential electrical system. Additional sign(s) on-site may be required to direct patients to the emergency treatment area entrance when the emergency treatment area is not visible from the site entry. The letters on the entry sign shall be red with a contrasting background, all capitalized, at least eight inches in height, and an arrow indicating direction.

(II) Entrances. Separate ambulance and pedestrian entrances at grade level shall be well-illuminated, identified by signs, and protected from inclement weather. The ambulance entry shall have a drive under canopy for protection from inclement weather. The emergency access to permit discharge of patients from automobile and ambulances shall be paved. Parking shall be provided near and convenient to the pedestrian entrance.

(III) Control station. A registration, reception, discharge or control station shall be located to permit staff observation and control of access to treatment room(s), pedestrian and ambulance entrances, and public waiting area(s). When a dedicated triage space is provided, it shall include a counter with a hand washing fixture with hands-free operable controls.

(IV) Public waiting room. A public waiting room shall be provided.

(V) Public facilities. Toilet facilities, public telephone(s), and drinking fountain(s) shall be provided for the exclusive use of the waiting room.

(VI) Diagnostic radiographic (X-ray) room. Imaging facilities for diagnostic services shall be readily available to the emergency suite. If a separate radiographic (X-ray) room is installed within the emergency suite, it shall comply with the requirements in subsection (l)(1)(A) of this section. When the diagnostic X-ray room is exclusively used for the emergency treatment area, the dressing rooms may be omitted.

(VII) Laboratory unit. Laboratory services shall be made available to the emergency suite. If a separate laboratory workroom is installed within the emergency suite, it shall comply with the requirements in subsection (n)(1)(C)(i) of this section. All laboratory services provided on site or by contractual arrangement shall comply with §133.41(h) of this title (relating to Hospital Functions and Services).

(VIII) Medical staff work area and charting area(s). A medical staff work area and charting area(s) shall be provided. The area may be combined with the reception and control area.

(IX) Clean storage room. A clean storage room shall be provided for clean supplies, linens and medications as needed. A hand washing fixture shall be provided with hands-free operable controls.

(X) Soiled workroom. The workroom shall contain a work counter, a clinical sink or equivalent flushing type fixture, hand washing fixture with hands-free operable controls, waste receptacles, and soiled linen receptacles.

(XI) Housekeeping room. The housekeeping room shall contain a floor receptor or service sink, storage space for housekeeping supplies and equipment,

and be located within the suite. When automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided.

(XII) Staff toilets. Toilets may be outside the suite but shall be convenient for staff use and include hand washing fixtures with hands-free operable controls. When a department has four or more treatment or examination rooms, toilet facilities shall be in the suite.

(iii) Other rooms. If a hospital provides the following rooms, the rooms shall meet these requirements.

(I) Examination room. When provided, the examination room for a single patient shall have a minimum clear area of 100 square feet clear floor area exclusive of fixed and movable cabinets and shelves. The minimum clear room dimension exclusive of fixed cabinets and built-in shelves shall be 9 feet. The examination room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls.

(II) Multi-bed examination room. In a multiple-bed examination room the clearance between the side of the bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of the beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed examination room shall contain cabinets, work counters, and a hand washing fixture with hands-free operable controls. One hand washing fixture shall be provided for every four beds/gurneys or fraction thereof. Fixtures shall be uniformly distributed. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area.

(III) Isolation room. The need for an airborne infection isolation room in the emergency suite shall be determined by the hospital and the infection risk assessment. When the hospital provides treatment rooms to perform procedures on persons who are known or suspected of having an airborne infectious disease, these procedures shall be performed in a designated treatment room meeting airborne infection isolation ventilation requirements. The isolation room shall have functional space in accordance with clause (i)(I) of this subparagraph, and meet the ventilation requirements contained in Table 3 of §133.169(c) of this title.

(IV) Secured holding room. When provided, this room shall be constructed to allow for security, patient and staff safety, patient observation, and sound mitigation. The secure holding room shall have a minimum clear area of 100 square feet clear floor area exclusive of fixed cabinets. The minimum clear room dimension exclusive of fixed cabinets shall be 10 feet.

(V) Orthopedic and cast room. The room(s) may be in separate room(s) or in the trauma room. The room(s) shall contain a work counter, storage for splints and orthopedic supplies, traction hooks, medication storage, examination light, and a hand

washing fixture with hands-free operable controls. When a cast room is provided it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures.

(VI) Film processing room. When a radiographic (X-ray) room is provided, a darkroom for processing film shall be provided unless the processing equipment does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the darkroom.

(VII) Decontamination room. A decontamination room shall have an exterior entry point and as far as practical from any other entry point to the emergency treatment area. The internal door from the decontamination room shall open directly to the corridor into the emergency treatment area. The door shall swing into the room and be lockable against ingress from the corridor. The room shall be a minimum of 80 square feet of clear floor area with a hand washing fixture with hands-free operable controls.

(B) Holding or observation room/area.

(i) When a holding or observation room/area is provided within or adjacent to the emergency suite, it shall comply with the following.

(I) A single holding/observation room shall have a minimum clear area of 100 square feet exclusive of fixed and movable cabinets and shelves. The holding/observation room shall contain a work counter and hand washing fixture with hands-free operable controls.

(II) The single holding/observation room shall be near the nurses station and near a patient toilet room which contains a hand washing fixture with hands-free operable controls.

(III) In a multiple-bed holding/observation room/area, the clearance between the side of the bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of the beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed holding/observation room/area shall contain cabinets, work counters, and a hand washing fixture with hands-free operable controls. One hand washing fixture shall be provided for every four holding/observation beds or fraction thereof. Fixtures shall be uniformly distributed. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this subclause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(IV) In a multiple-bed holding/observation room/area, a patient toilet room with a hand washing fixture with hands-free operable controls shall be provided within the room or area.

(ii) When a multiple-bed gurney holding or observation room is not within or adjacent to the emergency suite, the following additional spaces shall be provided:

(I) stretcher and wheelchair storage alcove. The alcove provided for stretcher and wheelchair storage shall be located out of the line of traffic;

(II) clean storage room. A clean storage room shall be provided within or adjacent to the holding or observation room. The clean storage room shall be provided for clean supplies, linen and medication as needed. A hand washing fixture shall be provided with hands-free operable controls;

(III) soiled workroom. A soiled workroom shall be provided within or adjacent to the holding or observation room. The workroom shall contain a work counter, a clinical sink or equivalent flushing type fixture, hand washing fixture with hands-free operable controls, waste receptacles, and soiled linen receptacles; and

(IV) housekeeping room. A housekeeping room shall be provided within or near the holding or observation room. The housekeeping room shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(C) Trauma center. When provided, a trauma center shall comply with subparagraph (B) of this paragraph and in addition contain the following.

(i) Trauma room. A minimum of one trauma room shall be provided with 250 square feet of clear floor area exclusive of aisles and fixed and moveable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 12 feet. The trauma room shall contain a work counter, cabinets, medication storage, and examination light.

(ii) Multiple-station trauma room. When multiple-patient stations are provided, the clearance between the head of the bed/gurney to the wall/partition shall be a minimum of three feet. The clearance between the side of a bed/gurney and a wall/partition shall be a minimum of six feet. The clearance between the sides of beds/gurneys shall be a minimum of twelve feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed trauma room shall contain cabinets, medication storage, work counter, examination light, and scrub sink with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagrams E of §133.169(h) of this title. Provisions shall be made for visual privacy between multiple stations.

(iii) Scrub facilities. A scrub station shall be located at the entrance to each trauma room either inside or outside of the room. One scrub station may serve two trauma beds/gurneys. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts. The scrub sinks shall be recessed out of the main line of traffic.

(iv) Doorways. All doorways openings from the ambulance entrance to the trauma room shall be a minimum of five feet wide.

(D) Emergency clinic. When an emergency clinic (which may also be referred to as "urgent care", "fast track", "express care", "minor care", etc.) is provided, the clinic shall be separate and distinct from the emergency treatment area and trauma center and shall meet all the requirements of subparagraph (A) of this paragraph. All facilities required by subparagraph (A) of this paragraph may be shared with the emergency treatment area and trauma center except for the emergency treatment room. The emergency treatment room(s) in the emergency clinic shall not be less than 100 square feet. The emergency exam room(s) in the emergency clinic shall not be less than 80 square feet.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Trauma rooms shall have ceiling heights not less than nine feet.

(ii) The decontamination room shall be equipped with two hand-held showerheads with temperature controls and a dedicated holding tank with a floor drain.

(B) Finishes.

(i) Flooring used in a trauma room, treatment room, examination room, holding area, and soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title. Seamless type flooring is not required in the examination room in the emergency clinic.

(ii) Ceilings in soiled workrooms, isolation rooms, and trauma rooms shall be of the monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(iii) The decontamination room floor shall be self-coved to a height of six inches. The room shall have all smooth, nonporous, scrubable, nonabsorbent and nonperforated surfaces.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Duct linings exposed to air movement shall not be used in ducts serving any trauma rooms, treatment rooms, examination rooms, holding areas, and clean room. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(B) When a trauma room is provided under paragraph (1)(C)(i) of this subsection, the air supply for the trauma/surgical room shall be from ceiling outlets that are as

near the work centers as possible, and a minimum of two low return inlets shall be located diagonally opposite from one another.

(C) Return air inlets shall be not lower than four inches nor higher than 12 inches from floor level.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) Medical gas systems. Medical gas systems shall be provided in accordance with §133.162(d)(4)(A)(iii) of this title.

(B) Ice machine. An ice machine shall be provided for therapeutic purposes and shall be located in the clean utility room. A self-dispensing ice machine shall be provided for ice for human consumption.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Each treatment and examination room in the emergency treatment area and trauma center shall have a minimum of six duplex electrical receptacles located convenient to the head of each bed.

(ii) Each treatment and examination room in the emergency clinic suite shall have a minimum of four duplex electrical receptacles located convenient to the head of each bed/table.

(iii) Each work counter and table shall have access to at least one duplex receptacle connected to the critical branch of the emergency electrical system.

(iv) The hospital shall provide X-ray film illuminators for handling at least four films simultaneously in all treatment, examination, and trauma rooms in the emergency treatment area. When the entire emergency treatment area is provided with digital imaging, a minimum of two X-ray film illuminators shall be provided within a central location within the emergency treatment area.

(B) Nurses calling systems. The nurse call system shall be in accordance with §133.162(d)(5)(L) of this title and Table 7 of §133.169(g) of this title.

(g) Employees suite.

(1) Architectural requirements.

(A) Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(B) Lockers, lounges, toilets and showers shall be provided within the hospital for employees and volunteers. These facilities are in addition to, and separate from, those required for the medical staff and the public.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(h) Engineering suite and equipment areas.

(1) Architectural requirements. Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(A) General. The following facilities shall be provided:

(i) an engineer's office with file space and provisions for protected storage of facility drawings, records, manuals, etc.;

(ii) a general maintenance shop(s) for repair and maintenance;

(iii) a separate room(s) for building maintenance supplies and equipment. Storage of bulk solvents and flammable liquids shall be in a separate building and not within the hospital building;

(iv) a medical equipment room which includes provisions for the storage, repair, and testing of electronic and other medical equipment;

(v) a separate room or building for yard maintenance equipment and supplies. When a separate room is within the physical plant the room shall be located so that equipment may be moved directly to the exterior. Yard equipment or vehicles using flammable liquid fuels shall not be stored or housed within the general hospital building; and

(vi) sufficient space in all mechanical and electrical equipment rooms for proper maintenance of equipment. Provisions shall also be made for removal and replacement of equipment.

(B) Additional areas or room(s). Additional areas or room(s) for mechanical, and electrical equipment shall be provided within the physical plant or installed in separate buildings or weatherproof enclosures with the following exceptions.

(i) An area shall be provided for cooling towers and heat rejection equipment when such equipment is used.

(ii) An area for the medical gas park and equipment shall be provided. For smaller medical gas systems, the equipment may be housed in a room within the physical plant in accordance with National Fire Protection Association 99, Standard for Health Care Facilities, 2002 edition (NFPA 99), Chapters 4 and 8.

(iii) When provided, compactors, dumpsters, and incinerators shall be located in an area remote from public entrances.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(i) General stores.

(1) Architectural requirements. Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(A) General. In addition to storage facilities in individual departments, a central storage room shall be provided. General stores may be located in a separate building on-site with provisions for protection against inclement weather during transfer of supplies.

(B) Receiving. Facilities for central storage areas shall be provided with an off- street unloading and receiving area protected from inclement weather.

(C) General storage room. General storage room with a total area of not less than 20 square feet per inpatient bed shall be provided. The storage room may be within the facility, or separate building on-site. Fifty percent of the storage may be provided off-premises. When additional inpatient beds are constructed, additional general storage shall be provided.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(j) Hospital-based skilled nursing units.

(1) Architectural requirements. When a hospital-based skilled nursing unit is provided, each unit shall comply with the requirements contained in subsection (t)(1) of this section and the requirements listed below. The skilled nursing unit may be separated from the rest of the hospital with two-hour fire protection rated construction in order to define areas for certification inspections.

(A) At least 50% of patient rooms and bathrooms and all public and common use areas in a newly constructed, or reconstructed hospital-based skilled nursing unit, are required to be handicapped accessible in accordance with §133.162(d)(1)(D) of this title.

(B) At least 10% of patient rooms and bathrooms and all public and common use areas shall be made handicapped accessible in accordance with §133.162(d)(1)(D) of this title when remodeling a hospital-based skilled nursing unit or remodeling an existing nursing unit to a hospital-based skilled nursing unit.

(C) Activity and dining space shall be part of the unit. It may be located in a separate room or open to the corridor and shall be convenient to the unit. The floor area of this space shall provide at least 30 square feet per patient bed with a minimum of 160 square feet. Additional space shall be required if this space is also used for other programs.

(D) When physical and occupational therapy services are provided for rehabilitating patients, spaces and equipment that conform to program intent shall be provided. These spaces may be located in the unit or elsewhere in the hospital.

(E) Each unit shall have at least one assisted bathing wheelchair shower or tub room per floor or nursing unit. The bathtub shall be accessible to patients in wheelchairs or the shower shall accommodate a gurney. The room shall be centrally located, convenient to the units and shall be directly accessible from the corridor. The room shall have space for drying and dressing and provided with hand washing fixture with hands-free operable controls and toilet training facilities with three feet of clear space on sides and front of the water closet.

(F) A housekeeping room shall be provided for the exclusive use of the unit. The housekeeping room shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(2) Details and finishes. Each unit shall comply with the requirements contained in subsection (t)(2) of this section and this paragraph.

(A) All portions of corridor walls in the unit with an uninterrupted length of two feet or more shall have graspable handrails. The handrails shall comply with NFPA 101, §7.2.2.4, and the provisions found in Title 16 TAC, Chapter 68, Texas Accessibility Standards, April 1, 1994 edition, issued by the Texas Department of Licensing and Regulation, under the Texas Architectural Barriers Act, Texas Government Code, Chapter 469. No handrail shall protrude more than three and one-half inches into the egress corridor. All handrail ends shall be returned to the wall.

(B) Floor finishes shall comply with the requirements of §133.162(d)(2)(B)(iii) of this title.

(3) Mechanical requirements. Mechanical requirements in each unit shall be in accordance with subsection (t)(3) of this section.

(4) Plumbing fixtures and piping systems. The plumbing fixtures and piping systems shall be in accordance with subsection (t)(4) of this section.

(5) Electrical Requirements. Electrical requirements shall be in accordance with subsection (t)(5) of this section. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(k) Hyperbaric suite.

(1) Architectural requirements. When a hyperbaric suite is provided, it shall meet the requirements of Chapter 20, NFPA 99, and Chapter 18, NFPA 101.

(A) Hyperbaric chamber clearances. Multiple occupancy chambers (Class A) shall be in accordance with NFPA 99, Chapter 20. The minimum clearances for individual (Class B) hyperbaric chambers and the side of a chamber and a wall/partition shall be a minimum of three feet. The clearance between sides of chambers shall be a minimum of six feet. The minimum distance at the chamber entry shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the chamber entry may be shared between two chambers. The chamber room shall contain cabinets, medication storage, work counter and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the chamber clear floor space/area. The requirements of this subparagraph are illustrated in Table 8, Diagram F of §133.169(h) of this title.

(B) Service areas. The following minimum service areas and facilities shall be provided convenient to the hyperbaric chamber suite.

(i) Patient waiting area. The area shall be out of traffic, under staff control, and shall have seating capacity in accordance with the functional program. Outpatients and inpatients shall be provided with separate waiting areas with screening for visual privacy

between the waiting areas. Patient waiting areas may be omitted for two or less individual hyperbaric chamber units.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Holding area. A holding area under staff control shall accommodate inpatients on stretchers or beds. Stretcher patients shall be out of the direct line of normal traffic. The patient holding area may be omitted for two or less individual hyperbaric chamber units.

(iv) Patient toilet rooms. Toilet rooms shall be provided with hand washing fixtures with hands-free operable controls and with direct access from the hyperbaric suite.

(v) Patient dressing room(s). A dressing room(s) for outpatients shall be provided and shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate wheelchair patients.

(vi) Staff facilities. Toilets with hand washing fixtures with hands-free operable controls may be outside the suite but shall be convenient for staff use. These facilities may be shared with an adjacent suite.

(vii) Consultation room. An appropriate consultation room for individual consultation with referring clinicians shall be provided for outpatients. This room may be shared with an adjacent suite.

(viii) Storage space. A clean storage space shall be provided for clean supplies and linens. The space shall contain a hand washing fixture with hands-free operable controls. The storage room may be shared with another department if convenient to both.

(ix) Soiled holding room. A soiled holding room shall be provided with waste receptacles and soiled linen receptacles. This room may be shared with an adjacent suite.

(x) Hand washing. A lavatory equipped for hand washing with hands-free operable controls shall be located in the room where the hyperbaric chambers are located.

(xi) Housekeeping room. The housekeeping room shall contain a floor receptor or service sink, storage space for housekeeping supplies and equipment, and be located nearby.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) Grounding of hyperbaric chambers shall be connected only to the equipment ground in accordance with NFPA 99, §3-3.2.1.2, and National Fire Protection Association 70, National Electrical Code, 1999 edition, (NFPA 70), Article 250 (A)-(C), and Article 517.

(B) Additional grounds such as earth or driven grounds shall not be permitted.

(C) The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(l) Imaging suite.

(1) Architectural requirements.

(A) General. Each hospital shall have a diagnostic radiographic (X-ray) room convenient to emergency, surgery, cystoscopy, and outpatient suites.

(i) All diagnostic imaging room sizes shall be in compliance with the manufacturer's recommendations for the specific equipment. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(ii) When radiation protection is required for any diagnostic imaging room, a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602, shall specify the type, location, and amount of radiation protection to be installed for the layout and equipment selections.

(iii) Each room where radiation protection is required shall include a shielded control alcove. The control alcove shall be provided with a view window designed to permit full view of the examination table and the patient at all times.

(iv) Warning signs capable of indicating that the equipment is in use shall be provided.

(v) Diagnostic and procedure room intended for patients with airborne infectious diseases shall meet the ventilation requirements as contained in Table 3 of §133.169(c) of this title.

(B) Diagnostic X-ray and radiographic and fluoroscopy (R&F) rooms. X-ray and R&F rooms shall be in compliance with the manufacturer's recommendations for the specific equipment. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(i) A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) A toilet room shall be provided including a hand washing fixture with hands-free operable controls and have direct access to each R&F room and a corridor.

(C) Noninvasive angiography imaging room. When noninvasive angiography imaging is provided, the room shall have minimum clear floor area of 250 square feet exclusive of built-in shelves or cabinets. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(i) A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) A viewing room or area shall be provided and shall be a minimum of 10 feet in length. The viewing room or area may be provided in combination with the control room.

(iii) A scrub sink shall be near the entrance to each angiographic room and shall be recessed out of the main traffic areas or corridor. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts.

(iv) Storage space for portable equipment and supplies shall be provided.

(D) Computerized tomography (CT) scanning. When CT services are provided, the CT room(s) size shall be in compliance with the manufacturer's recommendations and shall contain the following.

(i) A control room shall be provided with a view window permitting view of the patient. The control room shall be located to allow convenient film processing.

(ii) A patient toilet shall be provided conveniently to the procedure room. When directly accessible to the scan room, the toilet shall be arranged so that a patient may leave the toilet room without having to reenter the scan room. The toilet room shall have a hand washing fixture with hands-free operable controls.

(E) Mammography. When mammography services are provided, the room(s) shall have a minimum clear floor area of 100 square feet exclusive of built-in shelves or cabinets.

(i) A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) When mammography machines with built-in shielding for the operator are provided, the alcove may be omitted when approved by a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602.

(F) Magnetic resonance imaging (MRI). When MRI services are provided, the room shall be of sufficient size to house equipment but no less than 325 square feet of clear floor area exclusive of built-in shelves or cabinets.

(i) A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) A separate computer room shall be provided to accommodate the equipment.

(iii) When cryogen is provided, a storage room or closet shall have a minimum clear floor area of 50 square feet for two large dewars of cryogen. A storage room or closet shall be required in areas where service to replenish supplies is not readily available.

(iv) When a darkroom is provided, the room shall be located near the required control room and shall be outside the 10-gauss field.

(v) When spectroscopy is provided, caution should be exercised in locating it in relation to the magnetic fringe fields.

(vi) Magnetic shielding may be required to restrict the magnetic field plot. Radio frequency shielding is required to attenuate stray radio frequencies.

(vii) A patient holding area shall be provided and shall be located near the MRI unit and be large enough to accommodate stretchers.

(viii) A hand washing fixture with hands-free controls shall be provided near the entrance to the MRI room and shall be recessed out of the main traffic areas or corridor.

(ix) A 3T or larger magnetic strength MRI shall be secured behind locked doors. The patient and staff entrance to the MRI shall have a traffic pattern from the waiting, dressing, holding and work areas through a lockable control station before entering the MRI. At no time shall patients or nonpatients be allowed to enter this restricted area without MRI staff present when the magnet is active.

(G) Ultrasound room. When ultrasound services are provided, the room(s) size shall be in compliance with the manufacturer's recommendations. A patient toilet room shall be provided convenient to the procedure room and a corridor. The toilet room shall have a hand washing fixture with hands-free operable controls.

(H) Cardiac catheterization laboratory. The cardiac catheterization laboratory is normally a separate suite, but may be within the imaging suite. If provided, a cardiac catheterization laboratory shall comply with the requirements of subsection (dd)(1)(C) of this section.

(I) Service areas. The following common service areas shall be provided.

(i) Patient waiting area. The area shall be out of traffic and under direct staff visual control. When the waiting area serves both outpatient and inpatients, separate areas shall be provided and include visual privacy between the waiting areas.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Holding area. The holding area shall be out of direct traffic patterns and under visual control by staff. A minimum of one stretcher station shall be provided for each three diagnostic and procedure rooms or fraction thereof. The minimum clear floor space in the holding area shall be 80 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The area shall contain cabinets, a work counter, and a hand washing fixture with hands-free operable controls. The holding area may be reduced to 50 square feet exclusive of aisles and fixed and moveable cabinets and shelves for mammography, bone density and other similar procedures.

(iv) Post-procedure observation room. When invasive diagnostic X-ray services for outpatients are provided with anesthesia, a room for extended post-procedure observation of patients shall be provided. The minimum clear floor space for the observation space shall be 100 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The room shall contain cabinets, a work counter, and a hand washing fixture with hands-free operable controls.

(v) Patient toilet rooms. Toilet room(s) with hand washing facilities shall be located convenient to the waiting area.

(vi) Patient dressing rooms or cubicles. Dressing rooms or cubicles shall be convenient to the waiting areas and X-ray rooms. Each room shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate wheelchair patients.

(vii) Hand washing facilities. A hand washing fixture with hands-free controls shall be provided in or near the entrance to each diagnostic and procedure room unless noted otherwise. When a hand washing fixture is provided in the room, the fixture shall be located near the entrance to the room or near the staff entrance. When a hand washing fixture

is located outside the room, the fixture shall be recessed in the egress corridor and located within five feet of the entrance to the room. Hand washing facilities shall be arranged to minimize any incidental splatter on nearby personnel or equipment.

(viii) Staff facilities. Toilets may be outside the suite and may be shared with other departments but shall be convenient for staff use. When four or more diagnostic or procedure imaging rooms are provided, a staff toilet is required with a hand washing fixture with hands-free controls.

(ix) X-ray film illuminator viewers. When all the diagnostic and imaging procedures are provided with digital imaging, two mounted X-ray film illuminator viewers shall be provided in the central viewing area/room.

(x) Contrast media preparation. This room shall include a work counter, a sink with hands-free operable controls, and storage. One preparation room may serve any number of rooms. When prepared media is used, this area may be omitted, but storage shall be provided for the media.

(xi) Film processing room. A darkroom shall be provided for processing film unless the processing equipment normally used does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the procedure rooms and to the quality control area.

(xii) Quality control area or room. An area or room for film viewing shall be located near the film processor. All view boxes shall be illuminated to provide light of the same color value and intensity.

(xiii) Film storage (active). When X-ray film is used, it shall be stored in a room with a cabinet or shelves for filing patient film for immediate retrieval.

(xiv) Film storage (inactive). When X-ray film is used, a room for inactive film storage shall be provided. It may be outside the imaging suite, but must be under the administrative control of imaging suite personnel and be properly secured to protect films against loss or damage.

(xv) Storage for unexposed film. When X-ray film is used, storage facilities for unexposed film shall include protection of film against exposure or damage.

(xvi) Storage of cellulose nitre film. When used, cellulose nitrate film shall be stored in accordance with the requirements of National Fire Protection Association 40, Standard for the Storage and Handling of Cellulose Nitrate Motion Picture Film, 1994 edition.

(xvii) Additional spaces. When four or more diagnostic or procedure rooms are provided in the hospital, the following shall be required:

- (I) office(s) for radiologist(s) and assistant(s);
- (II) clerical office spaces, as necessary for the functional program;
- (III) consultation area/room;
- (IV) medication station. Storage and preparation of medication shall be done from a room, alcove area, or from a self-contained dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks are not acceptable for hand washing;
- (V) clean storage room. Clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls. When conveniently located, the clean storage room may be shared with another department; and
- (VI) soiled workroom. The soiled workroom shall not have direct connection to the diagnostic and procedure rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and soiled linen receptacle. When contaminated soiled material or fluid waste is not handled, only a soiled holding room shall be required.
- (xviii) Housekeeping room. The room may serve multiple departments when conveniently located.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Radiation protection shall be designed, tested and approved by a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602.

(I) Room shielding calculations for linear accelerators, teletherapy units and remote control brachytherapy units must be submitted to the Department of State Health Services' Radiation Control (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by RC inspectors, in the field, subsequent to use. Any changes in design or shielding which affects radiation exposure levels adjacent to those rooms, requires prior approval by RC. The RC mailing address is: Radiation Control, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.

(II) Facility design and environmental controls associated with licensable quantities of radioactive material in laboratories and/or imaging rooms shall be approved by RC prior to licensed authorizations.

(ii) Where protected alcoves with view windows are required, provide a minimum of one foot six inches from the edge where the glazing and the frame connect and the outside partition edge.

(iii) Imaging procedure rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(B) Finishes.

(i) Flooring used in contrast media preparation and soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) A lay-in type ceiling is acceptable for the diagnostic and procedure rooms.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The cryogen gas venting from the MRI unit shall be exhausted to the exterior. When a cryogen storage room is provided to replenish supplies, the storage room shall be vented and exhausted to the exterior.

(B) Self-contained air conditioning to supplement the cooling capacity in computer rooms is permitted.

(C) Air handling units serving the imaging suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph. When automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Each imaging procedure room shall have at least four duplex electrical receptacles.

(ii) A special grounding system in areas such as imaging procedures rooms where a patient may be treated with an internal probe or catheter shall comply with Chapter 9 of NFPA 99, and Article 517 of NFPA 70.

(iii) General lighting with at least one light fixture powered from a normal circuit shall be provided in imaging procedures rooms in addition to special lighting units at the procedure or diagnostic tables.

(B) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(m) Intermediate care suite (Step down suite).

(1) Architectural requirements.

(A) General. The requirements in this subsection apply to intermediate care units for acute care patients who require frequent monitoring that exceed the level of care for nursing units and less than that provided in critical care units. The suite may share services with an adjacent suite.

(B) Intermediate care services and facilities. The following services and facilities shall apply to all classifications of intermediate care unless otherwise noted.

(i) In a single-bed patient room, the minimum clear floor area shall be 150 square feet exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. A minimum of 12 feet width shall be provided for the head wall for each bed. A hand washing fixture with hands-free operable controls shall be located in the patient room and in the patient bathroom.

(ii) In a multi-bed intermediate care patient room the maximum capacity shall be no more than four patients per room. In a multiple-bed open ward patient room, the clearance between the side of a bed and a wall/partition shall be a minimum of four feet. The clearance between sides of beds shall be a minimum of eight feet. The minimum distance at the foot of the bed shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds. The ward shall contain cabinets, work counter, and washing fixture with hands-free operable controls located centrally to the beds. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram P of §133.169(h) of this title.

(iii) Each single-bed or multi-bed open ward patient room shall have access to a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet, a hand washing fixture with hands-free operable controls, bathing facilities, and a storage shelf or cabinet.

(iv) Each single and open ward patient room shall be located on an exterior wall and shall have a window. In a ward, one window may serve more than one patient. The window sill height shall not exceed three feet above the floor. Patient beds shall not be located more than 50 feet from an exterior window. Patients' views to outside windows shall be

direct and not through other clear vision panels. Windows shall be in accordance with subsection (t)(2)(A)(iv) and (v) of this section.

(v) The nurse station shall be located to permit direct visual observation of each patient served. Video cameras or mirrors shall not be substituted for direct visual observation. The nurse station shall have space for counters and storage. The counter height shall not exceed 42 inches. The nurse station may be combined with or include centers for reception and communication. In multi-bed intermediate care patient room the nurse station shall be located within the room and have space for counters and storage.

(vi) When individual nurse substations are provided and located at each patient room(s), they shall be located to permit direct visual observation of each patient served. The nurse substation shall have space for counter, storage space and a recessed sitting space. The substation shall be at a minimum recessed from the egress corridor one foot six inches.

(vii) Visual privacy shall be provided each patient in multi-bed rooms. Design for privacy shall not restrict independent patient access to the corridor, lavatory, or bathroom.

(viii) Each patient shall have a separate wardrobe, locker, or closet that is suitable for hanging full-length garments and for storing personal effects. A minimum of 12 lineal inches of hanging space shall be provided per patient.

(C) Service areas. Service areas shall be located in, adjacent to, or readily available to, each nursing unit. Each service area may be arranged and located to serve more than one nursing unit. The following service areas shall be provided.

(i) A visitors' waiting space shall be provided with a toilet facility(ies), public telephone(s), and drinking fountain(s). One waiting space may serve other units on the floor.

(ii) A nurses station with a hand washing fixture with hands-free operable controls and an adjacent but separate dictation space shall be provided when the single-bed intermediate care patient rooms concept is used. An adjacent nurse station may be used and shared when feasible.

(iii) Storage space shall be provided for emergency equipment in the suite.

(iv) Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be located with the clean work room.

(v) A soiled workroom shall be provided. The room shall contain a clinical sink or equivalent flushing rim type fixture with hot and cold mixing faucet, separate hand washing facilities with hands-free operable controls, and separate waste and soiled linen receptacles. When facilities for cleaning bedpans are provided elsewhere, the flushing rim clinical sink may be omitted.

(vi) A clean workroom or clean supply room shall be provided. A clean workroom when used for preparing patient care items shall contain a work counter, hand washing facilities with hands-free operable controls, and storage facilities for clean and sterile supplies. When used only for storage and holding as part of a distribution system of clean and sterile supplies, the work counter and hand washing facilities may be omitted.

(vii) A nourishment station containing a work counter with sink, microwave, refrigerator and storage cabinets and not located in the clean workroom shall be provided.

(viii) A conveniently located examination room shall be provided and have a minimum clear floor area of 100 square feet and contain a counter for writing and hand washing facilities with hands-free operable controls. This room may be omitted if all patient rooms on the floor are single-bed patient rooms.

(ix) A housekeeping room shall be provided and contain a service sink, and storage for housekeeping supplies and equipment. A shared nursing unit housekeeping room that is adjacent to the intermediate care suite is acceptable.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) At least one door to an intermediate care multi-bed open ward patient room shall be not less than four feet wide and arranged to minimize interference with movement of beds and large equipment.

(ii) Sliding doors in intermediate care rooms shall not have floor tracks and shall have hardware that minimizes jamming possibilities and break-away feature from any position and be in accordance with §133.162(d)(2)(A)(vi) of this title.

(B) Finishes.

(i) Flooring used in soiled workrooms shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in the soiled workroom shall be monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Room recirculating units shall not be used.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Receptacles at each bed location shall be served by two branch circuits, one or more from the critical branch panel of the emergency electrical system and one or more from the normal system. One critical branch circuit shall serve only one bed location. All branch circuits from the normal system shall be from a single panelboard. All branch circuits from the emergency electrical system shall be from a single panelboard.

(ii) A minimum of three hospital grade duplex outlets shall be conveniently located at the head of each bed. At least two of these duplex outlets shall be on the critical branch of the emergency electrical system.

(iii) One duplex receptacle connected to a normal branch circuit and one duplex outlet connected to the critical branch circuit shall be located on opposite sides of the head of each bed. In addition at least one duplex outlet shall be located on each wall. A dedicated outlet shall be provided at the television location.

(B) Illumination requirements.

(i) Each single patient room and multi-patient wards shall be provided with general lighting and night lighting. General lighting and night lighting shall be controlled at the room entrance. All controls for lighting in patient areas shall be of the quiet operating type. Control of night lighting circuits may be achieved by automatic means and in such instances control of night lighting at the room entrance shall not be required. At least one general light fixture and night lighting shall be powered from the critical branch of the essential electrical system.

(ii) A reading light shall be provided over each patient bed. Reading light control shall be readily accessible from each patient bed. Flexible light arms, if used, shall be mechanically controlled to prevent the bulb from coming in contact with bed linen. High heat-producing light sources such as incandescent and halogen shall be avoided to prevent burns to patients and/or bed linen. Light sources shall be covered with a diffuser or a lens.

(iii) A wall or ceiling-mounted lighting fixture shall be provided above each lavatory.

(iv) A ceiling-mounted fixture shall be provided in patient bathrooms where the lighting fixture above the lavatory does not provide adequate illumination

of the entire bathroom. Some form of fixed illumination shall be powered from the critical branch.

(C) Nurses calling systems. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(n) Laboratory suite.

(1) Architectural requirements.

(A) General.

(i) Laboratory facilities and services shall be provided by the hospital such as hematology, clinical chemistry, urinalysis, cytology, anatomic pathology, immunohematology, microbiology, bacteriology and others.

(ii) Each laboratory unit shall meet the requirements of Chapter 11 of NFPA 99 (relating to Laboratories), and Chapter 18 of NFPA 101 (relating to New Health Care Occupancies).

(B) Minimum laboratory facilities. When laboratory services are provided off site by contract, the following minimum facilities shall be provided within the hospital.

(i) Laboratory work room. The laboratory workroom shall include a counter and a sink with hands-free operable controls.

(ii) General storage. Cabinets or closets shall be provided for supplies and equipment used in obtaining samples for testing. A refrigerator or other similar equipment shall be provided for specimen storage waiting for transfer to off-site testing.

(iii) Blood storage facilities. Refrigerated blood storage facilities for transfusions shall be provided. The blood storage refrigerator shall be equipped with temperature monitoring and alarm signals.

(iv) Specimen collection facilities. A blood collection area shall be provided with a counter, space for seating, and hand washing fixture with hands-free operable controls. A toilet and lavatory with hands-free operable controls shall be provided for specimen collection. This facility may be outside the laboratory suite if conveniently located.

(C) On-site laboratory facilities. When the hospital provides on-site laboratory services, the following facilities shall be provided in addition to the requirements in subparagraphs (A) and (B) of this paragraph.

(i) Laboratory workroom(s). The laboratory work room shall include counter(s), space appropriately designed for laboratory equipment and sink(s) with hands-free operable controls.

(ii) General storage. Storage, including refrigeration for reagents, standards, supplies, and stained specimen microscope slides, etc. shall be provided. Separate facilities shall be provided for such incompatible materials as acids and bases, and vented storage shall be provided for volatile solvents.

(iii) Chemical safety facilities. When chemical safety is a requirement, provisions shall be made for an emergency shower and eye flushing devices.

(iv) Flammable liquids. When flammable or combustible liquids are used, the liquids shall be stored in approved containers, in accordance with National Fire Protection Association 30, Flammable and Combustible Liquids Code, 2003 edition.

(v) Radioactive materials. When radioactive materials are employed, storage facilities shall be provided.

(D) Bone marrow laboratory. A cryopreservation laboratory and a human leukocyte antigen laboratory shall be provided in hospitals providing bone marrow transplantation services.

(E) Service areas and facilities. The following service areas and facilities shall be provided.

(i) Hand washing facilities. Each laboratory room or work area shall be provided with a hand washing fixture(s) with hands-free operable controls.

(ii) Office spaces. The scope of laboratory services shall determine the size and quantity for administrative areas including offices as well as space for clerical work, filing, and record maintenance. At a minimum, an office space shall be provided for the use of the laboratory service director.

(iii) Staff facilities. Lounge, locker, and toilet facilities shall be conveniently located for male and female laboratory staff. These may be outside the laboratory area and shared with other departments.

(iv) Housekeeping room. A housekeeping room shall be located within the suite or conveniently located nearby.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title. Floors in laboratories shall comply with the requirements of §133.162(d)(2)(B)(iii) of this title except that carpet flooring shall not be used.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) No air from the laboratory areas shall be recirculated to other parts of the facility. Recirculation of air within the laboratory suite is allowed.

(B) When laboratory hoods are provided, they shall meet the following general requirements.

(i) The average face velocity of each exhaust hood shall be at least 75 feet per minute.

(ii) The exhaust shall be connected to an exhaust system to the exterior which is separate from the building exhaust system. Biological safety cabinets with HEPA filters and alarms to alert staff do not have to be exhausted to the exterior. If the air changes for biological safety cabinets as provided in Table 3, §133.169(c) of this title do not provide sufficient air for proper operation of the safety cabinets (when in use), supplementary make-up air (filtered and preheated) shall be provided around these units to maintain the required airflow direction and exhaust velocity. Make-up air system for safety cabinets shall be arranged to minimize "short circuiting" of air and to avoid reduction in air velocity at the point of contaminant capture.

(iii) The exhaust fan shall be located at the discharge end of the system.

(iv) The exhaust duct system shall be of noncombustible and corrosion-resistant material.

(v) Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(C) When special laboratory hoods are provided, they shall meet the following special standards for these types of hoods.

(i) Fume hoods, and their associated equipment in the air stream, intended for use with perchloric acid and other strong oxidants, shall be constructed of stainless steel or other material consistent with special exposures, and be provided with a water wash and drain system to permit periodic flushing of duct and hood. Electrical equipment intended for installation within such ducts shall be designed and constructed to resist penetration by water. Duct systems serving these hoods shall be constructed of acid-resistant stainless steel for at least 10 feet from the hood. Lubricants and seals shall not contain organic materials. When perchloric acid or other strong oxidants are only transferred from one container to another, standard laboratory fume hoods and the associated equipment may be used in lieu of stainless steel construction.

(ii) Each laboratory hood used to process infectious or radioactive materials shall have a minimum face velocity of 90-110 feet per minute, be connected to an independent exhaust system, with suitable pressure-independent air modulating devices and alarms to alert staff of fan shutdown or loss of airflow. Each hood shall also have filters with a 99.97% efficiency (based on the dioctyl-phthalate (DOP) test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination.

(iii) Fume hoods intended for use with radioactive isotopes shall be constructed of stainless steel or other material suitable for the particular exposure and shall comply with National Fire Protection Association 801, Standard for Facilities Handling Radioactive Materials, 2003 edition and NFPA 99, §11.3.5.

(iv) Each laboratory hood shall have a suitable pressure-independent air modulating device and alarm to alert staff of fan shutdown or loss of airflow. The alarm shall be audible within the laboratory and at a 24-hour manned location.

(D) Filtration requirements for air handling units serving the laboratory suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(E) Duct linings exposed to air movement shall not be used in ducts serving any laboratory room and clean room unless terminal filters of at least 80% efficiency are installed downstream of linings. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) General.

(i) Faucet spouts at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and the contents of beakers, test tubes, etc.

(ii) Drain lines from sinks used for acid waste disposal shall be made of acid-resistant material.

(iii) Drain lines serving some types of automatic blood-cell counters must be of carefully selected material that will eliminate potential for undesirable chemical reactions (and/or explosions) between sodium azide wastes and copper, lead, brass, and solder, etc.

(B) Medical gas systems. When provided, medical gas systems shall comply with §133.162(d)(4)(A)(iii) and (iv) of this title. The number of outlets in the laboratory for vacuum, gases, and air shall be determined by the functional program requirements.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(A) The blood storage refrigerator shall have an alarm device to indicate a temperature increase or malfunction and indicate an audible warning at a 24-hour manned location.

(B) The blood storage refrigerator shall be connected to the critical branch of the emergency essential electrical system.

(C) All exhausts hoods shall be connected to the emergency essential electrical system.

(o) Laundry suite. Laundry facilities shall be provided on site or off site. On-site laundry services may be within the hospital or in a separate building on-site. The laundry facilities shall be separated from patient rooms, areas of food preparation and storage, and areas in which clean supplies and equipment are stored.

(1) Architectural requirements.

(A) When laundry service is provided on site, it shall comply with the following.

(i) Soiled and clean linen processing rooms shall be provided. When the soiled and clean linen processing are combined in a single room, each process shall be physically separated within the room.

(ii) Adequate hand washing facilities shall be provided in both the soiled and clean processing areas.

(iii) A receiving, holding, and sorting room for control and distribution of soiled linen shall be provided. This area may be combined with the soiled linens processing room. Discharge from soiled linen chutes may be received in the soiled room/area or in a separate dedicated room.

(iv) A laundry processing room shall be provided with a commercial washer(s) and dryer(s) capable of processing at least a seven-day laundry supply within the regular scheduled work week.

(v) A clean linen processing room/area shall be provided with folding counters or tables. This area shall have provisions for inspections, folding, packing and mending of linen.

(vi) A holding room or area for storage and issuing of clean linen shall be provided but may be combined with clean linen processing room.

(vii) Storage space and cabinets for soaps, stain removers, and other laundry processing agents shall be located in the soiled and clean processing room/areas.

(viii) Laundry equipment shall be arranged so that the processing of laundry is an orderly work flow from soiled to clean operations. Cross-traffic shall be held to a minimum to prevent contamination.

(B) When laundry service is provided off site, the following minimum requirements shall be provided on site:

(i) a service entrance which shall have a drive under canopy for protection from inclement weather, for loading and unloading of linen;

(ii) a control station for pickup and receiving. This may be a room at the common loading dock, in the soiled linen holding room, or the central clean linen storage room;

(iii) a soiled linen holding room; and

(iv) a central clean linen storage/issuing room in addition to linen storage required at the individual patient units.

(C) The following areas/rooms shall be provided regardless of delivery type of laundry service:

(i) office space for the director of laundry services;

(ii) cart storage rooms for clean and soiled linen. The cart storage areas may be provided within the clean and soiled rooms. Carts may not be parked or stored in the egress corridor;

(iii) cart sanitizing facilities which comply with subsection (b) of this section;

(iv) staff toilet in the laundry suite or convenient for staff use and with a hand washing fixture with hands-free operable controls;

(v) lockers for staff use may be in laundry suite or part of a central locker room when convenient to the laundry; and

(vi) housekeeping room within the laundry suite or available near by.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The ventilation system shall include adequate intake, filtration, exchange rate, and exhaust in accordance with Table 3 and Table 4 of §133.169(c) and (d) of this title, respectively.

(B) Filtration requirements for air handling units serving the laundry suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(C) Direction of air flow of the HVAC systems shall be from clean to soiled areas.

(D) The ventilation system for soiled processing area shall have negative air pressure while the clean processing area shall have positive pressure.

(E) Lint interceptors shall be located outside the laundry area. Drainage piping that serves laundry equipment shall employ suds-control features.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(p) Medical records suite.

(1) Architectural requirements. The following rooms, areas, or offices shall be provided in the medical records suite:

(A) medical records administrator or technician office;

(B) review and dictating rooms or spaces;

(C) work area which includes provisions for sorting, recording, scanning, or microfilming records; and

(D) file room. When nondigital files are stored on site, the room shall be considered as hazardous. The construction protection for the storage room or area shall comply with Chapter 18 of NFPA 101, §18.3.2.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(q) Mental health and chemical dependency nursing suite.

(1) Architectural requirements. When mental health and chemical dependency patient care services are provided, the suite shall comply with the requirements contained in subsection (t)(1) of this section and the requirements of this paragraph.

(A) A minimum of two separate social spaces, one appropriate for noisy activities and the other for quiet activities, shall be provided. The combined total area shall be not less than 40 square feet per bed with not less than 120 square feet for each of the two spaces, whichever is greater.

(B) A room for group therapy shall be provided. The room shall not be less than 250 square feet. The group therapy room may be combined with the quiet space required in subparagraph (A) of this paragraph when the unit accommodates not more than 12 patients.

(C) Space shall be provided for occupational therapy at the rate of 15 square feet per bed with a minimum total area of 200 square feet, whichever is greater. Space shall include hand washing, work counters, storage, and displays. When the mental health and chemical dependency nursing unit contains less than 12 beds, the occupational therapy functions may be performed within the noisy activities area, if at least 10 additional square feet per patient served is included.

(D) A consultation room for each 12 beds or any portion thereof shall be provided. Each consultation room shall have a minimum floor space of 100 square feet. Each room shall be designed for acoustical and visual privacy.

(E) There shall be a suite in each nursing unit for mental health and chemical dependency patients intended for short-term occupancy by a single person requiring security and protection from self or others. The seclusion suite shall consist of seclusion room(s), an anteroom or a vestibule, and a toilet.

(i) Each seclusion room shall be located and designed in a manner affording direct visual supervision by nursing staff and shall be constructed to prevent patient hiding, escape, injury, or suicide. There shall be a minimum of one seclusion room for each 24 beds or any portion thereof.

(I) The floor area of each seclusion room shall be not less than 60 square feet. The minimum room dimension shall be 6 feet.

(II) The seclusion room shall have a minimum ceiling height of 9 feet.

(III) The door to each seclusion room shall have no hardware on the room side and shall open out. A vision panel shall be provided in each door to permit staff observation of the entire room while maintaining privacy from the public and other patients.

(IV) Each seclusion room shall have natural light (skylight or window) in order to maintain a therapeutic environment. Skylight wells or windows shall be not less than 400 square inches in area.

(ii) Access to the seclusion room from any public space such as a corridor shall be through an anteroom. When the seclusion suite is directly accessible from the nurse station, a vestibule may be provided in place of an anteroom. A cased opening to the vestibule in lieu of a door may be provided as long as the arrangement assures privacy from the public and other patients.

(I) At least one dimension of the anteroom or vestibule shall be 8 feet.

(II) The door to the anteroom shall swing out.

(iii) There shall be at least one toilet room directly accessible from the anteroom or vestibule.

(I) The toilet room shall be a minimum of 50 square feet.

(II) The toilet room door shall swing out into the anteroom or vestibule.

(III) A water closet and hand washing facilities shall be provided in the toilet room. An unbreakable wall hung mirror may be provided.

(F) When a smoking room is provided, all air shall have a dedicated exhaust system to the exterior.

(G) Service areas shall be provided in accordance with the requirements of subsection (t)(1)(F) of this section and the following additional requirements.

(i) Nurses and doctor's charting areas shall be provided with separation needed for acoustical privacy as well as space required for the function. A view window to permit observation of patient area by the charting nurse or physician may be used provided that it is located so that patient files cannot be read from outside the charting space.

(ii) A small kitchen for patient use shall be provided. It shall contain a sink, refrigerator, kitchen cabinets, ice dispenser, and a microwave. This kitchen may serve as a nourishment center for patients between meals. It may be located in the noisy activity area.

(iii) Patient laundry facilities with automatic washer and an electric dryer shall be provided. This requirement may be omitted in nursing units intended only for adolescent and gero-psychiatric patients.

(2) Details and finishes. Details and finishes in each mental health and chemical dependency nursing unit shall comply with the requirements contained in subsection (t)(2) of this section and this paragraph.

(A) Details.

(i) The type and degree of security and patient safety required in the suite shall be determined by hospital administration and described in the hospital's functional program narrative, unless stated otherwise within these rules.

(ii) All areas of the mental health suite, including entrances to patient rooms, shall be visible from the nurse station(s). Observation by video cameras of seclusion rooms, entrances, hallways, and activity areas shall be acceptable.

(iii) All exposed and accessible fasteners shall be tamper-resistant.

(iv) Suitable hardware shall be provided on doors to toilet rooms so that access to these rooms can be controlled by staff. Hardware shall be utilized which is appropriate to prevent patient injury.

(v) Only breakaway or collapsible clothes bars in wardrobes, lockers, and closets and shower curtain rods shall be permitted in nursing units for mental health and chemical dependency patients.

(vi) Wire coat hangers shall not be permitted in the suite.

(vii) Special fixtures, hardware, and tamper-proof screws are required throughout the suite.

(viii) Horizontal grab bars shall be constructed to prevent looping or tying of cords, ropes, etc.

(ix) Where glass fragments may create a hazard, safety glazing or other appropriate security features shall be incorporated.

(B) Finishes. Patient sleeping rooms, patient toilet rooms and seclusion rooms shall have monolithic ceilings and bonded walls for patient safety and security measures. The ceiling in the soiled workroom shall be monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title. Gero-psychiatric patient rooms and toilet rooms may omit the monolithic ceiling requirement when hospital administration provides a written statement (on hospital letterhead) that the type and degree of security is appropriate for the patient areas.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with subsection (t)(3) of this section and this paragraph.

(A) Special consideration shall be given to the type of heating and cooling units, ventilation outlets, and appurtenance installed in patient-occupied areas of mental health nursing units. The following shall apply:

(B) All air grilles and diffusers shall be of a type that prevents the insertion of foreign objects.

(C) All convector or HVAC enclosures exposed in the room shall be constructed with rounded corners and shall have enclosures fastened with tamper-resistant fasteners.

(D) HVAC equipment shall be of a type that minimizes the need for maintenance within the room.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with subsection (t)(4) of this section and this paragraph.

(A) Piping systems.

(i) Piped medical gas systems are not required.

(ii) Only tamper-proof sprinkler and tamper-proof showerheads from which it is not possible to suspend any objects shall be installed.

(B) Plumbing fixtures.

(i) Faucet controls shall not be equipped with handles that may be easily broken off.

(ii) Bedpan washers are not required in patient bathrooms.

(5) Electrical requirements. Electrical requirements shall be in accordance with subsection (t)(5) of this section and this paragraph.

(A) A nurses calling system is not required in patient rooms. However, when a nurses calling system is provided, the system shall meet the requirements of §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title. Pull cords shall not exceed 18 inches in length, and provisions shall be made to permit removal of call buttons and use of blank plates as required for security.

(B) Each patient room shall have duplex grounded receptacles. There shall be one receptacle at each side of the head of each bed and one on every other wall. Receptacles in areas intended for mental health and chemical dependency patients of all ages shall be protected by GFCI breakers installed in distribution panel enclosures serving the unit.

(C) Fifteen-ampere and 20-ampere, 125-volt receptacles intended to supply patient care areas shall be tamper-resistant as permitted by NFPA 70, §517-18, or shall be

protected by GFCI breakers. A tamper-resistant receptacle is one that is constructed to limit improper access to its energized contacts.

(r) Morgue.

(1) Architectural requirements.

(A) General. When a morgue or body-holding room is provided, it shall be located to avoid the need for transporting bodies of deceased patients through public areas. A body-holding room shall be provided as a minimum for a general hospital.

(B) Autopsy performed within hospital. When autopsies are performed within the hospital, the following rooms, areas, and equipment shall be provided.

(i) Refrigerated facilities shall be provided for body-holding.

(ii) The autopsy room shall contain work counters, hand washing facilities with hands-free operable controls, autopsy table and storage space for supplies, equipment and specimens.

(iii) A deep sink shall be provided for washing specimens.

(iv) A clothing change area shall be provided with shower, toilet, hand washing facilities and lockers.

(C) Service areas. The following service areas shall be provided:

(i) a pathologist office;

(ii) staff toilets. Toilets may be outside the suite but be convenient for staff use with hand washing fixture(s) with hands-free operable controls; and

(iii) a housekeeping room. A housekeeping room which meets the requirements of §133.162(d)(2)(A)(xxviii) of this title shall be provided for the exclusive use of the morgue when autopsies are performed.

(D) Minimum requirements. If autopsies are performed outside the hospital, a well-ventilated, temperature-controlled, nonrefrigerated body-holding room shall be provided.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Flooring used in the autopsy room shall be the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(B) Ceilings in the autopsy rooms shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The autopsy room shall be equipped with low exhaust grilles.

(B) The body-holding room shall be ventilated in accordance with Table 3 of §133.169(c) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. Refrigerators for body-holding in the autopsy room shall be connected to the equipment branch of the essential electrical distribution system.

(s) Nuclear medicine suite.

(1) Architectural requirements.

(A) General. When nuclear medicine services are provided, the facilities may be in a separate suite or combined with an imaging suite.

(i) When nuclear medicine requires radiation protection, a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602, shall specify the type, location, and amount of radiation protection to be installed for the layout, equipment selections and storage, handling and disposal of radioactive material.

(ii) The nuclear medicine room shall be sufficiently sized to house all fixed and moveable equipment and allow a minimum of three feet of clear and unobstructed working space on all sides of equipment accessible to staff and patient.

(B) Radioisotope room (Hot lab). When radiopharmaceutical preparation is performed on site, the room shall include sufficient space for equipment, storage of radionuclides, chemicals for preparation, dose calibrators, and record keeping. When prepared materials are used, storage and calculation area may be smaller than for on-site preparation.

(i) The room and isotope handling areas within the room shall have appropriate radiation shielding.

(ii) There shall be a shielded area or enclosed shielded cabinet for long-term storage of decaying radioisotopes.

(iii) When venting of radioactive gases is required, a hood shall exhaust to the exterior.

(C) Positron emission tomography (PET). When PET services are provided, scanner and cyclotron rooms shall be in compliance with the manufacturer's recommendations and provide a minimum of three feet of clear and unobstructed working space on all sides of equipment accessible to staff and patient.

(i) A control alcove shall be provided with a view window permitting view of the patient.

(ii) An equipment area large enough to contain necessary electronic and electrical gear shall be provided.

(iii) A dose administration room(s) with radiation shielding shall be located near the treatment room. Patients in route to procedure rooms shall not pass through public corridors and waiting rooms after injection with radioisotope.

(iv) A patient toilet with radiation shielding shall be provided with or adjacent to dose administration room(s). The patient toilet room shall contain a hand washing fixture with hands-free operable controls.

(D) Service areas.

(i) Patient waiting area. The area shall be out of traffic and under direct staff visual control. When the waiting area serves both outpatients and inpatients, separate areas shall be provided and include visual privacy between the waiting areas.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Dictation and report preparation area. The dictation and report preparation area may be incorporated with the control station.

(iv) Holding area. The holding area shall be under direct staff control, out of the direct line of traffic, and have space for stretchers. The holding area shall accommodate two stretchers for the first procedure room with one additional station for each additional procedure room.

(v) Patient toilet facilities. A toilet room with a hand washing fixture with hands-free operable controls shall be provided convenient to the waiting room and procedure room.

(vi) Staff toilet facilities. Toilets and hand washing fixtures with hands-free operable controls may be outside the suite but shall be convenient for staff use.

(vii) Patient dressing rooms or cubicles. Dressing rooms or cubicles shall be provided convenient to the waiting areas and procedure rooms. Each room or cubicle shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate wheelchair patients.

(viii) Exam room(s). When examination rooms are provided, each room shall have a minimum of 100 square feet of clear floor area exclusive of built-in shelves or cabinets. Each exam room shall be equipped with a work counter and a hand washing fixture with hands-free operable controls.

(ix) Dose administration area. When a dose administration area is provided, the area shall be located near the preparation area and include visual privacy for the patients.

(x) Computer control area/room. Computer control area shall be located within or adjacent to the treatment room(s). When a centralized computer area is provided, it shall be a separate room with access terminals available within the treatment rooms.

(xi) Film processing room. A darkroom shall be provided for film processing unless the processing equipment normally used does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the treatment room(s) and to the quality control area.

(xii) Quality control area or room. A quality control area shall include view boxes illuminated with light of the same color value and intensity.

(xiii) Film storage room (active). A room with cabinet or shelves for filing patient film for immediate retrieval shall be provided.

(xiv) Film storage room (inactive). A room for inactive film storage may be located outside the nuclear medicine suite, but must be under the administrative control of nuclear medicine personnel and properly secured to protect films against loss or damage.

(xv) If digital imaging is utilized throughout the suite, the darkroom film processing area and film viewers may be omitted.

(xvi) Storage for unexposed film. Storage facilities for unexposed film shall include protection of film against exposure or damage.

(xvii) Offices for physicians, oncologist, physicists, and assistants. Offices shall include provisions for individual consultation, viewing, and charting of film.

(xviii) Clerical office(s) spaces. Clerical office(s) spaces shall be provided.

(xix) Consultation room. A consultation room shall be provided.

(xx) Clean storage room. A clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls. When conveniently located, the clean storage room may be shared with another department.

(xxi) Soiled workroom. The soiled workroom shall not have direct connection to the nuclear medicine procedure or diagnostic rooms or sterile activity rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and soiled linen receptacle. When contaminated soiled material or fluid waste is not handled, only a soiled holding room is required.

(xxii) Housekeeping room. The housekeeping room shall be located within the suite.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Radiation protection shall be designed, tested and approved by a medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602.

(I) Room shielding calculations for the stipulated rooms within the nuclear medicine suite must be submitted to the Department of State Health Services, Radiation Control (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by RC inspectors, in the field, subsequent to use. Any changes in design or shielding which affects radiation exposure levels adjacent to those rooms, requires prior approval by RC.

(II) Facility design and environmental controls associated with licensable quantities of radioactive material in laboratories or procedure rooms must be approved by RC prior to licensed authorizations.

(ii) The nuclear medicine treatment rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(B) Finishes.

(i) Flooring used in the nuclear medicine procedure room, any work or treatment areas where radioactive material is handled, and soiled workroom shall be of the seamless monolithic type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in radiopharmacy, hot laboratory, and soiled workrooms shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) When radiopharmaceutical preparations are performed, vents and traps for radioactive gases shall be provided.

(B) Direction of air flow of the HVAC system shall be from nonradioactive spaces into the radioactive spaces. A minimum of two return air inlets located diagonally opposite from one another and near floor level shall be provided.

(C) In the PET suite, special ventilation systems together with monitors, sensors, and alarm systems shall be required to vent gases and chemicals. The ventilation shall be directly to the exterior.

(D) Filtration requirements for air handling units serving the nuclear medicine suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(E) Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood. Fume hoods shall be exhausted directly to the exterior.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Each nuclear medicine procedure room shall have at least four duplex electrical hospital grade receptacles.

(ii) Nuclear medicine procedures rooms shall have general lighting in addition to that provided by special lighting units at the procedure tables.

(B) Nurses calling systems. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(t) Nursing unit. The requirements in this subsection apply to nursing units in hospitals for all types of inpatient care. Facilities providing care to less than 15 pediatric inpatients may be included with an adult nursing unit. Additional requirements for a nursing unit providing care to 15 or more pediatric patients are contained in subsection (w) of this section.

(1) Architectural requirements. Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(A) Handicapped accessibility requirements. At least 10% of each patient room type, isolation room, bathing units and toilets in medical/surgical, intermediate care, universal care, antepartum, postpartum, mental health, chemical dependency, and pediatric nursing units and all public and common use areas shall be designed and constructed to be handicapped accessible. These requirements shall apply in all new construction and when an existing nursing unit or a portion thereof is converted from one service to another, i.e. mental health care to medical or surgical nursing care.

(B) Patient room suites. A patient room suite shall consist of the patient room and a bathroom. Patient room suites shall comply with the following requirements.

(i) Maximum patient room capacity. The maximum patient room capacity shall be two patients. In existing facilities where renovation work is undertaken and the present capacity is more than two patients, the maximum room capacity shall be no more than the present capacity with a maximum of four patients.

(ii) Single-bed patient room. In a single-bed patient room, the minimum clear floor area shall be 120 square feet.

(iii) Multi-bed (two) patient room. The clearance between the side of a bed and a wall/partition shall be a minimum of three feet. The clearance between sides of beds shall be a minimum of five feet. The minimum distance at the foot of the bed shall not be less than four feet for a single load area/room or seven feet for a double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds. The requirements of this clause are illustrated in Table 8, Diagram G of §133.169(h) of this title.

(iv) Multi-bed (two) accessible patient room. The clearance between the side of a bed and a wall/partition shall be a minimum of five feet. The clearance between sides of beds shall be a minimum of four feet. The minimum distance at the foot of the bed shall not be less than four feet for a single load area/room or seven feet for a double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds. The requirements of this clause are illustrated in Table 8, Diagram H of §133.169(h) of this title.

(v) Arrangement of patient rooms. Minor encroachments including columns and wall hung lavatories that do not interfere with functions may be ignored when determining space requirements for patient rooms.

(I) Required clear floor space in patient rooms shall be exclusive of toilet rooms, closets, lockers, built-in cabinets, wardrobes, alcoves, or vestibules.

(II) Visual privacy shall be provided each patient in multi-bed rooms. Design for privacy shall not restrict independent patient access to the corridor, lavatory, or bathroom.

(vi) Patient bathroom. Each patient shall have access to a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet with bed pan washers, hand washing fixture with hands-free operable controls, bathing facilities, and storage shelf or cabinet and serve not more than two patient rooms. Hand washing facilities shall be located in the patient room and in the patient bathroom. The hand washing fixture in the room shall be located outside of the patient's cubicle curtain in multi-bed patient room.

(vii) Patient storage. Each patient shall have a separate wardrobe, locker, or closet that is suitable for hanging full-length garments and for storing personal effects. A minimum of 12 lineal inches of hanging space shall be provided per patient.

(C) Airborne infection isolation suites. A minimum of one isolation suite shall be provided for each 30 acute care beds or fraction thereof. The suite may be located within a nursing unit or in a separate isolation unit. When a pediatric patient suite is located in an adult nursing unit and is not part of a pediatric or adolescent nursing unit, a minimum of one isolation room shall be designated for pediatric patient care. Each airborne infection isolation suite shall consist of a work area, a patient room, and a patient bathroom.

(i) The work area may be a separately enclosed anteroom or a vestibule that is open to and is located immediately inside the door to the patient room. It shall have facilities for hand washing, gowning, and storage of clean and soiled materials. One enclosed anteroom may serve multiple isolation rooms.

(ii) Each patient room shall have a clear floor area of 120 square feet exclusive of the work area and shall contain only one bed. A patient bathroom shall be provided in accordance with subparagraph (B)(vi) of this paragraph.

(iii) At least one airborne infection isolation suite with an enclosed anteroom shall be provided.

(iv) A door(s) from an anteroom to an airborne infection isolation room(s) and a door(s) from an egress corridor into an anteroom shall be provided with a self-closing device(s). When an isolation room does not have an anteroom, the door from the egress corridor into the isolation room shall be provided with a self-closing device. When sliding doors are used in isolation rooms in CCU suites and in surgical suite post-anesthesia care units, the self-closing device may not be required as long as assurances of negative air pressure are met when sliding doors are opened.

(v) Pressure differential monitors or air flow devices shall be installed outside the isolation room and anteroom. Devices shall be installed in corridors, passageways, etc.

(D) Protective environment suite. When specialized services for patients with extreme susceptibility to infection are provided, spatial requirements for the suite shall be identical to those for airborne infection isolation suites contained in subparagraph (C) of this paragraph with the exception that an enclosed anteroom shall be provided.

(E) Room for disturbed medical patients. Each general hospital shall provide at least one private patient room for patients needing close supervision for medical and/or psychiatric care. The room may be part of the mental health and chemical dependency nursing suite described in subsection (q) of this section. If the room is part of a nursing suite, the provisions of subparagraph (B)(ii) of this paragraph shall apply. Each room shall be designed in accordance with subsection (q)(2)(A) and (B) of this section.

(F) Service areas. Service areas shall be located in, or readily available to, each nursing unit. Each service area may be arranged and located to serve more than one nursing unit, but at least one service area shall be provided on each nursing floor. The following service areas shall be provided:

(i) an administrative center or nurses station with an adjacent but separate dictation space;

(ii) a nurses office;

(iii) an area for charting. The area may be combined with the nurses station when adequate space is provided for both;

(iv) a medication room, medicine alcove area, or a self-contained medicine dispensing unit under visual control of nursing staff. The medication alcove area may be located in the clean workroom. The self-contained medicine dispensing unit may be located in an alcove at the nurse station. The room, area or unit shall contain a work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances. Standard cup-sinks provided in many self-contained units are not adequate for hand washing;

(v) a nourishment station containing a work counter with sink, microwave, refrigerator and storage cabinets and not located in the clean workroom;

(vi) a multipurpose room for staff and patient conferences, education, demonstrations, and consultation. The room shall be conveniently accessible to each nursing unit and may serve several nursing units or departments. The room may be located on another floor if convenient for regular use;

(vii) a conveniently located examination/treatment room which may serve several nursing units located on the same floor. The room shall have a minimum clear floor area of 100 square feet and contain a counter for writing and hand washing facilities with hands-free operable controls. This room may be omitted if all patient rooms on the floor are single-bed patient rooms;

(viii) special assisted bathing facilities, including space for attendant, for patients on stretchers, carts, and wheelchairs at the ratio of one per 100 beds or a fraction thereof. This may be on another floor if convenient for use. The central bathing room shall contain a bathtub which is accessible to a patient in a wheelchair or a shower that can accommodate a gurney. The room shall have space for drying and dressing and be provided with a hand washing fixture with hands-free operable controls and a toilet with three feet of clear space on sides and front of the water closet;

(ix) staff lounge with unisex dressing cubicles, lockers, toilets and hand washing facilities. These facilities may be on another floor;

(x) securable closets or cabinet compartments for personal articles of nursing unit staff. The closets or lockers shall be located at or near the nurse station. At a minimum, these shall be large enough for purses and billfolds. Coats may be stored in closets or cabinets on each floor or in a central staff locker area;

(xi) clean workroom or clean supply room. When used for preparing patient care items, it shall contain a work counter, hand washing facilities with hands-free operable controls, and storage facilities for clean and sterile supplies. When used only for storage and holding as part of a distribution system of clean and sterile supplies, the work counter and hand washing facilities may be omitted;

(xii) clean linen storage for each nursing unit. This may be within a clean workroom, a separate closet, or an approved distribution system on each floor. If a closed cart system is used, storage may be in an alcove, but must be out of the path of normal traffic and under staff control;

(xiii) a soiled workroom or soiled holding room. The room shall contain a clinical sink or equivalent flushing rim fixture, hand washing facilities with hands-free operable controls, both with hot and cold water. The room shall have a work counter and space for separate covered containers for soiled linen and waste. When facilities for cleaning bedpans are provided elsewhere, the flushing rim clinical sink may be omitted;

(xiv) an equipment storage room or alcove. The room(s) or alcove(s) shall be located on the patient floor to keep the corridor width free of all equipment and supplies. Ten square feet of equipment storage or supplies shall be provided for each patient bed. Combustible supplies shall not be stored in an alcove in the egress corridors;

(xv) an emergency equipment storage room or alcove under direct visual control of the nursing staff;

(xvi) a housekeeping room which may also serve adjacent nursing units;

(xvii) stretcher and wheelchair storage space which is located without restricting normal traffic;

(xviii) public toilets with hand washing facilities. The toilets shall be located on each floor containing a nursing unit;

(xix) staff toilet conveniently located to each nursing unit. At least one staff toilet shall be located on each patient sleeping floor. Toilet may be unisex; and

(xx) an ice dispensing machine for each nursing unit which is located at the nourishment station or the clean work room.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Egress. Means of egress from each patient suite shall comply with the requirements of NFPA 101, §18.2.

(ii) Patient bathroom and toilet room doors. Door leaves to all patient bathrooms and toilet rooms shall be at least 36 inches wide and shall swing outward or be double acting so that nursing staff may gain access to a patient who has collapsed against the door. Doors lockable from the inside shall have hardware that allows staff to open the door from the outside.

(iii) Vision panels. Vision panels shall be provided in the door between an anteroom and an airborne infection isolation room or a protective environment room.

(iv) Patient room windows. Each patient sleeping room shall have an outside door or an outside window. When operable windows are provided and the operation of windows requires the use of tools or keys, the tools or keys shall be located at each nurses station, on the same floor, and easily accessible to staff. The allowable window sill height shall not exceed 36 inches above the floor.

(v) Location of patient room windows. Windows in patient sleeping rooms shall be located on an outside wall. These windows may face an atrium, an inner court, or an outer court provided the following requirements are met.

(I) Patient room atria windows. When patient room windows face an atrium, the atrium shall comply with the requirements of NFPA 101, §8.6.7. When windows are operable, an engineered smoke control system shall be provided in accordance with National Fire Protection Association 92B, Guide for Smoke Management Systems in Malls, Atria, and Large Areas, 2000 edition.

(II) Outer courts. Outer court (not enclosed by building on one side) onto which the required windows open shall have a minimum width, at all levels, of not less than three inches for each foot, or fraction thereof, of the height (average height of enclosing walls) of such court, but in no case shall the width be less than five feet. An outer

court shall have a horizontal cross-sectional area not greater than four times the square of its width.

(III) Inner courts. Inner court (enclosed by building on all sides) onto which the required windows open shall have minimum width, at all levels, of not less than one foot for each foot, or fraction thereof, of the height (average height of enclosing walls) of such courts, but in no case shall the width be less than 10 feet. When operable windows are provided, a horizontal, unobstructed, and permanently open air intake or passage having a cross-sectional area of not less than 21 square feet shall be provided at or near the bottom of the court. Metal decorative grilles not effectively reducing the open area by more than 5.0% shall be permitted at the ends. Walls, partitions, floor, and floor-ceiling assemblies forming intakes or passages shall be noncombustible and shall be constructed in accordance with NFPA 101, §18.3.1.1. An inner court shall have a horizontal cross-sectional area of not less than one and one-half times the square of its width.

(vi) Hand washing facilities. Hand washing facilities shall be conveniently located near the nurses station and in the medication area. One lavatory in an open medication area can meet this requirement.

(vii) Elevator lobbies. Elevator lobbies shall be provided in accordance with §133.164 of this title (relating to Elevators, Escalators, and Conveyors).

(viii) Patient's privacy. Cubicle curtains to assure privacy for each patient shall be provided in all multi-bed patient rooms.

(ix) Telephone access. Each patient shall have access to a telephone directly from each bed.

(B) Finishes.

(i) Seamless floors with coved wall bases described in §133.162(d)(2)(B)(iii)(III) of this title shall be provided in soiled workrooms.

(ii) Wall bases in the soiled workroom shall be made integral and coved with the floor, tightly sealed to the wall, constructed without voids that can harbor insects, retain dirt particles, and impervious to water.

(iii) Monolithic ceilings described in §133.162(d)(2)(B)(vi)(III) of this title shall be provided in airborne infection isolation rooms, protective environment rooms, and soiled workrooms.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Outside air shall be supplied to each patient room by a central air handling unit to provide make-up air for air exhausted from the bathroom in accordance with Note 3 of Table 3 of §133.169(c) of this title.

(B) Each patient room bathroom shall be exhausted continuously to the exterior in accordance with Table 3 of §133.169(c) of this title.

(C) The isolation room exhaust shall be a dedicated system which exhausts all air continuously to the exterior in accordance with Table 3 of §133.169(c) of this title. Multiple isolation rooms may be interconnected to the same exhaust system.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph. Each patient bathroom shall contain a water closet with a bedpan washer, bathtub or shower and a lavatory.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) Electric receptacles in nursing units.

(i) Each receptacle shall be grounded to the reference grounding point by means of an insulated copper grounding conductor.

(ii) Each patient bed location shall be supplied by at least two branch circuits, one from the critical branch of the emergency system as required by NFPA 99, §3-4 and one from the normal system. All branch circuits from the normal system shall originate in the same panelboard.

(iii) One duplex receptacle connected to a normal branch circuit and one duplex outlet connected to the critical branch circuit shall be located on opposite sides of the head of each bed. In addition at least one duplex outlet shall be located on each wall. A dedicated outlet shall be provided at the television location.

(iv) Each examination table shall have access to two duplex receptacles.

(v) Each work table or counter shall have access to one duplex receptacle for every six feet of table or counter space or fraction thereof.

(vi) One duplex receptacle protected with a GFCI shall be installed in the bathroom to permit the use of electrical appliances in front of the mirror.

(vii) Duplex receptacles shall be installed not more than 50 feet apart in corridors and within 25 feet of corridor ends.

(viii) The isolation exhaust system shall be connected to the emergency essential electrical system.

(B) Nurses calling systems. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(C) Illumination requirements.

(i) General illumination requirements. Nursing unit corridors shall have general illumination with provisions for reducing light levels at night. Illumination of corridors for egress purposes shall comply with NFPA 101, §18.2.8 and §18.2.9.

(ii) Illumination of the nurses station. Illumination of the nurses station and all nursing support areas shall include fixtures powered from the critical branch of the emergency electrical system NFPA 99, §4.4.2.2.3(d).

(iii) Patient suite lighting.

(I) Each patient room shall be provided with general lighting and night lighting. General lighting and night lighting shall be controlled at the room entrance. All controls for lighting in patient areas shall be of the quiet operating type. Control of night lighting circuits may be achieved by automatic means and in such instances control of night lighting at the room entrance shall not be required. At least one general light fixture and night lighting shall be powered from the critical branch of the essential electrical system.

(II) A reading light shall be provided for each patient. Reading light control shall be readily accessible from each patient bed. Flexible light arms, if used, shall be mechanically controlled to prevent the bulb from coming in contact with bed linen. High heat-producing light sources such as incandescent and halogen shall be avoided to prevent burns to patients and/or bed linen. Light sources shall be covered by a diffuser or a lens.

(III) A wall or ceiling-mounted lighting fixture shall be provided above each lavatory.

(IV) A ceiling-mounted fixture shall be provided in patient bathrooms where the lighting fixture above the lavatory does not provide adequate illumination of the entire bathroom. Some form of fixed illumination shall be powered from the critical branch.

(u) Obstetrical suite.

(1) Architectural requirements.

(A) General. When obstetrical services are provided, the obstetrical suite shall be located and arranged to preclude unrelated traffic through the suite. Regardless of the clinical model used for labor, delivery, recovery and postpartum, a hospital offering such services shall be able to demonstrate the availability of one room designed, equipped and held in reserve for emergency, caesarean section deliveries. This room shall be located either in the labor and delivery suite or surgical suite.

(B) Caesarean section (c-section) operating room(s). A minimum of one dedicated c-section operating room shall be located in either the obstetrical or surgical suite.

This room shall have a minimum clear floor area of 360 square feet with a minimum dimension of 18 feet exclusive of built-in shelves or cabinets. There shall be no direct access between operating rooms.

(C) Delivery room(s). A minimum of one delivery room shall be provided in every obstetrical suite. The delivery room shall have a minimum clear floor area of 300 square feet with a minimum dimension of 16 feet exclusive of fixed and moveable cabinets and built-in shelves. In facilities having only one c-section operating room, the delivery room shall be designed to function as an emergency c-section operating room. When two c-section operating rooms are provided, the delivery room requirement may be omitted.

(D) Infant resuscitation area. An infant resuscitation space shall be provided within the c-section operating room; delivery room; labor, delivery, and recovery room (LDR); and labor, delivery, recovery and postpartum room (LDRP) with a minimum clear floor area of 40 square feet in addition to the required area of each room or may be provided in a separate but immediately accessible room with a clear floor area of 150 square feet.

(E) Labor room(s). A minimum of two labor beds shall be provided for each delivery room. Each labor room shall be designed for one or two beds with a minimum clear floor area of 120 square feet per bed.

(i) An LDR or LDRP may be substituted for a labor room.

(ii) In facilities having only one delivery room, one of the two required labor beds shall be in a separate room with a minimum clear floor area of 160 square feet to serve as an emergency vaginal delivery room. Medical gas outlets shall be the same as for delivery room.

(iii) Each labor room shall contain a lavatory equipped with hands-free operable controls. Each labor room shall have direct access to a toilet room. One toilet room may serve two labor rooms.

(iv) Labor rooms shall be arranged so that doors are visible from a nurses work station.

(v) A minimum of one shower shall be provided for each four labor beds. Each shower room shall contain a toilet and hand washing fixture with hands-free operable controls.

(F) Recovery room(s). Recovery room(s) shall contain not less than two beds. There shall be enough space for baby and crib and a chair for the support person. Visual privacy of the new family shall be provided. LDRs or LDRPs may be substituted for recovery rooms.

(i) In multiple recovery patient stations, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of five feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the

bed/gurney shall not be less than eight feet for single load area/room or twelve feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram N of §133.169(h) of this title.

(ii) A nurse station and charting area shall be provided and arranged to permit staff visual observation of recovery beds.

(iii) A work counter, facilities for dispensing medicine, storage for supplies and equipment, and a clinical sink with bedpan-flushing device shall be provided.

(iv) One hand washing fixture with hands-free operable controls shall be provided for every three recovery beds or fraction thereof. Fixtures shall be uniformly distributed.

(v) There shall be cubicle curtains at each station for patient privacy.

(G) Postpartum and antepartum suite. Postpartum and antepartum patient suites shall be provided in accordance with subsection (t)(1)(B) of this section.

(H) LDR.

(i) When provided, each LDR room shall have controlled access and shall be located so that a patient may be transported to the c-section operating room without the need to pass through other functional areas.

(ii) Each LDR room shall be designed for single occupancy and have a minimum clear floor area of 200 square feet exclusive of the infant resuscitation area, built-in shelves or cabinets, alcove, vestibule or other adjoining rooms. The minimum clear room dimension shall not be less than 11 feet.

(iii) A hand washing fixture with hands-free operable controls shall be provided in each LDR room.

(iv) Each LDR shall have direct access to and exclusive use of a bathroom with a shower, or tub with shower, hand washing fixture with hands-free operable controls and a toilet.

(I) LDRP. When provided, each LDRP room shall have controlled access and shall be located on an exterior wall and have a window in accordance with subsection (t)(2)(A)(iv) and (v) of this section.

(i) Each room shall be designated for single occupancy and have a minimum clear floor area of 260 square feet exclusive of the infant resuscitation area, built-in

shelves or cabinets, alcove, vestibules, or other adjoining rooms. The minimum clear room dimension shall not be less than 11 feet.

(ii) A hand washing fixture with hands-free operable controls shall be provided in each LDRP room.

(iii) Each LDRP shall have direct access to and exclusive use of a bathroom with a shower, or tub with shower, hand washing fixture with hands-free operable controls and a toilet.

(J) Isolation rooms. When patients who have airborne infectious diseases are treated, an isolation room shall be provided in the obstetrical suite which complies with the functional space requirements as specified in subparagraphs (G)-(I) of this paragraph, and with the ventilation requirements for infection isolation rooms in Table 3 of §133.169(c) of this title.

(K) Nursery suite. One infant station for each LDRP and each postpartum bed shall be provided in the nursery. Nurseries shall be located and arranged convenient to the postpartum nursing unit and near or part of the obstetrical suite. The nurseries shall be located and arranged to preclude the need for nonrelated pedestrian traffic. Each nursery unit shall meet the following requirements.

(L) Full-term nursery. A full-term nursery shall have a maximum of 16 infant stations. The clearance between the side of a bassinet and a wall/partition shall be a minimum of two feet six inches. The clearance between sides of bassinets shall be a minimum of four feet. The minimum distance at the foot of the bassinet shall not be less than five feet for single load area/room or seven feet for double load area/room. Three feet of the passage space at the foot of the bassinet may be shared between two bassinets. The requirements of this subparagraph are illustrated in Table 8, Diagram I of §133.169(h) of this title. Additional area shall be provided to accommodate workroom functions if these are located within the nursery area as specified in subparagraph (N)(iv) of this paragraph.

(i) When a rooming-in program is used, the total number of bassinets in full-term nursery units shall be not less than one bassinet for every two LDRP and postpartum beds.

(ii) When a rooming-in program is used but all infants are returned to the nursery at night, a reduction in bassinets shall not be allowed.

(iii) There shall be one lavatory with hands-free operable controls for each six infant stations or fraction thereof. Fixtures shall be uniformly distributed but not in the clear floor area of the infant stations.

(iv) An observation window to permit the viewing of infants from public areas shall be provided. The public viewing areas shall not encroach into the egress corridor.

(M) Continuing care nursery suite. Hospitals with 25 or more maternity beds shall provide a continuing care nursery for infants requiring close observation. The suite shall have a maximum of 16 infant stations. The clearance between the side of the bassinet and a wall/partition shall be a minimum of three feet. The clearance between sides of bassinets shall be a minimum of six feet. The minimum distance at the foot of the bassinet shall not be less than six feet for single load area/room or nine feet for double load area/room. Three feet of the passage space at the foot of the bassinet may be shared between two bassinets. The requirements of this subparagraph are illustrated in Table 8, Diagram J of §133.169(h) of this title. Additional area shall be provided to accommodate workroom functions if these are located within the nursery area as specified in subparagraph (N)(iv) of this paragraph.

(i) The continuing care nursery shall be located on an exterior wall and shall have a window(s). In the nursery, one window may serve more than one bassinet. The window sill height shall not exceed five feet above the floor. Bassinets shall not be located more than 50 feet from an exterior window. A newborn's view to outside windows shall be direct. When partitions are used, the newborn's view to the outside windows may be through no more than two separate clear vision panels.

(ii) The continuing care nursery shall not be located within a full-term nursery.

(iii) There shall be a minimum of one lavatory with hands-free operable controls for each four infant stations or fraction thereof. Fixtures shall be uniformly distributed but not in the clear floor area of the infant stations.

(N) General requirements for nurseries. Each nursery regardless of type shall meet the following requirements:

(i) Observation windows to permit the viewing of infants from public areas for full-term nurseries and from workroom(s) into adjacent nurseries shall be provided. Windows between nurseries may be provided for the convenience of staff observation.

(ii) Ten square feet per bassinet shall be provided for convenient, accessible storage for linens, infant supplies, and equipment.

(iii) A room for consultation, demonstration, breast feeding or breast pumping shall be provided convenient to the unit. A counter with sink with hands-free operable controls, refrigeration and freezer, storage for pump and attachments, and educational materials shall be provided in or convenient to the room.

(iv) Each nursery room shall be served by a connecting workroom(s). The workroom shall contain scrubbing and gowning facilities at the entrance for staff and housekeeping personnel, work counter, refrigerator, storage for supplies, and hand washing fixture with hands-free operable controls. One workroom may serve no more than two nursery rooms provided that required services are convenient to each. No nursery shall open directly into another nursery.

(v) The workroom serving the full-term and continuing care nurseries may be omitted if equivalent work and storage areas and facilities, including those for scrubbing and gowning, are provided within that nursery at the entrance. Space required for work areas located within the nursery is in addition to the area required for infant care. Adequate provisions shall be made for storage of emergency carts and equipment, and for sanitary storage and disposal of soiled waste for the nursery.

(vi) Charting and dictation facilities shall be provided for physicians and nurses. This may be in a separate room or part of the workroom.

(vii) An examination/treatment room or space shall be provided and shall contain a work counter, storage, and lavatory equipped for hand washing with hands-free operable controls. The examination/treatment room or space shall have a minimum clear area of 80 square feet in addition to the required area of each workroom exclusive of fixed and movable cabinets and shelves. The examination treatment space shall be located within the nursery.

(viii) An airborne infection isolation room is required in at least one level of nursery care and the neonatal critical care unit. The isolation room shall be enclosed and separated from the nursery unit with provisions for observation of the infant from adjacent nurseries or control area(s). The minimum size of the room shall be 120 square feet of clear floor area. The isolation room shall contain cabinets, a work counter, and a hand washing fixture with hands-free operable controls. Fixed and moveable cabinets and shelves shall not encroach upon bed/gurney clear floor space/area. The isolation room shall comply with the ventilation requirements in Table 3 of §133.169(c) of this title.

(ix) A housekeeping room shall be provided for the exclusive use of the nursery.

(O) Neonatal critical care unit (NCCU). When an NCCU is provided, the unit shall comply with the following.

(i) The NCCU shall be conveniently located near the obstetrical suite and be arranged to preclude unrelated traffic.

(ii) Each room and ward shall be located on an exterior wall and shall have a window. In a ward, one window may serve more than one patient. The window sill height shall not exceed five feet above the floor. Patient beds shall not be located more than 50 feet from an exterior window. Patients' views to outside windows shall be direct. When partitions are used, the patient's direct view to the exterior may be through no more than two separate clear vision panels. Window shall be in accordance with subsection (t)(2)(A)(v) of this section.

(iii) The NCCU shall have a clearly identified public entrance and reception area arranged to permit visual observation and contact with all traffic entering the unit. Gowning facilities, lockers, and scrub area shall be provided at each public entrance to the

patient care area(s) of the NCCU. All scrub sinks shall be provided with hands-free operable controls and large enough to contain splashing.

(iv) A control station shall be provided in a central area and shall have space for counters and storage, and shall have convenient access to a hand washing fixture with hands-free operable controls. The control station may be combined with or include centers for reception, communication and patient monitoring.

(v) NCCU patients may be housed in private rooms or a room with multiple bassinets or cribs. Each unit shall not exceed 24 bassinets or cribs. There shall be at least one enclosed private room for every six bassinets or cribs.

(vi) A single-bassinet/crib patient NCC room shall have a minimum clear floor area of 120 square feet per bassinet/crib exclusive of work counter, vestibule, sink and aisle. A minimum of 12 feet width shall be provided for the head wall for each bed.

(vii) In a multiple-bassinet/crib room/ward the clearance between the side of a sleeping unit and a wall/partition shall be a minimum of five feet. The clearance between sides of sleeping units shall be a minimum of eight feet. The minimum distance at the foot of the bassinet shall not be less than ten feet for single load area/room or sixteen feet for double load area/room. Four feet of the passage space at the foot of the bassinet may be shared between two bassinets. The fixed and moveable cabinets and shelves shall not encroach upon the bassinet/crib clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram K of §133.169(h) of this title.

(viii) A minimum of one isolation room shall be provided with a minimum clear floor area of 120 square feet per bassinet/crib exclusive of work counter, vestibule, sink and aisle. A minimum of 12 feet width shall be provided for the head wall for each bed. A toilet room is not required.

(ix) A lavatory equipped for hand washing with hands-free operable controls shall be provided in each single-bed room. In rooms with multiple beds, one lavatory with hands-free operable controls for each four patient stations or fraction thereof shall be provided. These lavatories shall be located convenient to infant stations.

(x) Each NCCU shall be served by a connecting workroom containing gowning facilities at the entrance for staff and housekeeping personnel, a work space with counter, storage facilities, a lavatory or sink equipped for hand washing with hands-free operable controls, and individual closet or lockers for personal effects of nursing personnel. One workroom may serve not more than two NCCUs.

(xi) A storage space for infant formula shall be provided. This functional space may be outside the NCCU but shall be available for use at all times.

(xii) A breast feeding or pump room shall be provided convenient to the unit. Provision shall be made, either within the room or conveniently located nearby, for a

sink with hands-free operable controls, counter, refrigeration and freezer, storage for pump and attachments, and educational materials.

(xiii) A room(s) shall be provided within the NCCU for parents and infants for extended private time together and the room is not considered a patient room. The room(s) shall have direct access to toilet facilities and a hand washing fixture with hands-free operable controls. The room(s) shall have a sleeping area for at least one parent, and sufficient space for the infant's bassinet/crib and equipment. The room(s) shall have electrical and medical gas outlets as specified for NCCU bassinet/cribs. This room(s) shall have direct communication with the NCCU staff.

(xiv) Twenty square feet of equipment storage shall be provided for each patient station. The storage areas shall be out of the way of the corridor traffic.

(xv) Charting and dictation space shall be provided for physicians and nurses.

(xvi) A respiratory therapy work area and storage room shall be provided.

(xvii) Blood gas lab facilities shall be immediately accessible to the NCCU.

(xviii) A staff lounge shall include toilet facilities with a hand washing fixture with hands-free operable controls. The lounge(s) shall be located so that staff may be recalled quickly to the patient area in emergencies. Toilet facilities may be shared as long as privacy is maintained for changing areas.

(xix) Physicians and other staff on 24-hour on-call work schedules shall be provided with sleeping rooms with access to a shower(s), toilet(s), and lavatory(ies). If on-call room(s) are not within the NCCU served, a dedicated telephone or intercom system shall connect the on-call room(s) to the NCCU.

(xx) A waiting room/area shall be provided and contain toilet room(s) with hand washing facilities. Waiting room/area maybe shared with other waiting room/areas if conveniently located.

(xxi) A consultation room shall be provided, if not provided elsewhere in the suite.

(xxii) A housekeeping room shall be provided exclusively within or immediately adjacent to the NCCU. It shall not be shared with other nursing units or departments.

(P) Infant formula facilities. Infant formula facilities shall meet the following requirements.

(i) When infant formula is prepared on site, the infant formula preparation room shall contain a lavatory equipped for hand washing with hands-free operable controls, warming facilities, refrigerator, work counter, formula sterilizer, and storage facilities. The formula room may be located near the nurseries or at another appropriate place within the hospital. Direct access from the formula preparation room to any nursery room is prohibited.

(ii) An infant formula clean-up room shall be provided and include a hand washing fixture with hands-free operable controls, facilities for bottle washing, a work counter, and sterilization equipment.

(iii) When commercial infant formula is used, the separate clean-up and formula preparation rooms may be omitted. The storage and handling may be done in the nursery workroom or in another appropriate room in the hospital that is conveniently accessible at all hours.

(iv) A refrigerated storage and warming facilities for infant formula shall be provided and be accessible for use by nursery personnel at all times.

(Q) Service areas. The following service areas shall be provided to support an obstetrical suite unless otherwise noted.

(i) Control station. The control station shall be located to permit direct visual surveillance of all traffic which enters the obstetrical suite.

(ii) Office. A supervisor's office shall be provided.

(iii) Waiting room/area. A waiting room/area shall be provided and contain toilet room(s) with hand washing facilities, public telephone(s), and drinking fountain(s).

(iv) Scrub facilities. Two scrub stations shall be within 5 feet of the entrance to each c-section operating room and delivery room. Two scrub stations may serve two c-section operating rooms or delivery rooms if the scrub stations are located adjacent to the entrance of each c-section operating room or delivery room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts. Viewing panels shall be provided for observation of c-section operating rooms and delivery rooms from the scrub area.

(v) Sterilizing facilities. Sterilizing facilities with high speed sterilizers shall be conveniently located to serve all c-section operating rooms and delivery rooms. A work space and a hand washing fixture with hands-free operable controls shall be included. High speed autoclaves should only be used in an emergency situation (e.g. replacements unavailable for dropped instruments). Sterilization facilities would not be necessary when spare instruments are available.

(vi) Anesthesia workroom. An anesthesia workroom shall be provided with work counter, sink with hands-free operable controls, and storage space for small style D or E medical gas cylinders and other anesthesia equipment.

(vii) Medication station. Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not adequate for hand washing. The medication station may be shared with the clean work room.

(viii) Nourishment station. The nourishment station shall contain sink with hands-free operable controls, work counter, self-dispensing ice machine, refrigerator, cabinets, and not located in the clean work room. Space shall be included for temporary holding of unused or soiled dietary trays. A nourishment station is not required in the nursery suite.

(ix) General storage room(s). A minimum of 50 square feet per operating room is required for general storage space(s). The storage space is exclusive of soiled holding, sterile supplies, clean storage, drug storage, locker rooms. In addition to general storage, equipment storage shall be provided for labor, LDR and LDRP rooms.

(x) Emergency storage. Equipment used for emergencies shall be stored in a room or alcove under direct visual control of the nursing staff.

(xi) Storage alcove. The alcove provided for stretcher storage, portable X-ray equipment, warming devices, auxiliary lamps, etc. shall be located out of direct line of traffic.

(xii) Obstetrical suite staff clothing change rooms. Appropriately sized areas shall be provided for male and female personnel working within the obstetrical suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker/changing rooms shall be provided for male and female staff. The shower and toilet room(s) may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the obstetrical suite can shower, change, and move directly into the restricted areas of the obstetrical suite.

(xiii) Lounge. A lounge shall be provided in hospitals with four or more obstetrical surgical and delivery rooms. The lounge shall permit staff use without leaving the obstetrical surgical suite or delivery suite and may be accessed from the obstetrical suite staff clothing change rooms or staff changing room for delivery suite. The lounge shall not have direct access from outside the surgical suite. When the lounge is remote from the clothing change rooms, toilet facilities and a hand washing fixture with hands-free operable controls accessible from the lounge shall be provided.

(xiv) Staff toilet facilities. Toilet facilities located in the obstetrical suite for exclusive staff use shall be provided and contain hand washing facilities with hands-free operable controls. The toilet room may be accessible from a staff lounge, when provided.

(xv) Nurses' toilet. A nurses' toilet room shall be provided at the labor and recovery area(s) and shall include hand washing fixture with hands-free operable controls.

(xvi) Dictation and report preparation area. This may be accessible from the lounge area.

(xvii) On-call rooms. Physicians and staff on 24-hour on-call work schedules shall be provided with sleeping rooms with access to a toilet, lavatory and shower. If not contained within the unit itself, the area shall have a telephone or intercom connection to the obstetrical suite(s).

(xviii) Clean workroom or clean supply room. A clean workroom is required. It shall contain a work counter, a hand washing fixture with hands-free operable controls, storage facilities for clean supplies, and a space to package reusable items. The storage for sterile supplies must be in a separated room. When the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and hand washing fixture may be omitted.

(xix) Soiled workroom. The soiled workroom shall be for the exclusive use of the obstetrical suite and shall be in addition to the soiled workroom required for the obstetrical surgical suite. The soiled workroom for the obstetrical c-section operating room or delivery room suite shall not have direct connection with operating rooms or other sterile activity rooms. The soiled workroom shall contain a clinical sink with hands-free operable controls or equivalent flushing type fixture, work counter, sink equipped for hand washing, waste receptacle, and linen receptacle. There shall be a designated soiled workroom for the exclusive use of the NCCU.

(xx) Housekeeping rooms. A separate housekeeping room containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided for the exclusive use of the obstetrical suite, the c-section operating room, and nurseries (one for each).

(xxi) Triage room. When triage services are provided, there shall be a minimum of one triage room in the obstetrical suite.

(I) An obstetrical triage room shall be a minimum clear floor area of 100 square feet with a minimum dimension of nine feet. The obstetrical triage room shall contain cabinets, work counter, examination light, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area.

(II) When a multiple-bed/gurney triage patient station is provided, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the

bed may be shared between two beds/gurneys. The multiple-bed/gurney triage room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. Privacy shall be provided for each patient with cubicle curtains or movable screens. The requirements of this subclause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(III) A patient in a triage bed shall have access to a patient toilet room without entering the corridor.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) C-section operating rooms and delivery rooms shall have ceiling heights not less than nine feet.

(ii) Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over operating rooms or delivery rooms, unless special provisions are made to minimize such noise as contained in Table 1 of §133.169(a) of this title.

(iii) When vision panels are provided in labor rooms, LDRs, and LDRPs, the windows shall be located, draped, or otherwise arranged to preserve patient privacy from casual observation from outside the labor room.

(iv) Shower controls shall be outside the wet area for use by nursing staff for labor room showers. In the LDRP rooms shower control outside of the wet area may be omitted.

(v) When viewing windows are provided in a NCCU, provision shall be made to control casual viewing of infants.

(vi) Noise control and sound attenuation in a NCCU shall be a design factor and meet the requirements contained in Table 1 of §133.169(a) of this title.

(B) Finishes.

(i) Finishes for LDR and LDRP rooms shall be selected for ease of cleaning and resistance to strong detergents.

(ii) Flooring in c-section operating rooms, delivery rooms, labor rooms, isolation room, and soiled workroom shall be of the seamless type in accordance with the requirements of §133.162(d)(2)(B)(iii)(III) of this title. LDR and LDRP rooms shall have seamless type flooring below the bed and four feet at each side of the bed and foot of the bed.

(iii) Ceilings and walls in c-section operating rooms, delivery rooms, soiled workroom, isolation and anteroom, and sterile processing room shall be of the monolithic type in accordance with §133.162(d)(2)(B)(vi)(III) of this title. Acoustic lay-in ceiling is permissible in the LDR and LDRP rooms.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) The air supply for the c-section operating room and delivery room shall be from ceiling outlets near the center of the work area. Return air shall be from near the floor level. Each c-section operating room and delivery room shall have at least two return air inlets located as remotely from each other as practical. (Design should consider turbulence and other factors of air movement to minimize fall of particulate into a wound site).

(B) Air supply for LDRs, LDRPs, and nurseries shall be from ceiling outlets or high wall outlets. Return air shall be from near the floor level. Each LDR, LDRP, and nursery shall have at least two return air inlets located diagonally opposite from each other.

(C) The ventilation system for anesthesia storage rooms shall conform to the requirements of NFPA 99, §4-3.1.1.2.

(D) Each c-section operating room, delivery room and nursery shall have temperature and humidity indicating devices mounted at eye level.

(E) Air handling units serving the obstetrical and surgical suite shall be equipped with filter having efficiencies equal to, or greater than specified in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) General.

(i) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in c-section operating rooms and delivery rooms unless special precautions are taken to protect the spaces below from leakage and condensation from necessary overhead piping systems. Any required secondary protection shall be labeled every 20 feet "code required secondary drain system". The labeling shall be in highly visible print.

(ii) Floor drains shall not be installed in c-section rooms and delivery rooms.

(iii) Bedpan-flushing devices shall be installed in all patient toilet rooms serving LDRs and LDRPs.

(B) Medical gas systems. Medical gas systems shall be provided in accordance with §133.162(d)(4)(A)(iii)-(vi) of this title.

(i) Nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 6 of §133.169(f) of this title.

(ii) Nonflammable medical gas and clinical vacuum outlets for the infant resuscitation area or room shall be provided in addition to the required medical gas and vacuum for the mother in accordance with Table 6 of §133.169(f) of this title.

(iii) When a labor room is intended to function as an emergency delivery room the nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 6 of §133.169(f) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) X-ray film illuminators for handling at least four films simultaneously shall be provided in each c-section operating room, labor, and delivery room. When the entire obstetrical suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(ii) Each c-section operating room shall have at least eight duplex hospital grade receptacles.

(iii) Each delivery room, LDR and LDRP shall have at least six duplex hospital grade receptacles.

(iv) Operating rooms and delivery rooms shall have at least three of the required duplex hospital grade receptacles located convenient to the head of the procedure table.

(v) Newborn and continuing care nurseries shall have one normal and one critical duplex outlet for every two bassinets.

(vi) In the infant resuscitation area or room, three duplex hospital grade receptacles shall be provided for the infant in addition to those required for the mother.

(vii) The electrical circuit(s) to equipment in wet areas shall be provided with five milliamperere GFCI. GFCI circuits shall not be used in c-section operating rooms and delivery rooms. When GFCIs are used in critical areas, provisions shall be made to ensure that other essential equipment is not affected by activation of one interrupter.

(viii) C-section operating rooms and delivery rooms shall have general lighting in addition to that provided by special lighting units at the surgical and obstetrical tables. Each fixed special lighting unit at the operating or delivery table shall be connected to an independent circuit powered by the critical branch of the essential electrical system. Portable units may share circuits.

(ix) Indirect lighting and high-intensity lighting shall be provided in the NCCU(s). The lighting shall be able to be adjusted over individual patient care spaces. No direct ambient lighting shall be permitted in the infant care spaces, and any direct ambient lighting used outside the infant care area shall be located or framed so as to avoid any infant's direct line of sight to the fixture. This does not exclude the use of direct procedure lighting.

(x) Receptacles at each bed location in a NCCU shall be served by two branch circuits, one or more from the critical branch panel of the emergency electrical system and one or more from the normal system. One critical branch circuit shall serve only one bed location. All branch circuits from the normal system shall be from a single panelboard. All branch circuits from the emergency electrical system shall be from a single panelboard.

(xi) A minimum of seven hospital grade duplex outlets shall be conveniently located at the head of each NCCU bed, crib or bassinet. At least three of these duplex outlets shall be on the critical branch of the emergency electrical system.

(B) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(v) Outpatient suite.

(1) Architectural requirements.

(A) General. Outpatient services that the hospital provides to patients under the hospital license shall be within the hospital. Outpatient services and facilities (diagnostics, imaging, surgical, etc.) may be provided throughout the hospital within other suites, departments or units within the hospital. When an organized outpatient suite is provided for the hospital, it shall be in one identifiable contiguous location within the hospital and meet all the elements described in this subsection. To be included in the hospital license, an outpatient suite located in an office building or other building shall be physically connected to the hospital and become contiguous to the hospital. In no case may one leave the hospital, traverse the other occupancies, and then reenter the hospital to access the remaining portion of the hospital. A hospital may not occupy two or more noncontiguous areas of nonhospital occupancies, which contain intervening space of the nonhospital occupancies even if on the same floor or other floors. Outpatient facilities physically connected to the hospital with a common wall or an enclosed connection shall comply with the requirements of NFPA 101, Chapter 18.

(B) Site, administration and public areas. The following shall be provided.

(i) Parking. When an outpatient suite is provided, four parking spaces shall be required for each surgical procedure room, treatment room, and diagnostic room, plus additional spaces for each staff member.

(ii) Entrance. When an established outpatient suite in one identifiable location provides surgical services, an illuminated covered drive through entrance shall be provided.

(iii) Public waiting area. Toilet facilities, public telephone, and drinking fountain shall be provided. When pediatric services are provided, pediatric and adult patients waiting areas shall be separate.

(iv) Control station. A control station shall be located to permit staff observation of waiting area and control of access to treatment rooms, procedure rooms, diagnostic rooms, and the surgical suite.

(v) Wheelchair storage alcove. The alcove provided for wheelchair storage shall be located out of line of traffic.

(vi) Interview space. Interview spaces shall be provided for social services, credit, and admissions. Provisions shall be made for privacy and dignity of the patient during interview, examination, and treatment.

(vii) Offices. General or individual offices shall be provided for business transaction, records, and administrative and professional staff.

(viii) Multipurpose rooms. Multipurpose rooms for conferences, meetings, and health education purposes shall be provided.

(C) Examination, treatment, and observation rooms. When examination, treatment, or observation facilities are provided, the following shall be included.

(i) Examination room. The room shall have a minimum clear floor area of 100 square feet exclusive of fixed cabinets and shelves. Each examination room shall contain a work counter, cabinets, examination light and hand washing fixture with hands-free operable controls. A clearance of three feet shall be provided at each side and the foot of the examination table.

(ii) Special purpose examination rooms. The special purpose examination room shall comply with the requirements of an examination room as described in clause (i) of this subparagraph, but room size and configuration may be modified for specialized equipment.

(iii) Treatment room. The room shall have a minimum clear floor area of 120 square feet exclusive of fixed and movable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 10 feet. The treatment room shall

contain a work counter, cabinets, medication storage, examination light and a hand washing fixture with hands-free operable controls.

(iv) Observation room. The room shall be located to permit close observation from either a nurse station or the control station. The room shall have a minimum clear area of 80 square feet exclusive of fixed and movable cabinets and shelves. Patients shall have access to a toilet room without entering the general corridor area.

(v) Multiple-bed holding/observation room/area. In a multiple-bed holding/observation room/area, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed holding/observation room/area shall contain cabinets, work counters, and a hand washing fixture with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(D) Diagnostic facilities. Services shall be available to the outpatient suite. When separate radiology units are located within the outpatient suite, the requirements in subsection (l) of this section shall be met.

(E) Laboratory. Services shall be made available to the outpatient suite. When a separate laboratory unit is installed within the outpatient suite, the requirements in subsection (n) of this section shall be met. All laboratory services provided within the outpatient suite or by a written contractual arrangement shall comply with the requirements of §133.41(h) of this title.

(F) Surgical facilities. Outpatient surgical facilities may be provided separately or may be shared with the inpatient facilities.

(i) When a separate outpatient surgery suite is provided, it shall meet the requirements in subsection (ee) of this section.

(ii) The following additional rooms and areas shall be provided in each surgical suite wherever outpatient surgical procedures are performed. A preoperative area for outpatient use shall be provided. The area shall include a waiting room, public toilet facilities, sitting space for ambulatory patients, and at least one or more of the following: a single patient preoperative room, multiple-bed/gurney preoperative patient stations, single patient preoperative/recovery room, or multiple-bed/gurney preoperative/recovery patient stations. Traffic patterns shall be arranged for patients to enter the preoperative area from outside the surgical suite, prepare for surgical procedure and then move directly into the restricted corridor of the operating suite.

(I) When a single patient preoperative room is provided the minimum clear area is 100 square feet exclusive of aisles and fixed and moveable cabinets and

shelves. The room shall contain cabinets, work counter, and a hand washing fixture with hands-free operable controls.

(II) When a multiple-bed/gurney preoperative patient station is provided, the clearance between the side of the bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed/gurney preoperative patient room shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. One hand washing fixture with hands-free operable controls shall be provided for every four stations or fraction thereof. Privacy shall be provided for each patient with cubicle curtains or movable screens. The requirements of this subclause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(III) When a single patient preoperative/recovery room is provided the minimum clear area is 120 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The room shall contain cabinets, work counter, and hand washing fixture with hands-free operable controls.

(IV) When a multiple-bed/gurney preoperative/recovery patient station is provided, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of four feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than eight feet for single load area/room or twelve feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-bed/gurney preoperative/recovery patient station shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. One hand washing fixture with hands-free operable controls shall be provided for every four stations or fraction thereof. Privacy shall be provided for each patient with cubicle curtains or movable screens. The requirements of this subclause are illustrated in Table 8, Diagram M of §133.169(h) of this title.

(iii) A secondary recovery lounge (for outpatients requiring additional observation) with a nurse's station and a hand washing fixture with hands-free operable controls shall be provided. One hand washing fixture with hands-free operable controls shall be provided for every four secondary recovery stations or fraction thereof. In each secondary recovery station, the clearance between a side of lounge/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of lounge/gurney shall be a minimum of six feet. The minimum distance at the foot of the lounge/gurney shall not be less than six feet for single load area/room or nine feet for double load area/room. Three feet of passage space requirement at the foot of the lounge/gurney may be shared between two loungers/gurneys. The fixed and movable cabinets and shelves shall not encroach upon the lounge/gurney clear floor space/area. Privacy shall be provided for each patient with cubicle curtains or movable screens. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(iv) A toilet room for use by outpatients shall be provided directly accessible from the outpatient preoperative, recovery and secondary recovery lounge areas. The toilet room shall contain a water closet and a hand washing fixture with hands-free operable controls. There shall be one outpatient toilet room for every ten patient stations or fraction thereof. Toilet rooms may be shared if convenient to the outpatient preoperative, recovery and secondary recovery lounge areas.

(G) Special procedure room(s). When outpatient special procedures services are provided within the outpatient suite, the special procedure room(s) shall comply with the requirements in subsection (dd) of this section.

(H) Service areas. The following service areas and facilities shall be provided within the outpatient suite unless noted otherwise.

(i) Nurse station(s). The nurse station shall contain a work counter, communication system, space for supplies, and provisions for charting.

(ii) Hand washing fixtures. Hand washing fixtures with hands-free operable controls shall be available at all patient care areas.

(iii) Patient toilet room(s). Toilet room(s) shall be conveniently located to treatment room(s), examination room(s), and diagnostic room(s) and shall include hand washing fixture(s) with hands-free operable controls.

(iv) Staff toilet facilities. Toilet rooms equipped with hand washing fixtures with hands-free operable controls shall be provided for the exclusive staff use. Toilet facilities may be provided in conjunction with the staff lounge.

(v) Staff lounge. A staff lounge with separate male and female staff clothing change rooms and toilets with hand washing fixtures with hands-free operable controls shall be provided in hospitals having a total of six or more diagnostic and treatment rooms.

(vi) Medication station. Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, a hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean workroom.

(vii) Dictation and report preparation area. This area may be accessible from the lounge.

(viii) Cast room. When a cast room is provided, it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures.

(ix) Wheelchair and stretcher storage. Wheelchair and stretcher storage space or alcove shall be provided and located out of direct line of traffic.

(x) Storage. Storage facilities shall be provided for office supplies, sterile supplies, pharmaceutical supplies, splints and other orthopedic supplies, and housekeeping supplies and equipment.

(xi) Ice machine. A self-dispensing ice machine shall be provided.

(xii) Clean workroom. A clean workroom or clean supply room shall be provided.

(xiii) Storage room. A storage room for the outpatient services shall be provided at least equal to 5.0% of the total area of the outpatient suite. This required storage room area may be combined with general stores.

(xiv) Soiled workroom. A soiled workroom shall be provided. It shall not have direct access to any patient treatment, examination, diagnostic rooms, or sterile rooms. The room shall contain a clinical sink or equivalent flushing rim fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle.

(xv) Housekeeping room. The housekeeping room shall be located within the suite. The room may be shared with an adjacent emergency suite when directly accessible from both sides.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph. Treatment rooms shall be provided with seamless flooring in accordance with requirements contained in §133.162(d)(2)(B)(iii)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Filtration requirements for air handling units serving the outpatient and surgical suite shall be equipped with filters having efficiencies equal to, or greater than specified for patient care areas in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph. Sinks used for the disposal of plaster of paris shall have a plaster trap.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(w) Pediatric and adolescent nursing unit.

(1) Architectural requirements. When a facility offers pediatric care services and the nursing unit contains a total of 15 or more patient beds, cribs or bassinets, the unit shall meet

the requirements contained in this subsection. Units containing less than 15 beds, cribs or bassinets, may be a part of the medical/surgical nursing unit. Each pediatric and adolescent nursing unit shall comply with the requirements contained in subsection (t)(1) of this section and the following requirements.

(A) Patient rooms. Patient rooms in a pediatric and adolescent nursing unit containing hospital beds or cribs shall comply with subsection (t)(1)(B) of this section with the following exceptions:

(i) The minimum clear floor space in a private patient room within a dedicated pediatric unit intended for a crib shall be 100 square feet exclusive of toilet room, closet, built-in cabinets, wardrobe, alcove, or vestibules. Minor encroachments including columns and wall hung lavatories that do not interfere with functions may be ignored.

(ii) Patient rooms used for multiple cribs shall have no more than six cribs in a room. The clearance between the side of a crib and a wall/partition shall be a minimum of three feet six inches. The clearance between sides of crib shall be a minimum of six feet. The minimum distance at the foot of the crib shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the crib may be shared between two cribs. The fixed and moveable cabinets and shelves shall not encroach upon the crib clear floor space/area. One hand washing fixture with hands-free operable controls shall be provided for every three patients cribs. The requirements of this clause are illustrated in Table 8, Diagram L of §133.169(h) of this title.

(B) Airborne infection isolation suites and protective environment suites.

(i) Airborne infection isolation suites shall comply with the requirements contained in subsection (t)(1)(C) of this section and shall be located within the pediatric and adolescent nursing unit.

(ii) Protective environment suites shall comply with the requirements contained in subsection (t)(1)(D) of this section and shall be located within the pediatric and adolescent nursing unit.

(C) Pediatric nursery suite. When provided, the pediatric nursery suite shall be located in the pediatric nursing unit and shall consist of a nursery, examination/treatment room, workroom, and formula preparation room and contain the following elements.

(i) Nursery. Each pediatric nursery shall contain not more than eight bassinets. The clearance between the side of bassinet and a wall/partition shall be a minimum of three feet. The clearance between sides of bassinets shall be a minimum of six feet. The minimum distance at the foot of the bassinet shall not be less than six feet for single load area/room or nine feet for double load area/room. Four feet of the passage space at the foot of the bassinet may be shared between two bassinets. The fixed and moveable cabinets and shelves shall not encroach upon the bassinet clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram J of §133.169(h) of this title. Additional area shall be provided to

accommodate workroom functions if these are located within the nursery area as specified in clauses (ii) and (iii) of this subparagraph.

(I) One hand washing fixture with hands-free operable controls shall be provided for every four patients bassinets in each pediatric nursery.

(II) Each pediatric nursery shall be provided with viewing windows for observing infants from public areas and workroom(s).

(ii) Nursery workroom. A connecting workroom shall be provided which shall contain gowning facilities at the entrance for staff, visitors, and housekeeping personnel, work space with counter, refrigerator, lavatory or sink equipped for hand washing, and storage. One workroom shall serve no more than two nurseries provided that required services are convenient to each. The workroom may be omitted if only one nursery is provided and the equivalent work area and facilities are provided within the nursery in which case the gowning facilities shall be located near the entrance to the nursery and shall be separated from the work area.

(iii) Examination/treatment room or area. An examination/treatment room or area shall be provided. The examination/treatment area may be located in a separate room or a designated part of the nursery. It shall contain a work counter, storage facilities, and a lavatory for hand washing.

(iv) On-site formula preparation. Where infant formula is prepared on the hospital site, the hospital shall provide cleanup facilities for washing and sterilizing supplies. These shall consist of a lavatory or sink equipped for hand washing, a bottle washer, work counter space, and an equipment sterilizer. A separate room for preparing infant formula shall be provided. The room shall contain a lavatory or sink equipped for hand washing, hot plate, refrigerator, work counter, formula sterilizer, and storage facilities. It may be located in the pediatric nursery or in another appropriate place within the hospital. There shall be no direct access from the formula room to a nursery.

(v) Commercially prepared formula. If a commercial infant formula is used, the storage and handling may be done in the nursery workroom or in another appropriate room elsewhere in the hospital which has a work counter, sink equipped for hand washing, and storage facilities.

(vi) Housekeeping room. A housekeeping room shall be located in the pediatric nursery suite.

(D) Service areas. The service areas in the pediatric and adolescent nursing unit shall comply with the requirements listed in subsection (t)(1)(F) of this section and the following requirements.

(i) Multipurpose or individual room(s) shall be provided for dining, educational, and play purposes. Special provision shall be made to minimize the impact noise

transmission through the floor of the multipurpose room(s) to occupied spaces below. Requirements in Table 1 of §133.169(a) of this title shall be met.

(ii) Patient toilet room(s) shall be provided convenient to multipurpose room(s) and central bathing facilities.

(iii) Storage closets or cabinets for toys and educational and recreational equipment shall be provided.

(iv) Storage space shall be provided for replacement of cribs and adult beds to provide flexibility for interchange of patient accommodations.

(2) Details and finishes. Each pediatric and adolescent nursing unit shall comply with the requirements contained in subsection (t)(2) of this section.

(3) Mechanical requirements. Mechanical requirements in each pediatric and adolescent nursing unit shall comply with the requirements contained in subsection (t)(3) of this section and this paragraph.

(A) Special consideration for safety shall be given to the type of heating and cooling units, ventilation outlets, and appurtenances installed in patient areas of pediatric and adolescent nursing units.

(B) All air grilles and diffusers shall be of a type that prevents the insertion of foreign objects.

(C) All convector or HVAC enclosures exposed in the room shall be constructed with rounded corners and shall have enclosures fastened with tamper-resistant fasteners.

(4) Plumbing fixtures and piping systems. Plumbing fixtures and piping systems shall be in accordance with subsection (t)(4) of this section.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(x) Pharmacy suite.

(1) Architectural requirements.

(A) General. The pharmacy room or suite shall be located for convenient access, staff control, and security for drugs and personnel.

(B) Dispensing area. The pharmacy room or suite shall include the following functional spaces and facilities:

- (i) area(s) for pickup, receiving, reviewing and recording;
- (ii) extemporaneous compounding area with sufficient counter space for drug preparation and sink with hands-free operable controls;
- (iii) work counter space for automated and manual dispensing activities;
- (iv) storage or areas for temporary storage, exchange, and restocking of carts; and
- (v) security provisions for drugs and personnel in the dispensing counter area.

(C) Manufacturing. The pharmacy room or suite shall provide the following functional spaces and facilities for the manufacturing area(s):

- (i) bulk compounding area with work space and counters; and
- (ii) area(s) for packaging, labeling and quality control.

(D) Storage. The following spaces shall be provided in cabinets, shelves, and/or separate rooms or closets:

- (i) space for bulk storage, active storage, and refrigerated storage;
- (ii) storage in a fire safety cabinet or storage room that is constructed under the requirements for protection from hazardous areas in accordance with NFPA 101, Chapter 12, for alcohol or other volatile fluids, when used;
- (iii) storage in a secure vault, safe, or double locking wall cabinet for narcotics and controlled drugs; and
- (iv) storage space for general supplies and equipment not in use.

(E) Intravenous (IV) solutions area. When IV solutions are prepared in a pharmacy, a sterile work area shall be provided and be in compliance with 22 TAC, §291.26 (relating to Pharmacies Compounding Sterile Pharmaceuticals) and the United States Pharmacopoeia, Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

- (i) The IV work area shall consist of a preparation room, hood room and, if provided, a separate chemo-hood room. Access to the preparation room shall be through the pharmacy only, access to the hood room or chemo-hood room shall be through the preparation room only.
- (ii) The preparation room shall contain a work counter, gowning area and shelving.

(iii) A hand washing fixture with hands-free operable controls shall be in the preparation room and within five feet of each entrance to the hood room or chemo-hood room. Hand washing fixtures and floor drains are not allowed inside the hood room or chemo-hood room.

(iv) Laminar-flow hoods/work stations shall be located inside the hood room.

(F) Compounding aseptic isolator (CAI). When a CAI is used for compounding, in lieu of the IV solutions area, it may be done within the pharmacy provided it complies with the following.

(i) The CAI shall provide isolation from the room and maintain the International Organization for Standardization (ISO) Class 5 (100 particles greater than or equal to 0.5 microns per cubic foot) levels during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.

(ii) The particle counts sampled shall be 6 to 12 inches upstream of the critical exposure site within the CAI and maintain ISO Class 5 levels during compounding operations.

(iii) The facility shall obtain documentation from the manufacturer that the CAI will meet this standard when located in worse than ISO Class 7 (10,000 particles greater than or equal to 0.5 microns per cubic foot environments).

(G) Administrative area(s). The following functional spaces and facilities shall be included for the administrative area(s):

(i) office area for the chief pharmacist and any other offices areas required for records, reports, accounting activities, and patients profiles;

(ii) poison control center with storage facilities for reaction data and drug information centers; and

(iii) a room or area for counseling and instruction when individual medication pick-up is available for inpatients or outpatients.

(H) Satellite pharmacy facilities. When provided, the room(s) shall include a work counter, a sink with hands-free operable controls, storage facilities, and refrigerator for medications. As applicable, items required in subparagraphs (B) and (C) of this paragraph may be incorporated into the satellite pharmacy.

(I) Service areas and facilities. The following service areas and facilities shall be provided.

(i) Hand washing facilities. A hand washing fixture with hands-free operable controls shall be located in each room where open medication is handled except for IV prepared chemo-hood rooms.

(ii) Staff facilities. Toilet rooms with hand washing fixture with hands-free operable controls may be outside the suite but shall be convenient for staff use.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Flooring in the IV solutions area for the preparation room, hood room and chemo-hood room shall be seamless and coved to the wall.

(B) IV solutions area ceiling and wall finishes for the preparation room, hood room and chemo-hood room shall be interlocking monolithic panels and sealed together or monolithic epoxy-painted gypsum board. The ceiling shall be coved to the wall.

(C) All penetrations in the walls and ceilings shall be sealed.

(D) The door from hood room shall swing into the preparation room. The door from preparation room shall swing into the chemo room. The door from preparation room shall swing into pharmacy.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) When IV solutions are prepared, the required laminar-flow system shall include a nonhygroscopic filter rated at 99.97% (HEPA). A pressure gauge shall be installed for detection of filter leaks or defects.

(B) When fume hoods are used for chemotherapy, the air/fumes shall be exhausted directly to the exterior. The hood exhaust shall not use the building exhaust system. When more than one fume hood is in the same hood room and the work stations face each other, at least six feet must separate work area openings.

(C) When fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(D) All air entering the IV solutions area for the preparation room, hood room and chemo-hood room shall be HEPA filtered.

(E) In the IV solutions area the air pressure in the preparation room shall be positive to the pharmacy, the hood room shall be positive to the preparation room and the chemo-hood room shall be negative to the preparation room.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) Material used for plumbing fixtures shall be nonabsorptive and acid-resistant.

(B) Water spouts used at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and the contents of carafes, etc.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) Under-counter receptacles and conduits shall be arranged (raised) to not interfere with cleaning of the floor below or of the equipment.

(B) Exhaust hoods shall have an indicator light indicating that the exhaust fan is in operation.

(C) Electrical circuit(s) to equipment in wet areas shall be provided with five milliamperes GFCI.

(y) Radiotherapy suite. When radiotherapy services are provided, the suite may contain equipment for electron beam therapy, radiation therapy, or both. The following facilities shall be provided.

(1) Architectural requirements.

(A) Cobalt, linear accelerators, and simulation rooms require radiation protection. A medical physicist licensed under the Texas Medical Physics Practice Act, Occupations Code, Chapter 602, shall specify the type, location, and amount of radiation protection to be installed for the layout and equipment selections. Room layouts and construction shall prevent the escape of radioactive particles. Openings into the room, including doors, ductwork, vents, and electrical raceways and conduits, shall be baffled to prevent direct exposure to other areas of the facility.

(B) Cobalt, linear accelerator, and simulator rooms shall be sized in accordance with the installed equipment requirements, patient access on a stretcher, medical staff access to the equipment and patient, and access for servicing the equipment.

(C) When a mold room is provided, it shall contain a ventilation hood exhausted to the exterior and a hand washing fixture with hands-free operable controls.

(D) A block room with storage for the linear accelerator may be combined with the mold room.

(E) A hot laboratory in support of cobalt therapy shall be provided.

(F) The following service areas shall be provided unless these are accessible from other departments such as imaging or outpatient areas:

(i) a stretcher hold area adjacent to the treatment rooms, screened for privacy, and combined with a seating area for outpatients;

(ii) exam rooms for each treatment room. The rooms shall be a minimum of 100 square feet and shall be provided with hand washing facilities;

(iii) a patient gowning area with provisions for safe storage of valuables and clothing. At least one space shall be sized to allow for staff-assisted dressing;

(iv) convenient access to a housekeeping room;

(v) film file area;

(vi) film storage area for unprocessed film; and

(vii) a radioisotope decay room. This room may be combined with the hot lab.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Radiation protection shall be designed, tested and approved by a medical physicist licensed under the Texas Civil Statutes, Occupations Code, Chapter 602.

(ii) Room shielding calculations for linear accelerators, cobalt and simulation rooms shall be submitted to the Department of State Health Services' Radiation Control (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by inspectors, in the field, subsequent to use. Any changes in design or shielding, which affects radiation exposure levels adjacent to those rooms, requires prior approval by RC.

(iii) The cobalt, simulation and linear accelerator rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(iv) Properly designed rigid support structures for ceiling-mounted equipment shall be located above the finished ceiling.

(B) Finishes.

(i) Flooring in the soiled workroom and any work or treatment areas in the radiotherapy suite where radioactive materials are handled shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Walls shall be constructed of materials that are easily decontaminated from accidental radioactive spills and finished in accordance with §133.162(d)(2)(B)(iv) of this title.

(iii) Ceilings in the hot laboratory and soiled workroom shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(B) Each hood used to process radioactive materials shall have a minimum face velocity of 90-110 feet per minute, be connected to an independent exhaust system, with suitable pressure-independent air modulating devices and alarms to alert staff of fan shutdown or loss of airflow. Each hood shall also have filters with a 99.97% efficiency (based on the dioctyl-phthalate (DOP) test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination.

(4) Plumbing fixtures and piping systems. Piping systems and plumbing fixtures shall comply with the requirements of §133.162(d)(4) of this title.

(5) Electrical requirements. Each radiotherapy suite shall comply with the requirements of §133.162(d)(5) of this title and this paragraph.

(A) Each radiotherapy procedure room shall have at least four electrical receptacles.

(B) Ground fault circuit interrupters shall not be used in radiotherapy procedure rooms.

(C) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(z) Rehabilitation nursing unit.

(1) Architectural requirements. When provided, each rehabilitation nursing unit shall comply with the requirements contained in subsection (t)(1) of this section and the following requirements.

(A) Accessibility requirements. All patient rooms, bathing units and toilets in each rehabilitation nursing unit and all public and common use areas shall be designed and constructed to be handicapped accessible in accordance with §133.162(d)(1)(D) of this title.

These requirements shall apply in all new construction and when an existing nursing unit or a portion thereof is converted to rehabilitation nursing care from other nursing care, e.g. mental health care to rehabilitation care.

(B) Patient room suites. Patient room suites shall comply with the requirements of subsection (t)(1)(B) and the following requirements.

(i) Multi-bed patient room. The clearance between the side of a bed and a wall/partition shall be a minimum of five feet. The clearance between sides of beds shall be a minimum of four feet. The minimum distance at the foot of the bed shall not be less than four feet for single load area/room or seven feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds. The fixed and moveable cabinets and shelves shall not encroach upon the bed clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram H of §133.169(h) of this title.

(ii) Training toilet room. When a training toilet room is provided, there shall be three feet of clearance on both sides and front of the water closet fixture. The room shall be designed to comply with accessibility requirements of §133.162(d)(1)(D) of this title.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with subsection (t)(4) of this section. All plumbing fixtures shall comply with the requirements for the handicapped in accordance with §133.162(d)(1)(D) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(aa) Rehabilitation therapy suite. Rehabilitation therapy may include one or more categories of services. Where two or more rehabilitation services are provided, the services may share common areas when appropriate.

(1) Architectural requirements.

(A) Occupational therapy. When occupational therapy services are provided, the following rooms or areas shall be included:

(i) an activity area with work areas, counters and a hand washing fixture with hands-free operable controls. Work areas and counters shall be suitable for wheel chairs;

(ii) an area for teaching daily living activities with space for a bed, kitchen counter with appliances and sink, bathroom, and a table and chair. The daily living activities area may be combined with the activity area;

(iii) an office for the occupational therapist; and

(iv) a storage room for supplies and equipment.

(B) Physical therapy. When physical therapy services are provided, the following rooms or areas shall be included.

(i) Provisions shall be made for thermotherapy, diathermy, ultrasonics, and hydrotherapy when required by the functional program.

(ii) Treatment area(s) shall be provided with a minimum of 70 square feet of clear floor area for each patient station, exclusive of four foot aisle space. Privacy screens or curtains shall be provided at each treatment station.

(iii) A hand washing fixture with hands-free operable controls shall be provided in each treatment room/space. One hand washing fixture may serve up to four patient stations when cubicles or open room concepts are used and when the fixture is conveniently located.

(iv) An area shall be provided for exercise and may be combined with treatment areas in open plan concepts.

(v) An office shall be provided for the physical therapist.

(vi) Separate storage shall be provided for soiled linen, towels, and supplies.

(vii) A storage area or room for equipment, clean linen, and supplies shall be provided.

(viii) When outpatient physical therapy services are provided, the suite shall have as a minimum patient dressing areas, showers and lockers. These shall be accessible and usable by the disabled.

(C) Prosthetics and orthotics. When prosthetics and orthotics services are provided, the following rooms or areas shall be included:

(i) work space with counters and shelves for technicians;

(ii) a treatment space for evaluating and fitting with privacy screens or curtains; and

(iii) a storage area or room for equipment and supplies.

(D) Speech and hearing. When speech and hearing services are provided, the following rooms or areas shall be included:

(i) a space for evaluating and treatment with privacy screens or curtains; and

(ii) a storage area or room for equipment and supplies.

(E) Service areas. The following areas or items shall be provided in a rehabilitation therapy suite, but may be shared when multiple rehabilitation services are offered:

(i) patient waiting area(s) out of traffic with space for wheelchairs;

(ii) patient toilet facilities containing hand washing fixtures, with hands-free operable controls;

(iii) reception and control station(s). The reception and control station shall be located to provide supervision of activities areas. The control station may be combined with office and clerical spaces;

(iv) office and clerical space;

(v) wheelchair and stretcher storage room or alcove which shall be in addition to other storage requirements;

(vi) lockable closets, lockers or cabinets for securing staff personal effects;

(vii) staff toilets. The toilets may be outside the suite but shall be convenient for staff use and contain hand washing fixtures with hands-free operable controls;

(viii) soiled holding room; and

(ix) housekeeping room with service sink, conveniently accessible.

(2) Details and finishes.

(A) Details. Details shall be in accordance with §133.162(d)(2)(A) of this title.

(B) Finishes. Finishes shall be in accordance with §133.162(d)(2)(B) of this title and this paragraph.

(i) Flooring in a treatment room and soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Wall finishes shall be in accordance with the requirements of §133.162(d)(2)(B)(iv) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Air handling units serving the rehabilitation therapy suite shall be equipped with filters having efficiencies equal to, or greater than specified for patient care areas in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(bb) Renal dialysis suite. Outpatient renal dialysis shall not be performed in the hospital's inpatient renal dialysis suite unless authorized under §133.41(t) of this title. When outpatient renal dialysis is provided within a hospital building, the service and facilities shall be separated from the hospital with a two-hour fire rated partition. The owner of the outpatient renal dialysis facility must obtain a separate license under Texas Health and Safety Code, Chapter 251, End Stage Renal Disease Facilities. Mechanical, electrical and plumbing services may be contracted from the hospital and the hospital shall maintain all rights and controls of all systems. When inpatient renal dialysis services are provided, the following rooms or areas shall be included.

(1) Architectural requirements.

(A) Dialysis services (acute). Dialysis services (acute) may be performed in critical care units and designated areas in the hospital, with appropriate equipment and space.

(B) Treatment area(s). The treatment area(s) shall be separate from the administrative area(s).

(i) Individual patient treatment room(s) shall have a minimum of 120 square feet of clear floor area exclusive of fixed and movable cabinets and shelves. The patient treatment room shall contain cabinets, work counter, and a hand washing fixture with hands-free operable controls.

(ii) In multiple-treatment stations, the clearance between the side of a station and a wall/partition shall be a minimum of three feet. The clearance between sides of stations shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multiple-treatment stations shall contain cabinets, work counters, and hand washing fixtures with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the patient treatment station clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(iii) A nurse station shall be located within the dialysis treatment area(s) and designed to provide visual observation of all patient stations. The nurse station shall have counters for storage and access to a hand washing fixture(s) with hands-free operable controls.

(iv) Privacy shall be provided for each patient in the open treatment area with cubicle curtains or moveable screens.

(v) Storage and preparation of medication may be done from a medicine preparation room, medicine alcove or from a self-contained medicine dispensing unit and shall be under visual control of nursing staff. A work counter, a hand washing fixture that is operable without the use of hands, a refrigerator, and double-locked storage for controlled substances shall be provided. (Standard cup-sinks provided in many self-contained units are not adequate for hand washing.)

(C) Home training room. When home training is provided in the unit, a private treatment area of at least 120 square feet exclusive of fixed and movable cabinets and shelves shall be provided. This room shall contain a work counter, a hand washing fixture with hands-free operable controls, and a separate drain for fluid disposal.

(D) Isolation rooms.

(i) When renal dialysis treatment is provided for persons who are known or suspected of having airborne infectious disease, these procedures shall be performed in a designated treatment room of not less than 120 square feet of floor area meeting airborne infection isolation ventilation requirements as contained in Table 3 of §133.169(c) of this title. Bathing facilities are not required.

(ii) When medical isolation for hepatitis B surface antigen (HbsAg) is provided, it shall be in a separate dedicated treatment room for a single patient with a minimum of 100 square feet clear area exclusive of fixed and movable cabinets and shelves. The treatment room shall include a work counter and a hand washing fixture with hands-free operable controls, and space for patient care supplies and equipment. The dialyzed equipment shall be designated and reserved for individual renal dialysis patients. The equipment shall be disinfected after each use. Disinfection of equipment shall occur in the treatment room.

(E) Service areas and facilities.

(i) Patient toilet(s). Patient toilet rooms shall be convenient to the treatment area(s) and include hand washing fixture(s) with hands-free operable controls.

(ii) Storage space. A storage space shall be available for wheelchairs, supply carts and stretchers. This storage shall be located out of the direct line of traffic and in addition to other storage requirements.

(iii) Water treatment room. The water treatment and equipment for the dialysis shall be located in a dedicated enclosed room.

(iv) Mixing room. Dialysis solutions may be processed from a central batch delivery system or prepared in an on-site mixing room. When provided, a mixing room shall include a work counter, sink with hands-free operable controls, storage space, and holding tanks.

(v) Dialyzers reprocessing room. When provided, the room shall be arranged for the separation and one-way movement of soiled and clean materials. This room shall include a work counter, service sink, separate hand washing fixture with hands-free operable controls, refrigerator and storage space.

(vi) Breakdown room. When provided, the room shall include a work counter, service sink, separate hand washing fixture with hands-free operable controls, and storage space. This function may be included as part of the soiled processing area of the dialyzers reprocessing room.

(vii) Nourishment station. When provided, the nourishment station shall include a work counter, a sink with hands-free operable controls, refrigerator, microwave, and storage cabinets.

(viii) Hand washing facilities. Hand washing facilities shall be provided in each examination room and treatment room. In an open multiple-treatment area one hand washing fixture shall be provided for every four treatment stations or fraction thereof.

(ix) Dictation and report preparation area. This area may be incorporated with the nurse station if adequate work space is provided.

(x) Staff facilities. Toilets may be outside the suite but shall be convenient for staff use.

(xi) Offices work area. Office space and clinical work area shall include space for records storage and report preparation.

(xii) Clean workroom. When the functional program dictates preparing patient care items, a clean workroom shall be provided and contain a work counter, a hand washing fixture with hands-free operable controls, and storage facilities for clean and sterile supplies. This function may be within the mixing room.

(xiii) Clean linen storage. There shall be a designated area for clean linen storage. This may be within a clean workroom, a mixing room, a separate closet, or an approved distribution system. If a closed cart system is used, storage of the cart shall be in an alcove.

(xiv) Soiled workroom. The soiled workroom shall contain a work counter, a clinical sink with hands-free operable controls or equivalent flushing type fixture, separate hand washing facilities, and separate waste and linen receptacles.

(xv) Housekeeping room. A housekeeping room for the exclusive use of the unit shall contain a service sink and storage for housekeeping supplies and equipment.

(2) Details and finishes.

(A) Details. Details shall be in accordance with §133.162(d)(2)(A) of this title.

(B) Finishes. Finishes shall be in accordance with §133.162(d)(2)(B) of this title and this paragraph.

(i) Flooring in a treatment room and soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Wall finishes shall be in accordance with the requirements of §133.162(d)(2)(B)(iv) of this title.

(iii) Ceilings in the isolation and hepatitis B rooms shall be of the monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Air handling units serving the renal dialysis suite shall be equipped with filters having efficiencies equal to, or greater than specified for patient care areas in Table 4 of §133.169(d) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph. The dialysis water treatment shall meet the standards as described in the American National Standard, Hemodialysis Systems, July 2003 edition, published by the American Association for the Advancement of Medical Instrumentation (AAMI), 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201, telephone (703) 525-4890.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General. Each treatment area and treatment room shall have at least two duplex electrical receptacles located on each side of a patient bed or lounge chair.

(B) Grounding. All equipment and appliances shall be properly grounded in accordance with the National Fire Protection Association 99, Standard for Health Care Facilities, §§3-3.2.1.2(a)(2) and 7-5.1, 2002 Edition (NFPA 99), published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, Post Office Box 9101, Quincy, Massachusetts 02269-9101, 1-800-344-3555.

(C) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(cc) Respiratory therapy suite. The type and extent of respiratory therapy services vary greatly in each hospital. Therapy can be delivered from a large centralized area or basic services can be provided at the patient bedside.

(1) Architectural requirements.

(A) Respiratory therapy suite. When respiratory services are provided from a centralized area, the following rooms or areas shall be included:

- (i) an office for the respiratory therapist;
- (ii) office and clerical space with provision for filing and retrieval of patient records;
- (iii) receiving/decontamination workroom with work counter or table, a deep sink, and a hand washing fixture with hands-free operable controls; and
- (iv) a storage room for clean and sterile supplies which is separate from the receiving/decontamination workroom.
- (v) When a blood gas analyzer is provided, it shall be located in a room and contain a counter and hand washing sink. When a portable blood gas analyzer is used, it may be used in rooms which have a work counter and hand washing facilities with hands-free operable controls. Storage of the unit may occur in an alcove or equipment storage room.

(B) Outpatient respiratory therapy services. When respiratory therapy services are provided for outpatients, the following additional areas and facilities shall be included in the centralized respiratory therapy suite:

- (i) patient waiting area with space for wheelchairs;
- (ii) reception and control station(s) with visual control of waiting and activities areas;
- (iii) patient toilet facilities which include hand washing fixtures with hands-free operable controls;
- (iv) office and clerical space; and
- (v) consultation/education room.

(C) Cough-inducing and aerosol-generating procedures. All cough-inducing procedures performed on patients who may have infectious Mycobacterium tuberculosis shall be performed in rooms, booths or special enclosures using local exhaust

ventilation devices with HEPA filters located at the discharge end and exhaust directly to the outside.

(D) Service areas. The following areas and facilities shall be provided for the respiratory therapy suite but may be shared with other departments when conveniently located:

(i) wheelchair and stretcher storage room or alcove which is in addition to other storage requirements;

(ii) lockable closets, lockers or cabinets for securing staff personal effects;

(iii) staff toilets which include a hand washing fixture with hands-free operable controls. Staff toilets may be located outside suite if location is near and convenient; and

(iv) housekeeping room. The housekeeping room shall be located within the suite or nearby, and shall contain a service sink and storage space for housekeeping supplies and equipment.

(2) Details and finishes.

(A) Details. Details shall be in accordance with §133.162(d)(2)(A) of this title.

(B) Finishes. Finishes shall be in accordance with §133.162(d)(2)(B) of this title and this paragraph.

(i) Flooring in a decontamination room shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Wall finishes shall be in accordance with the requirements of §133.162(d)(2)(B)(iv) of this title.

(iii) Ceilings shall be in accordance with §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

(dd) Special procedure suite.

(1) Architectural requirements.

(A) General. When special procedures such as endoscopy, bronchoscopy, and cardiac catheterization and other similar special procedures are provided, procedure rooms may be in a separate suite or may be part of the surgical suite.

(i) Special procedure rooms may be incorporated in an outpatient suite.

(ii) When special procedure rooms are part of the surgical suite and noninvasive procedures are performed, these rooms are not required to be part of the sterile environment.

(iii) Nonsurgical or noninvasive procedure rooms shall have a minimum clear floor area of 250 square feet, and a minimum clear dimension between fixed cabinets and built-in shelves shall be 14 feet.

(iv) A hand washing fixture or a scrub sink with hands-free controls shall be located within five feet of the entrance to each nonsurgical procedure room either in the room or outside. Hand washing facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts and recessed out of the main traffic areas.

(v) When general anesthesia or inhalation anesthetizing agents are used during special procedures, these rooms shall comply with the detail, finish, mechanical and electrical requirements for an operating room contained in subsection (ee) of this section.

(B) Special procedure rooms for surgical cystoscopic and other endourologic procedures.

(i) The procedure room shall have a minimum clear floor area of 350 square feet exclusive of fixed cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 15 feet.

(ii) Procedure rooms shall be designed for visual and acoustical privacy for the patient.

(iii) One scrub station shall be located within five feet of the outside entrance of each special procedure surgical room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment or supply carts. The scrub sinks shall be recessed out of the main traffic areas. The scrub sink shall be located off the restricted areas of the special procedure surgical procedure rooms. Scrub sinks or sinks shall not be located inside the sterile area.

(iv) Appropriately sized areas shall be provided for male and female changing rooms within the special procedure surgical suite. These areas shall contain

lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker/changing rooms shall be provided for male and female staff. The shower and toilet room(s) may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the special procedure surgical suite can shower, change, and move into the restricted portions of special procedure surgical suite.

(C) Catheterization laboratory. A catheterization procedure room may be in a separate suite, part of a special procedure suite, surgical suite, or in the imaging suite. The following items and facilities shall be provided.

(i) The room(s) shall be located in an area restricted to authorized personnel.

(ii) The procedure room shall be a minimum of 400 square feet of clear floor area exclusive of fixed and movable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 18 feet.

(iii) A control room shall have a view window which permits complete observation of the patient from the control console. The control room shall be large enough to contain the efficient functioning of the X-ray and image recording equipment.

(iv) An area for viewing images and film file room shall be provided. When digital imaging is provided throughout the suite, a minimum of two X-ray film illuminators shall be provided within a central location within the catheterization laboratory and the film file room may be omitted.

(v) An equipment room large enough to contain X-ray transformers, power modules, and necessary electronics and electrical gear shall be provided.

(vi) Appropriately sized areas shall be provided for male and female changing rooms within the catheterization laboratory suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker/changing rooms shall be provided for male and female staff. The shower and toilet room(s) may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the catheterization laboratory can shower, change, and move into the restricted portions of catheterization laboratory.

(vii) One scrub station shall be located within five feet of the outside entrance of each cardiac catheterization laboratory procedure room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment or supply carts. The scrub sinks shall be recessed out of the main traffic areas. The scrub sink shall be located off the restricted areas of the cardiac catheterization laboratory. Scrub sinks or sinks shall not be located inside the sterile area.

(viii) Sterilizing facilities for immediate or emergency use shall be provided unless instruments are all disposable. A work space and hand washing fixture with hands-free operable controls shall be included.

(D) Patient holding and preparation area. In suites with two or more special procedure rooms, a patient holding and preparation area shall be provided to accommodate ambulatory and stretcher patients and meet the following requirements:

(i) two-stretcher stations shall be provided for first procedure room with one additional station for each additional procedure room;

(ii) the minimum clear floor space in a private holding and preparation room shall be 100 square feet exclusive of toilet room, built-in cabinets, work counter, alcove, or vestibules. A hand washing fixture with hands-free operable controls shall be provided. A minimum of 10 feet width shall be provided for the head wall;

(iii) in a multiple-bed holding and preparation area, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title;

(iv) a control station and charting area arranged to permit staff visual observation of holding and preparation area;

(v) a work counter and a hand washing fixture with hands-free operable controls for every four beds/gurneys located in the preparation area; and

(vi) cubicle curtains at each station for patient privacy.

(E) Recovery room or area. In suites with two or more special procedure rooms, a recovery room or area shall be provided to accommodate ambulatory and stretcher patients and meet the following requirements:

(i) a minimum of one patient recovery station shall be provided for each special procedure room;

(ii) in a single patient recovery room, there shall be a minimum clear area of 130 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of 10 feet width shall be provided for the head wall. The room shall contain cabinets, work counter, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area;

(iii) when multiple-bed/gurney recovery patient stations are provided, the clearance between side of bed/gurney and a wall/partition shall be a minimum of four feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than eight feet for single load area/room or twelve feet for double load area/room. Four feet of passage space requirement at the foot of the bed may be shared between two beds/gurneys. The multiple-bed/gurney recovery patient station shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. One hand washing fixture with hands-free operable controls shall be provided for every four stations or fraction thereof. The requirements of this clause are illustrated in Table 8, Diagram M of §133.169(h) of this title;

(iv) a nurse station with a hand washing fixture with hands-free operable controls and charting area shall be provided and arranged to provide visual observation of recovery room area;

(v) a staff toilet room with a hand washing fixture with hands-free operable controls shall be provided and located within the working area to maintain staff availability to patients;

(vi) cubicle curtains shall be provided at each station for patient privacy; and

(vii) the recovery room or area may be within the patient holding area.

(F) Instrument processing room. When instruments and equipment are processed, cleaned and disinfected within the suite, dedicated rooms shall be provided. The room may serve multiple procedure rooms. The following rooms shall be included.

(i) A decontamination room shall be provided and equipped with work counters, two sinks remote from each other and a hand washing fixture with hands-free operable controls. One of the sinks shall be utility type.

(ii) A clean room shall be provided and the process of cleaning the instruments or equipment shall flow from the contaminated area to the clean area, and finally, to storage. The room shall include a work counter and a hand washing sink fixture with hands-free operable controls. Instruments and equipment shall be protected from contamination.

(iii) When endoscopy scope wash rooms are provided, cleaning, washing and drying may occur in the same room. The room shall contain two sinks.

(G) Service areas. The following services shall be provided for all types of special procedure rooms unless noted otherwise.

(i) Control station. In facilities with two or more special procedure rooms in a suite, a nurse station shall be provided and located to permit visual surveillance of all traffic which enters the special procedure rooms suite.

(ii) Dictation and report preparation area. This area may be incorporated with the control station.

(iii) Medication station. Provision shall be made for the storage and distribution of medication to be administered to patients. This may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit. The medicine preparation room, medicine alcove area or self-contained medicine dispensing unit shall be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean work room.

(iv) Outpatient services. When outpatient services are provided in the special procedure suite, a separate waiting/change area shall include waiting room, dressing/gowning area, and toilet facilities and a hand washing fixture with hands-free operable controls.

(v) Patient toilet room(s). Toilet room(s) shall be conveniently located to special procedure rooms and patient changing areas and shall include hand washing fixture(s) with hands-free operable controls.

(vi) Staff toilet facilities. Facilities shall be provided for exclusive staff use and include a hand washing fixture with hands-free operable controls. The toilet may be accessible from a staff lounge, when a staff lounge is provided.

(vii) Storage. A storage room(s) shall be provided for equipment and supplies used in the special procedure suite. Each special procedure suite shall provide a minimum of 150 square feet of storage area or 50 square feet per procedure room, whichever is greater.

(viii) Wheelchair and stretcher storage. Wheelchair and stretcher storage space/alcove shall be provided and located out of direct line of traffic.

(ix) Staff storage. Storage space for employees' personal effects shall be provided.

(x) Ice machine. An ice machine shall be provided.

(xi) Clean storage room. A clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls.

(xii) Soiled workroom. The soiled workroom shall not have direct connection to the special procedure or diagnostic rooms or other sterile or clean activity rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle.

(xiii) Housekeeping room. A housekeeping room shall be provided for the exclusive use of the special procedure suite. It shall be directly accessible from the suite and shall contain a floor receptor or service sink and storage for supplies and housekeeping equipment.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details. Special procedure rooms shall have ceiling heights not less than nine feet.

(B) Finishes.

(i) Flooring used in special procedure rooms, decontamination room, and in the soiled workroom shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceiling finishes in special surgical procedure rooms and isolation rooms, soiled workroom and sterile processing rooms shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(iii) A lay-in type ceiling is acceptable in nonsurgical special procedure rooms.

(iv) A nonsurgical or noninvasive catheterization lab shall have a washable ceiling.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Air supply for the special procedure rooms shall be from ceiling outlets that are as near the work centers as possible. A minimum of two low return inlets shall be located diagonally opposite from one another.

(B) Return air inlets shall be not lower than four inches nor higher than 12 inches from floor level.

(C) Smoke removal systems shall be provided in accordance with §133.162(d)(3)(D)(iv)(II) of this title, for special procedure rooms that have piped-in nitrous oxide medical gas or where anesthesia is administered to patients.

(D) The decontamination room shall meet the ventilation requirements that are contained in Table 3 of §133.169(c) of this title.

(E) Each special procedure room and recovery room shall have wall-mounted temperature and humidity indicating devices.

(F) When patients with airborne infectious disease are treated, the room shall meet requirements for airborne infection ventilation for patient care areas in accordance with Table 3 of §133.169(c) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in special procedure rooms and sterile processing rooms unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(B) A medical gas system shall be provided in accordance with §133.162(d)(4)(A)(iii) and (iv), and Table 6 of §133.169(f) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) X-ray film illuminators for handling at least four films simultaneously shall be provided in a central location. When the entire special procedure suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminators viewers shall be provided.

(ii) Each special procedure room shall have at least six duplex electrical hospital grade receptacles.

(iii) In locations where mobile X-ray, laser, or other equipment requiring special electrical configuration is used, the additional receptacles shall be distinctively marked for the special use.

(iv) The electrical circuit(s) to equipment in wet areas shall be provided with GFCIs. GFCI circuits shall not be used in special procedure rooms. When ground fault circuit interrupters are used in critical areas, provisions shall be made to ensure that other essential equipment is not affected by activation of one interrupter.

(v) Special grounding system in areas such as special procedure rooms where a patient may be treated with an internal probe or catheter the ground system shall comply with Chapter 10, NFPA 99 and Article 517, NFPA 70.

(vi) Special procedures rooms shall have general lighting in addition to that provided by special lighting units at the procedure tables.

(B) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(ee) Surgical suite.

(1) Architectural requirements.

(A) General.

(i) A public waiting room shall be provided.

(ii) Toilet facilities, public telephone(s), and drinking fountain(s) shall be provided within or nearby.

(iii) The surgical suite shall be located and arranged to preclude unrelated traffic through the suite.

(iv) When outpatient surgery is provided within the surgical suite additional requirements in subsection (v)(1)(F) of this section shall be provided.

(B) General operating room(s). A minimum of one operating room shall be provided and shall have a minimum clear floor area of 400 square feet exclusive of fixed and movable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 20 feet. There shall be no direct access between operating rooms.

(C) Operating rooms for cardiovascular, orthopedic, neurological, and other special surgical procedures that require additional personnel and large equipment.

(i) When provided, these rooms shall have a minimum clear floor area of 600 square feet, with a minimum of 20 feet clear dimension exclusive of fixed or wall-mounted cabinets and built-in shelves.

(ii) An additional room shall be provided in the restricted area of the surgical suite, preferably adjoining this operating room, where extra corporeal pump(s), supplies and accessories can be stored and serviced.

(iii) When complex orthopedic surgery and neurosurgery are performed, additional rooms shall be provided in the restricted area of the surgical suite, preferably adjoining the specialty operating rooms, for storage of equipment used during these procedures.

(D) Preoperative patient holding area(s) or room(s). In facilities with two or more operating rooms, a patient holding area or rooms shall be provided. The preoperative

patient holding area may be used for secondary recovery. The area shall meet the following requirements.

(i) The minimum clear floor space in a private preoperative holding room shall be 100 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of nine feet width shall be provided for the head wall.

(ii) In a multiple-bed preoperative holding area, the clearance between the side of a bed/gurney and a wall/partition shall be a minimum of three feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than seven feet for single load area/room or ten feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The fixed and moveable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram D of §133.169(h) of this title.

(iii) A control station and charting area shall be provided and arranged to permit staff visual observation of holding and preparation area.

(iv) A work counter with hand washing fixture with hands-free operable controls shall be provided and located in the preparation area.

(v) Cubicle curtains shall be provided at each station for patient privacy.

(vi) One hand washing fixture with hands-free operable controls shall be provided for every four preoperative holding beds or fraction thereof. Fixtures shall be uniformly distributed. One hand washing fixture with hands-free operable controls shall be provided within each single-bed preoperative holding room.

(E) Post-anesthesia care units.

(i) Post-anesthesia care units (PACU) for surgical patients shall contain a medication distribution station, nurse station with charting facilities, clinical sink provisions for bedpan cleaning, and storage space for stretchers, supplies and equipment. The nurse station shall be arranged to permit the staff to have full visual control of the PACU area.

(ii) A minimum of one and a half patient stations per operating room shall be provided for post-anesthesia care or fraction thereof. A minimum of two stations shall be provided when there is only one operating room.

(iii) The minimum clear floor space in a private recovery room shall be 130 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of 10 feet width shall be provided for the head wall. The room shall contain cabinets, work counter, and hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area.

(iv) In multiple-bed/gurney recovery patient stations, the clearance between the side of bed/gurney and a wall/partition shall be a minimum of five feet. The clearance between sides of beds/gurneys shall be a minimum of six feet. The minimum distance at the foot of the bed/gurney shall not be less than eight feet for single load area/room or twelve feet for double load area/room. Four feet of the passage space at the foot of the bed may be shared between two beds/gurneys. The multi-bed/gurney recovery patient station shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the bed/gurney clear floor space/area. The requirements of this clause are illustrated in Table 8, Diagram N of §133.169(h) of this title.

(v) Special provisions shall be made to keep medical isolation infectious patients separate during surgical recovery. An isolation room meeting the requirements in subsection (t)(1)(C) of this section may meet this requirement if conveniently located near the surgical suite and otherwise complies with requirements for a PACU except that a patient toilet room is not required. The recovery isolation room shall have a minimum clear floor area of 120 square feet. In addition, the recovery isolation room medical gas system outlet requirements shall be in accordance with Table 6 of §133.169(f) of this title for recovery room(s).

(vi) Cubicle curtains shall be provided for patient privacy.

(vii) At least one door to the PACU room shall be within the surgical suite.

(viii) Staff toilet facilities and a hand washing fixture with hands-free operable controls shall be located within or immediately adjacent to the PACU.

(ix) One hand washing fixture shall be provided for every four recovery beds or fraction thereof in open wards. Fixtures shall be uniformly distributed. One hand washing fixture shall be provided within each single-bed recovery room.

(F) Separation of recovery patients. Provisions shall be made for separating all patients subject to general anesthesia from those who did not receive general anesthesia. This requirement may be satisfied by providing separate recovery rooms, cubicles, secondary recovery rooms or scheduling of procedures.

(G) Service areas. Services, except for the enclosed soiled workroom and the housekeeping room, may be shared with the obstetrical facilities if the functional program reflects this concept. Service areas, when shared with delivery rooms, shall be designed to avoid the passing of patients or staff between the operating room and the delivery room areas.

(i) Control station. A control station located to permit visual surveillance of all traffic entering the surgical suite shall be provided.

(ii) Office. A supervisor's office or station shall be provided.

(iii) Scrub facilities. Two scrub stations shall be located in the restricted corridor within five feet of the entrance of each operating room. Two scrub stations may serve two operating rooms if the scrub stations are located adjacent to the entrance of both operating rooms. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment, or supply carts. Viewing panels shall be provided for observation of the surgical room interior. The scrub sinks shall be recessed out of the main traffic areas. The alcove shall be located within the restricted areas of the surgical suite. Scrub sinks shall not be located inside the sterile area.

(iv) Substerile facilities. Sterilizing facilities located conveniently to the operating rooms for immediate or emergency use with work counter shall be provided.

(v) Anesthesia workroom. The anesthesia workroom shall contain a work counter, sink with hands-free operable controls and storage space for medical gas cylinders and other anesthesia equipment.

(vi) Medication station. Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean work room.

(vii) General storage room(s). A minimum of 50 square feet per operating room is required for general storage space(s). The minimum requirement for three operating rooms or less is 150 square feet. This storage room is exclusive of soiled holding, sterile supplies, clean storage, drug storage, locker rooms and storage alcoves.

(viii) Orthopedic surgery storage. Splints and traction equipment shall be stored in an enclosed storage room. Storage shall be outside the operating room but must be conveniently located.

(ix) Storage alcove. An alcove(s) located out of the direct line of traffic shall be provided for the storage of stretchers, portable X-ray equipment, fracture tables, warming devices, auxiliary lamps, etc.

(x) Surgical suite staff clothing change rooms. Appropriately sized areas shall be provided for male and female personnel working within the surgical suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker/changing rooms shall be provided for male and female staff. The shower and toilet room(s) may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the surgical suite can shower, change, and move directly into the restricted areas of the surgical suite.

(xi) Lounge. A lounge shall be provided in hospitals with three or more operating rooms. The lounge shall permit staff use without leaving the surgical suite and may be accessed from the clothing changing rooms. The lounge shall not have direct access from outside the surgical suite. When the lounge is remote from the clothing change rooms, toilet facilities and a hand washing fixture with hands-free operable controls accessible from the lounge shall be provided.

(xii) Staff toilet facilities. Toilet facilities located in the surgical suite for exclusive staff use shall be provided and contain a hand washing fixture with hands-free operable controls. The toilet room may be accessible from a staff lounge, when provided.

(xiii) Dictation and report preparation area. This may be accessible from the lounge area.

(xiv) Cast room. When a cast room is provided it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures. This room may be located in the emergency room.

(xv) Ice machines. An ice machine shall be provided for therapeutic purposes. A self-dispensing ice machine shall be provided for human consumption.

(xvi) Clean workroom or clean supply room. A clean workroom is required when clean materials are assembled within the surgical suite prior to use or following the decontamination cycle. It shall contain a work counter, a hand washing fixture with hands-free operable controls, storage facilities for clean supplies, and a space to package reusable items. The storage for sterile supplies must be in a separate room. When the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and hand washing fixture may be omitted.

(xvii) Sterile core. When a surgical suite contains a sterile core, it shall be free of any cross-traffic of staff and supplies from the soiled/decontaminated areas to the sterile/clean areas. The use of facilities outside the operating room for soiled/decontaminated processing, clean assembly and sterile processing shall be designed to move the flow of goods and personnel from dirty to clean without compromising universal precautions or aseptic techniques in both departments.

(xviii) Soiled workroom. The soiled workroom shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle. The clinical sink and work counter may be eliminated if the room is used only for temporary holding of soiled material and cleaning of equipment/instruments and sterilization is provided outside the surgical suite. Provisions shall be made for the disposal of liquid waste. The soiled workroom shall be provided for the exclusive use of the surgical suite, shall be located in the restricted area of the surgical suite, and shall not have direct connection with operating rooms, delivery rooms or other sterile activity rooms.

(xix) Housekeeping room. A housekeeping room containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided for the exclusive use of the surgical suite and shall be directly accessible from the surgical suite.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) Operating rooms shall have ceiling heights not less than nine feet.

(ii) Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over operating suites, unless special provisions are made to minimize such noise.

(B) Finishes.

(i) Flooring within operating rooms, soiled workrooms and sterile processing rooms shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Walls in operating rooms, special procedures rooms, and soiled workrooms shall comply with the requirements of §133.162(d)(2)(B)(iv)(II) of this title.

(iii) Ceilings in operating rooms, isolation rooms, soiled workroom and sterile processing rooms shall be monolithic as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph.

(A) Air supply for the operating rooms shall be from ceiling outlets near the center of the work area to efficiently control air movement. A minimum of two return air inlets located diagonally opposite from one another and near floor level shall be provided. Design should consider turbulence and other factors of air movement to minimize airborne particulate matter. Where extraordinary procedures require special designs, the installation shall be reviewed on a case by case basis.

(B) Smoke removal systems shall be provided in accordance with §133.162(d)(3)(D)(iv)(II) of this title.

(C) The ventilation system for anesthesia storage rooms and medical gases storage shall conform to the requirements of Chapter 5, NFPA 99, §5.1.3.3.3.

(D) Each operating room, PACU, and recovery room shall be provided with conveniently mounted temperature and humidity indicating devices.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title and this paragraph.

(A) General.

(i) Drainage and waste piping shall not be installed above or below ceilings in operating rooms, and sterile processing rooms unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(ii) Floor drains shall not be installed in operating rooms. Flushing rim type floor drains may be installed in cystoscopic operating rooms. If a floor drain is installed in cystoscopy, it shall contain a nonsplash, horizontal-flow flushing bowl beneath the drain plate.

(iii) Sinks used for the disposal of plaster of paris shall have plaster trap.

(B) Medical gas systems. Medical gas systems and outlets shall be provided in accordance with §133.162(d)(4)(A)(iii) and Table 6 of §133.169(f) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) X-ray film illuminators for handling at least four films simultaneously shall be provided in each operating room. When the entire surgical suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(ii) Each operating room shall have at least eight duplex electrical hospital grade receptacles of which three shall be located convenient to the head of the procedure table. Each PACU recovery station shall have a minimum of seven receptacles at the head of each bed.

(iii) Special grounding system for critical care areas such as operating rooms, and special procedure rooms where patients are subjected to invasive procedures and connected to line-operated, electromedical devices shall comply with NFPA 99, Chapter 9, and NFPA 70, Article 517.

(iv) Operating rooms and special procedure rooms shall have general lighting in addition to that provided by special lighting units at the surgical tables. Each

fixed special lighting unit at the operating or delivery table shall be connected to an independent circuit powered by the critical branch of the essential electrical system. Portable units may share circuits. At least one general lighting fixture shall be served from a normal branch panel.

(v) Operating rooms shall be provided with one or more battery-powered emergency lighting units as required by NFPA 99, §13.4.1.2.6(E).

(vi) Operating rooms shall be provided with at least one receptacle powered from a normal power panel. Receptacle shall be labeled, "Normal power receptacle, use only in the event of loss of critical system."

(B) Nurses calling system. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

(ff) Universal care suite.

(1) Architectural requirements. Architectural requirements shall be in accordance with §133.162(d)(1) of this title and this paragraph.

(A) General. When a universal care suite is provided, the universal care suite shall be a separate suite(s) operated separately from other suites in the hospital.

(i) All universal care suite patient rooms shall be single patient rooms and have a minimum clear floor area of 200 square feet per bed exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. A minimum of 13 feet width shall be provided for the head wall.

(ii) Minor encroachments including columns and wall hung lavatories that do not interfere with functions may be ignored when determining space requirements for patient rooms. Required clear floor space for patient rooms shall be exclusive of toilet rooms, closets, lockers, built-in cabinets, wardrobes, alcoves, or vestibules.

(iii) Each universal care suite patient room shall be located on an exterior wall and shall have a window. Windows shall be in accordance with subsection (t)(2)(A)(iv) and (v) of this section.

(iv) Each universal care suite patient room shall have access to a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet, a hand washing fixture with hands-free operable controls and bathing facilities, and storage shelf or cabinet.

(v) A hand washing fixture with hands-free operable controls shall be located in each patient room near the entrance of the room and in the patient bathroom.

(vi) A minimum of one airborne infection isolation room and patient bathroom shall be provided in accordance with subsection (t)(1)(C)(iii), (iv) and (v) of this section. The universal care suite infection isolation room shall have a minimum clear floor

area of 200 square feet per bed exclusive of anterooms, vestibules, toilet rooms, closets, lockers, wardrobes, and/or alcoves. A minimum of 13 feet width shall be provided for the head wall. The universal care suite isolation patient room shall have a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet, a hand washing fixture with hands-free operable controls and bathing facilities, and storage shelf or cabinet.

(vii) Viewing panels in the door or walls of these rooms are required. Curtains or other means shall be provided to cover the viewing panels when visual privacy is required.

(viii) Each patient shall have a wardrobe, locker, or closet that is suitable for hanging full-length garments and for storing personal effects. A minimum of 12 lineal inches of hanging space shall be provided per patient.

(ix) Each universal care room shall be provided with X-ray film illuminators for handling at least two films simultaneously. When the entire universal care suite is provided with digital imaging system capabilities, a minimum of two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(B) Pediatrics. When a universal care suite is provided for pediatrics, the suite shall comply with the requirements contained in this paragraph and the following.

(i) A sleeping space shall be provided for parents who spend long hours with the patient. This space may be within the patient room or separate from the patient area but shall be in communication with the universal care suite staff.

(ii) A room shall be provided for private consultation and shall be located within, or convenient to, the universal care suite. The multipurpose room noted in subparagraph (D)(iv) of this paragraph will meet this requirement if conveniently located.

(iii) Storage space for infant formula shall be provided. This functional space may be outside the universal care suite but shall be available for use at all times.

(iv) Storage cabinets or closets for toys and games shall be provided within the room.

(v) Storage closet for cots, bed linens, and other items needed for overnight accommodation of parents shall be provided in the general location of sleeping accommodations.

(C) Universal care suite services and facilities. The following services and facilities shall be provided.

(i) A visitors' waiting space shall be provided with toilet facility(ies), public telephone(s), and drinking fountain(s). One waiting space may serve other units.

(ii) The nurse station shall be located to permit direct visual observation of each patient served. Video cameras or mirrors shall not be substituted for direct visual observation. The nurse station shall have space for counters and storage. The counter height shall not exceed 42 inches. The nurse station may be combined with or include centers for reception and communication.

(iii) When individual nurse substations are provided and located at each patient room(s), they shall be located to permit direct visual observation of each patient served. The nurse substation shall have space for counter, storage space and a recessed sitting space. The substation shall be at a minimum recessed from the egress corridor one foot six inches.

(iv) Charting and dictation area(s) for physicians for recording, record storage and reviews shall be provided. Dictation space may be in a separate room or alcove. Suitable space shall be provided when computers are used for the clinical records.

(v) Storage space shall be provided for emergency equipment in the unit.

(vi) Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be located with the clean work room.

(vii) A soiled workroom shall be provided and contain a clinical sink or equivalent flushing rim type fixture with hot and cold mixing faucet, separate hand washing facilities with hands-free operable controls, and separate waste and soiled linen receptacles.

(viii) A soiled holding room may be provided when all the universal care suite patient toilet rooms have bedpan washers. The soiled holding room shall contain a hand washing fixture with hands-free operable controls and separate waste and soiled linen receptacles.

(ix) A clean workroom or clean supply room shall be provided. A clean workroom when used for preparing patient care items shall contain a work counter, hand washing facilities, and storage facilities for clean and sterile supplies. When a clean supply room is used only for storage and holding as part of a distribution system of clean and sterile supplies, the work counter and hand washing facilities may be omitted.

(x) A nourishment station shall contain a work counter, a sink with hands-free operable controls, refrigerator, cabinets, and not be located in the medication room or the clean workroom. Space shall be included for temporary holding of unused or soiled dietary trays.

(xi) An ice machine shall be provided for ice for treatment and patient use. Ice-making equipment for treatment may be in the clean workroom or the nourishment station.

(xii) An intravenous solution support shall be provided at each patient bed. The intravenous solution shall not be suspended directly over the patient.

(xiii) The stretcher storage alcove provided for stretcher or bassinet storage shall be located out of direct line of traffic.

(xiv) Securable closets or cabinet compartments for the personal effects of nursing personnel, located in or near the nurse station, shall be provided. At a minimum, these shall be large enough for purses and billfolds. Coats may be stored in closets or cabinets on each floor or in a central staff locker area.

(xv) Twenty square feet of equipment storage shall be provided for each patient station. These storage areas shall be out of the way of the corridor traffic.

(xvi) A housekeeping room shall be provided and contain a service sink, storage for housekeeping supplies, and equipment. A shared nursing unit housekeeping room that is adjacent to the universal care suite is acceptable.

(D) Other required areas/rooms. The following areas/rooms shall be provided and may be located outside the unit if conveniently accessible.

(i) Offices. Room(s) shall be provided for the universal care suite medical staff, nursing management and administrative personnel. The offices shall be large enough to permit consulting with members of the universal care suite staff and visitors. The offices shall be linked with the unit by telephone or an intercommunications system.

(ii) Staff lounge. A staff lounge shall include toilet facilities with a hand washing fixture with hands-free operable controls. The lounge(s) shall be located so that staff may be recalled quickly to the patient area in emergencies. One lounge may serve multiple units when the lounge is adjacent to the units.

(iii) On-call rooms. Physicians and other staff on 24-hour on-call work schedules shall be provided with sleeping rooms with access to a shower(s), toilet(s), and lavatory(ies). If an on-call room(s) is not within the universal care suite served, a dedicated telephone or intercom system shall connect the on-call room(s) to the universal care suite.

(iv) Multipurpose room(s). A multipurpose room shall be provided for patient conferences, reports, education, training sessions, and consultation. This room(s) must be accessible to the universal care suite.

(2) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title and this paragraph.

(A) Details.

(i) At least one door to a universal care suite room shall be not less than four feet wide and arranged to minimize interference with movement of beds and large equipment.

(ii) Sliding doors in the universal care suite shall not have floor tracks and shall have hardware that minimizes jamming possibilities, in accordance with §133.162(d)(2)(A)(vi) of this title.

(iii) Glazing in viewing panels shall be safety glass, wire glass, or clear plastic.

(iv) Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over the universal care suite, unless special provisions are made to minimize such noise.

(v) Each patient shall have access to a telephone directly from each bed. The telephone may be omitted at a pediatric universal care suite bed.

(B) Finishes.

(i) Flooring used in universal care suite patient rooms, patient toilet rooms, and soiled workrooms shall be of the seamless type as required by §133.162(d)(2)(B)(iii)(III) of this title.

(ii) Ceilings in the soiled workroom shall be monolithic type as required by §133.162(d)(2)(B)(vi)(III) of this title.

(3) Mechanical Requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title and this paragraph. Room recirculating units shall not be used.

(A) Outside air shall be supplied to each patient room by a central air handling unit to provide make-up air for air exhausted from the bathroom in accordance with Note 3, Table 3 of §133.169(c) of this title.

(B) Each patient room bathroom shall be exhausted continuously to the exterior in accordance with Table 3 of §133.169(c) of this title.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(5) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title and this paragraph.

(A) General.

(i) Receptacles at each bed location in a universal care suite shall be served by two branch circuits, one or more from the critical branch panel of the emergency electrical system and one or more from the normal system. One critical branch circuit shall serve only one bed location. All branch circuits from the normal system shall be from a single panelboard. All branch circuits from the emergency electrical system shall be from a single panelboard.

(ii) A minimum of seven hospital grade duplex outlets shall be conveniently located at the head of each bed. At least three of these duplex outlets shall be on the critical branch of the emergency electrical system.

(iii) One duplex receptacle connected to a normal branch circuit and one duplex outlet connected to the critical branch circuit shall be located on opposite sides of the head of each bed. In addition at least one duplex outlet shall be located on each wall. A dedicated outlet shall be provided at the television location.

(iv) Hospital grade receptacles in the pediatric universal care suite shall be tamper-resistant or provided with GFCIs.

(B) Illumination requirements.

(i) Each single patient room and multi-patient wards shall be provided with general lighting and night lighting. General lighting and night lighting shall be controlled at the room entrance. All controls for lighting in patient areas shall be of the quiet operating type. Control of night lighting circuits may be achieved by automatic means and in such instances control of night lighting at the room entrance shall not be required. At least one general light fixture and night lighting shall be powered from the critical branch of the essential electrical system.

(ii) A reading light shall be provided over each patient bed. Reading light control shall be readily accessible from each patient bed. Flexible light arms, if used, shall be mechanically controlled to prevent the bulb from coming in contact with bed linen. High heat- producing light sources such as incandescent and halogen shall be avoided to prevent burns to patients and/or bed linen. Light sources shall be covered with a diffuser or a lens.

(iii) A wall or ceiling-mounted lighting fixture shall be provided above each lavatory.

(iv) A ceiling-mounted fixture shall be provided in patient bathrooms where the lighting fixture above the lavatory does not provide adequate illumination of the entire bathroom. Some form of fixed illumination shall be powered from the critical branch.

(C) Nurses calling systems. The nurse call shall be in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title.

§133.164. Elevators, Escalators, and Conveyors.

(a) General. All hospitals with two or more floor levels shall have at least one electrical or electrical hydraulic elevator. Elevators shall also give access to all building levels normally used by the public. Escalators and conveyors are not required but, when provided, shall comply with these requirements and the requirement of §18.3 of the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101, (800) 344-3555.

(b) Requirements for new elevators, escalators, and conveyors. New elevators, escalators and conveyors shall be installed in accordance with the requirements of A17.1 Safety Code for Elevators and Escalators, 2000 edition, published by the American Society of Mechanical Engineers (ASME) and the American National Standards Institute (ANSI). All documents published by the ASME/ANSI as referenced in this section may be obtained by writing the ANSI, United Engineering Center, 345 East 47th Street, New York, N.Y. 10017.

(1) Elevator lobby. An elevator lobby shall be provided. The elevator lobby shall have at least 10 feet of clear floor space in front of each elevator door.

(2) Elevator shaft openings. When elevator shaft openings occur in a smoke compartment with patient sleeping rooms or occur in a smoke compartment adjacent to the patient sleeping rooms, the elevator shaft openings shall resist the passage of smoke by one of the following means.

(A) Provide a lobby with separation partitions to resist the passage of smoke from the means of egress. When elevator lobby space extends into the egress corridor, the means of egress from one side of the egress corridor through the lobby to the other side of the egress corridor is not permitted during emergency conditions.

(B) Provide a mechanical means of exhausting smoke from the elevator shaft. The smoke removal exhaust system for the elevator shaft shall operate automatically upon the initiation of the activation of the smoke detectors located in each elevator lobby, which also initiates automatic recall of the elevator cabs to the designated level of discharge. The activation of the smoke exhaust system shall provide a negative pressure at each level.

(C) Provide swinging doors that are held open by magnetic hold open devices and close the doors at the elevator door opening upon activation of the fire alarm system.

(D) Provide a horizontal automated moving door like a "Won-Door" two feet or more from the elevator door opening that will close automatically by the activation of the fire alarm system and have emergency capabilities of opening and closing.

(E) The elevator shaft opening protection shall not be required at the elevator main level of recall.

(3) Cars and doors.

(A) Cars of hospital type elevators for patient transport shall not be less than five feet eight inches wide and not less than eight feet six inches deep inside the cab.

(B) The car door opening shall be not less than four feet wide and seven feet high.

(C) Elevator doors shall be B-labeled one-hour fire protection rated doors in buildings less than four stories; and one and one-half hour fire protection rated doors in buildings four or more stories.

(4) Type of controls and alarms. Elevator cab lighting, control, communication and signal systems shall be connected in accordance with NFPA 99, §4.4.2.2.2.2.

(5) Location. Conveyors, elevators, dumbwaiters, and pneumatic conveyors serving various stories of a building shall not open to an exit.

(6) Elevator machine rooms. Elevator machine rooms that contain solid-state equipment for elevators having a travel distance of more than 50 feet above the level of exit discharge or more than 30 feet below the level of exit discharge shall be provided with independent ventilation or air conditioning systems required to maintain temperature during fire fighters' service operation for elevator operation. The operating temperature shall be established by the elevator equipment manufacturer's specifications and shall be posted in each such elevator machine room. When standby power is connected to the elevator, the machine room ventilation or air conditioning shall be connected to standby power.

(c) Requirements for existing elevators, escalators, and conveyors. Existing elevators, escalators, and conveyors shall comply with ASME/ANSI A17.3, Safety Code for Existing Elevators and Escalators, 1996 edition. All existing elevators having a travel distance of 25 feet or more above or below the level that best serves the needs of emergency personnel for fire-fighting or rescue purposes shall conform to Fire Fighters' Service Requirements of ASME/ANSI A17.3 as required by NFPA 101, §9.4.3.

(d) Testing. All elevators and escalators shall be subject to routine and periodic inspections and tests as specified in ASME/ANSI A17.1, Safety Code for Elevators and Escalators, 2000 edition. All elevators equipped with fire fighter service shall be subject to a monthly operation with a written record of the findings made and kept on the premises as required by NFPA 101, §9.4.6.

(e) Certification. A certificate of inspection evidencing that the elevators, escalators, and related equipment were inspected in accordance with the requirements in Health and Safety Code (HSC), Chapter 754, Subchapter B, and determined to be in compliance with the safety standards adopted under HSC, §754.014, administered by the Texas Department of Licensing and Regulation, shall be on record in each hospital.

(f) Requirements for new hospitals. All new hospitals having patient facilities (such as patient sleeping rooms, dining rooms, or recreation areas) or critical services (such as operating, delivery, diagnostic, or therapy) on floors other than on the main entrance floor shall have the following number of hospital type elevators:

(1) at least one hospital type elevator for the first 59 beds;

(2) at least two elevators for the first 60 to 200 patient bed spaces. One elevator shall be the hospital type;

(3) at least three elevators for 201 to 350 patient bed spaces. Two elevators shall be hospital type; or

(4) for hospitals with over 350 patient beds, as determined from a study of the hospital plan and the estimated vertical transportation requirements for the facility.

§133.165. Building with Multiple Occupancies.

(a) Multiple hospitals located within one building.

(1) Identifiable location. Each hospital shall conform with all the requirements contained in Chapter 18 of the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), relating to New Health Care Occupancies. All documents published by NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address or telephone number: National Fire Protection Association, 1 Batterymarch Park, Post Office Box 9101, Quincy, MA 02269-9101 or (800) 344-3555.

(A) The guest hospital shall be in one separately contiguous location.

(B) In no case may a person leave the guest hospital, traverse the host hospital, and then reenter the guest hospital to access the remaining portion of the guest hospital.

(C) A connecting stair within the host hospital may be used to connect the vertical contiguous areas of the guest hospital.

(D) A guest hospital may not occupy two or more noncontiguous areas of a host hospital which contain intervening space of the host hospital even if on the same floor.

(E) Construction of the host hospital building shall conform to the requirements of NFPA 101, Chapter 18, and the building shall be fully sprinklered.

(2) Separate facilities. Each hospital shall provide the following separate facilities:

(A) a nursing unit in accordance with the requirements of §133.163(t) of this title (relating to Spatial Requirements for New Construction);

(B) an administration office with an adjacent waiting room or waiting area;

(C) a medical records room which conforms with the requirements of §133.163(p) of this title;

(D) a pharmacy suite in accordance with §133.163(x) of this title;

(E) employee locker facilities which comply with requirements of §133.163(g)(1) of this title;

(F) a housekeeping room in accordance with the requirements of §133.162(d)(2)(A)(xxviii) of this title (relating to New Construction Requirements);

(G) emergency facilities. Each hospital shall provide emergency facilities as required by §133.163(f)(1)(A) of this title. When general hospitals share a building, each general hospital shall provide emergency facilities as required by §133.163(f)(1)(A)(i) and (ii) of this title;

(H) imaging and other diagnostic services and facilities, in accordance with §133.41(s) of this title (relating to Hospital Functions and Services) and §133.163(l) of this title respectively;

(I) laboratory services and a laboratory suite which comply with §133.41(h) of this title, and §133.163(n)(1)(B) of this title respectively;

(J) surgical or obstetrical facilities for each general hospital, in accordance with §133.163(u) and §133.163(ee) of this title;

(K) dietary services and dietary suite, including staff dining facilities, which comply with §133.41(d) of this title and §133.163(e) of this title respectively;

(L) external signage at the building entrance which identifies each hospital; and

(M) internal signage which provides directions to each hospital.

(3) Means of egress. Means of egress from the host or guest hospital shall not be through a psychiatric hospital or a crisis stabilization unit or other area subject to locking. Means of egress may traverse through a hospital which conforms with the requirements of §133.161 of this title (relating to Requirements for Buildings in which Existing Licensed Hospitals are Located) or §133.162 of this title. Stairs must have guardrails from the floor of the guest hospital to the level of exit discharge in accordance with NFPA 101, §7.2.2.4.5.

(4) Additional services and facilities. Additional services and facilities when required in each licensed hospital may be provided by contractual agreement with the other hospital when the services and facilities comply with the specific requirements of §133.41 of this

title and §133.163 of this title. Some services may be provided by contractual agreement with a commercial contractor; however, the following minimal facilities shall be provided on site by the host hospital and be located in one of the hospitals. If the host hospital fails to provide the facilities and services, the guest hospital shall describe to the department how it plans to provide services:

(A) cart cleaning and sanitizing services and facilities which comply with §133.163(b) of this title;

(B) general stores services and facilities which comply with §133.163(i) of this title;

(C) housekeeping rooms as required in §133.162(d)(2)(A)(xxviii) of this title;

(D) parking facilities, in accordance with §133.162(c)(2) of this title;

(E) physical and/or occupational therapy services and facilities, in accordance with §133.41(x) of this title, and §133.163(aa) of this title respectively;

(F) patient activity facilities. The patient activity facilities shall comply with the requirements for the specific service in accordance with §133.163 of this title as follows: hospital-based skilled units §133.163(j)(1)(C); mental health and chemical dependency nursing units §133.163(q)(1)(B); pediatric and adolescent nursing unit §133.163(w)(1)(D)(i); and rehabilitation therapy suite §133.163(aa)(1)(A)(i) and (ii);

(G) respiratory care services and respiratory therapy suite which comply with §133.41(u) of this title and §133.163(cc) of this title respectively;

(H) body-holding room which complies with §133.163(r)(1)(D) of this title;

(I) central sterile supply which complies with §133.41(v)(2)(L) of this title and §133.163(c) of this title respectively;

(J) waste and waste disposal services, and waste processing and storage units shall comply with §133.41(y) of this title; and

(K) emergency water storage requirement of §133.162(d)(4)(A)(i)(VIII) shall be required for each the hospital and be located in one of the hospitals.

(5) Building systems and equipment.

(A) The following systems shall be provided separately in each hospital at a 24-hour staffed location.

(i) Nurses calling systems shall be provided separately in each hospital in accordance with §133.162(d)(5)(L) and Table 7 of §133.169(g) of this title (relating to Tables).

(ii) Medical gas alarms shall be provided in each hospital.

(iii) Fire alarm annunciator panels shall be provided in each hospital so that each hospital can monitor the other.

(iv) An emergency generator annunciator panel shall be provided in each hospital.

(B) Where applicable, the following systems may serve more than one hospital provided the systems meet the new construction requirements of §133.162 of this title:

(i) air conditioning, heating and ventilating systems;

(ii) drainage systems;

(iii) elevators;

(iv) fire sprinkler systems. The guest hospital may not be constructed in a host hospital when the host hospital is not fully sprinklered. The host and guest hospitals shall be fully sprinklered;

(v) medical piping systems;

(vi) stand pipe systems;

(vii) steam systems;

(viii) water supply systems, hot and cold (including emergency water storage); and

(ix) electrical service and equipment.

(I) Where applicable, the building electrical service, lighting, essential electrical system, and fire alarm system, may be a part of or extension of those in the existing hospital, provided the existing systems meet these requirements. The host hospital shall be responsible for maintenance, testing and upkeep of the essential electrical system. Power and lighting distribution panels shall be within each hospital served and comply with the requirements of §133.162(d)(5)(E). Electrical installation details shall conform with all requirements contained in §133.162(d)(5)(A).

(II) When the existing essential electrical system is nonconforming, the following options are available:

(-a-) a separate conforming essential electrical system shall be provided in the guest hospital; or

(-b-) separate transfer switches connected to the existing on-site generator(s) shall be provided when adequate capacity is available and the host hospital existing nonconforming system shall be corrected. Corrections shall be made in accordance with a plan of correction approved by the department.

(b) Hospitals located in buildings with licensed health care facilities other than hospitals.

(1) Before a hospital is licensed in a building containing other licensed health care facilities, all the requirements of this chapter and the following requirements shall be met.

(A) Construction of the building shall conform to the requirements of NFPA 101, Chapter 18, and the building shall be fully sprinklered.

(B) The hospital shall be in one identifiable contiguous location and shall be separated (vertically and horizontally) with two-hour fire rated noncombustible construction from the other licensed health care facility and comply with the requirements of this chapter.

(i) In no case may a person leave the hospital, traverse other licensed healthcare facilities, and then reenter the hospital to access the remaining portion of the hospital.

(ii) A connecting stair(s) and elevator(s) within the building shall be provided to connect the vertical contiguous areas of the hospital.

(iii) A hospital may not occupy two or more noncontiguous areas of other licensed healthcare facilities which contain intervening space of the other licensed healthcare facilities even if on the same floor.

(iv) Access to the hospital shall be directly from a main lobby or an elevator lobby, if on an upper floor. The required means of egress from the hospital may be through the other licensed health care facility except not through a psychiatric hospital or a crisis stabilization unit or other area subject to locking.

(I) Each licensed facility shall be identified with external signage at the building entrance.

(II) Internal signage shall provide direction to the hospital.

(v) The hospital shall have services and facilities separate from the other licensed health care facility. The required facilities shall be located within the proposed hospital proper.

(vi) Common use of facilities using time-sharing concepts may be permitted on a case by case basis when the other health care facilities comply with the

requirements contained in NFPA 101, Chapter 18, and §133.163 of this title, and provided this chapter and the other health care facility licensing regulations allow.

(C) The equipment and systems required in each new hospital may be provided exclusively for the hospital or by contractual agreement with a licensed health care facility. The equipment and systems shall be in accordance with §133.162 of this title.

(i) The following equipment and systems shall be provided for the exclusive use of the hospital, except where noted otherwise:

(I) breaker serving the hospital. Where the hospital is served by the building's normal electrical system, the breaker serving the hospital shall originate in the main switchboard and shall be labeled, "Hospital Service - Contact Hospital Representative Prior to Opening Breaker";

(II) electrical service for power and lighting. The hospital distribution panel board(s) shall be within the hospital;

(III) type I essential electrical system. An electrical room for the distribution of type I essential electrical system shall be provided separate from the building electrical room. The hospital staff shall have access at all times to the essential electrical system room and the building's electrical room(s). The hospital shall be responsible for maintenance, testing and upkeep of the essential electrical system. When the existing essential electrical system owned and operated by the other licensed health care facility is nonconforming, the following options are available:

(-a-) a separate conforming essential electrical system shall be provided in the new hospital; or

(-b-) separate transfer switches connected to the existing on-site generator(s) shall be provided when adequate capacity is available and the other health care facility existing nonconforming system shall be corrected. Corrections shall be made in accordance with a plan of correction approved by the department;

(IV) an emergency generator. An emergency generator may be shared when adequate capacity is available. Separate transfer switches shall be provided to serve the hospital and other licensed health care facilities. The hospital shall be the owner of the generator, have access to the generator at all times, and shall be responsible for maintenance, testing and upkeep of the generator;

(V) emergency water storage requirement of §133.162(d)(4)(A)(i)(VIII) of this title shall be located within the hospital;

(VI) a fire alarm system. When the other licensed health care facilities have a fire alarm control center or a main building alarm panel at the main lobby entrance, the hospital shall have an annunciator panel at a 24-hour staffed location. The hospital

staff shall have access at all times to the main building fire alarm system panels and shall be responsible for verifying the maintenance and upkeep of such system;

(VII) fireman's test valve for the fire sprinkler system;

(VIII) air conditioning, heating and ventilating systems;

(IX) medical piping systems with alarm. The medical gas supply sources may be shared provided the hospital is owner of the medical gas system source and is responsible for maintenance, testing and upkeep of the supply sources. The hospital and other occupancies shall have separate main supply shutoff valves. The hospital shall be provided with an alarm panel within the hospital that monitors the medical gas system supply source serving the other licensed health care facilities;

(X) medical vacuum and medical air; and

(XI) nurses calling systems.

(ii) Where applicable, the following systems may be a part or extension of those in the existing licensed health care facility, provided the existing systems meet the requirements of this chapter for new construction:

(I) drainage systems;

(II) elevators. The hospital shall be served by the number and size of elevators cabs in accordance with §133.164 of this title (relating to Elevators, Escalators, and Conveyors). The elevators cab lighting, control, communication, and signal systems shall be connected to the life safety panel of the essential electrical system;

(III) fire sprinkler systems. The new hospital may not be constructed in the other health care facility when the other health care facility is not fully sprinklered. The new hospital and the other health care facility shall be fully sprinklered;

(IV) stand pipe systems;

(V) steam systems. The hospital is responsible for providing all backup systems (such as boilers) as required in this chapter;

(VI) domestic water supply systems, hot and cold; and

(VII) mechanical chilled and hot water systems.

(2) When hospitals and psychiatric hospitals share one building, the building systems and equipment may be shared in accordance with subsection (a)(5)(B) of this section, or be provided separately.

(c) Hospitals in buildings with nonhealth care occupancies.

(1) General. Before a hospital is licensed in a building also containing occupancies other than health care occupancies, all requirements of this chapter and the following requirements shall be met.

(A) Construction of the building shall conform to the requirements of NFPA 101, Chapter 18, and the building shall be fully sprinklered.

(B) The hospital shall be in one identifiable contiguous location and shall be separated (vertically and horizontally) with two-hour fire rated noncombustible construction from the other occupancies.

(i) In no case may a person leave the hospital, traverse other occupancies, and then reenter the hospital to access the remaining portion of the hospital.

(ii) A connecting stair(s) and elevator(s) within the building shall be provided to connect the vertical contiguous areas of the hospital.

(iii) A hospital may not occupy two or more noncontiguous areas of other occupancies which contain intervening space of the other occupancies even if on the same floor.

(C) Access to the hospital shall be through a dedicated hospital lobby or from the building's main lobby. The building's main lobby shall be part of the hospital and shall comply with the requirements of §133.162 of this title.

(i) External signage shall be provided at the building entrance which identifies the hospital.

(ii) Internal signage shall be provided to give directions to the hospital.

(D) The required means of egress from the hospital shall be independent of and shall not traverse through the other occupancies.

(E) Stairs shall have guardrails and handrails from the floor of the hospital to the level of exit discharge in accordance with NFPA 101, § 7.2.2.4.5.

(2) Services and facilities. Services and facilities shall be provided exclusively for the hospital in accordance with subchapters C, H, and I of this title (relating to Operational Requirements, Fire Prevention and Safety Requirements, and Physical Plant and Construction Requirements, respectively). Required services and facilities shall not be shared with the other occupancies except as noted in paragraph (3) of this subsection.

(3) Building equipment and facilities. The equipment and systems shall be in accordance with §133.162 of this title.

(A) The following equipment and systems shall be provided for the exclusive use of the hospital except where noted otherwise:

(i) type I essential electrical system. An electrical room for the distribution of type I essential electrical system shall be provided separate from the building electrical room. The hospital staff shall have access at all times to the essential electrical system room and the building's electrical room(s). The hospital shall be responsible for maintenance, testing and upkeep of the essential electrical system;

(ii) emergency generator. An emergency generator may be shared when adequate capacity is available. Separate transfer switches shall be provided to serve the hospital and other building occupancies. The hospital shall be the owner of the generator, have access to the generator at all times, and shall be responsible for maintenance, testing and upkeep of the generator;

(iii) emergency water storage located within the hospital;

(iv) fire alarm system. When the building has a fire alarm control center or a main building alarm panel at the main lobby entrance, the hospital shall have an annunciator panel at a 24-hour staffed location. The hospital staff shall have access at all times to the main building fire alarm system panels and shall be responsible for verifying the maintenance and upkeep of such system;

(v) fireman's test valve for the fire sprinkler system;

(vi) medical gas systems. The medical gas supply sources may be shared provided the hospital is owner of the medical gas system supply source and is responsible for maintenance, testing and upkeep of the supply sources. The hospital and other occupancies shall have separate main supply shutoff valves. The hospital shall be provided with an alarm panel within the hospital that monitors the medical gas system serving the other occupancies;

(vii) medical vacuum and medical air;

(viii) air conditioning, heating and ventilating systems. Air handling units of other occupancies may not be used for the hospital. The hospital air handling units may share the supply source for other occupancies but shall not return air from the other occupancies back to the air handling unit(s); and

(ix) nurses calling systems.

(B) Where applicable, the following systems may be a part or extension of those in the existing building occupancies provided the existing systems meet the requirements of this chapter for new construction:

(i) breaker serving the hospital. Where the hospital is served by the building's normal electrical system, the breaker serving the hospital shall originate in the

main switchboard and shall be labeled, "Hospital Service - Contact Hospital Representative Prior to Opening Breaker";

(ii) electrical service for power and lighting. The hospital's distribution panelboard(s) shall be within the hospital;

(iii) drainage systems;

(iv) elevators. The hospital shall be served by the number and size of elevators cabs in accordance with §133.164 of this title. The elevators cab lighting, control, communication, and signal systems shall be connected to the life safety panel of the essential electrical system;

(v) fire sprinkler systems. The hospital may not be constructed in the other type of building occupancies when the other types of occupancies are not fully sprinklered. The hospital and the other occupancies shall be fully sprinklered;

(vi) stand pipe systems;

(vii) fire pump, where applicable; The hospital staff shall have access at all times to the location of the fire pump to verify compliance and maintenance;

(viii) steam systems. The hospital is responsible for providing all backup systems (such as boilers) that are required in this chapter; and

(ix) domestic water supply systems, hot and cold.

§133.166. Mobile, Transportable, and Relocatable Units.

(a) Definitions.

(1) Mobile unit--Any pre-manufactured structure, trailer, or self-propelled unit equipped with a chassis on wheels and intended to provide shared medical services to the community on a temporary basis. Some of these units are equipped with expanding walls and designed to be moved on a daily basis.

(2) Relocatable unit--Any structure, not on wheels, that is built to be relocated at any time and provide medical services. These structures vary in size.

(3) Transportable unit--Any pre-manufactured structure or trailer, equipped with a chassis on wheels, intended to provide shared medical services to the community on an extended temporary basis. These units are designed to be moved periodically, depending on need.

(b) General. When mobile, transportable and relocatable units are utilized to provide patient treatment services on the hospital premises, these units shall be treated as buildings and constructed to the required occupancy as follows.

(1) When such units are provided for diagnostic, treatment or procedural services to patients who are litter borne, under general anesthesia, or incapable of self-preservation, the unit shall be constructed in accordance with Chapter 18 of the National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), relating to health care occupancy, published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101, (800) 344-3555.

(2) When such units provide diagnostic, treatment, or procedural services to patients who are not litter borne, not under general anesthesia, and are capable of self-preservation, the unit may be constructed in accordance with Chapter 38 of NFPA 101 (relating to Business Occupancy).

(c) Common elements.

(1) Site requirements.

(A) Sites shall have a level concrete or asphalt pad and be designed for the structural loads of the unit.

(B) The sites shall provide hazard-free drop-off zones and adequate parking for patients. The site and location of the unit shall not restrict access for fire or emergency vehicles.

(C) Each site shall provide access to the unit for the handicapped, and wheelchair and stretcher patients.

(D) When a mobile, transportable, or relocatable unit is not physically attached to the hospital and provides inpatient services, a covered walkway or enclosure from the hospital to the unit shall be provided to ensure patient safety from the outside elements.

(E) The location of the unit shall be such that engine exhaust fumes from the unit are kept away from any fresh air intake of the hospital.

(F) When a mobile, transportable, or relocatable unit is permanently connected appropriately for the climate to the hospital or the unit does not move on a regular basis, i.e. every 90 days or less, the units shall be provided with the following equipment and systems connected to the hospital:

(i) fire alarm system;

(ii) sprinkler system;

(iii) electrical system and the essential electrical system;

(iv) water and waste water system;

(v) medical gas systems; and

(vi) nurses calling systems.

(2) Support services. Support services shall meet the requirements of this chapter for new construction. These support services and areas shall be provided either within the mobile, transportable, or relocatable unit or located within the hospital adjacent to the unit served.

(3) Details and finishes. Details and finishes shall be in accordance with §133.162(d)(2) of this title .

(4) Mechanical requirements. Mechanical requirements shall be in accordance with §133.162(d)(3) of this title.

(5) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §133.162(d)(4) of this title.

(6) Electrical requirements. Electrical requirements shall be in accordance with §133.162(d)(5) of this title.

§133.167. Preparation, Submittal, Review and Approval of Plans, and Retention of Records.

(a) General.

(1) Hospital owners/operators may not begin construction of a new building, additions to or renovations or conversions of existing buildings until the department approves final construction documents.

(2) Plans and specifications describing the construction of new buildings and additions to or renovations and conversions of existing buildings shall be prepared by registered architects and/or licensed professional engineers and meet the requirements of this subchapter.

(3) The names of spaces used in the functional program narrative, preliminary documents, final construction documents and specifications shall be consistent with the names of the spaces used in this chapter.

(4) The department shall notify the hospital owner/operator of the result of its review of each type of submission discussed in this section.

(5) The hospital owner/operator shall respond to all department requests for additional information, including providing a plan of correction for deficiencies cited by the department.

(6) Once final construction documents are approved, the hospital owner/operator shall request inspections in accordance with §133.168 of this title (relating to Construction, Inspections, and Approval of Project).

(7) When construction is delayed for longer than one year from the plan approval or self-certification approval date, construction documents shall be resubmitted to the department for review and approval. The plans shall be accompanied by a new Application for Plan Review, plan review fee, and functional program narrative.

(8) The hospital owner/operator shall provide written notification to the department when a project has been placed on hold, canceled or abandoned.

(9) The department may close a project file after one year of assigning an application number to a project if the project has been placed on hold. Plan review fees are nonrefundable.

(b) Submission of projects and assignment of application number.

(1) The hospital owner/operator or representative shall submit the following items to the department in care of the mailing or overnight delivery address that appears on the Application for Plan Review:

(A) a completed and signed Application for Plan Review. The Application for Plan Review may be obtained by calling the department's Architectural Review Group, telephone (512) 834-6649;

(B) the applicable plan review fee in accordance with §133.26 of this title (relating to Fees);

(C) a functional program narrative in accordance with subsection (d) of this section; and

(D) final construction documents in accordance with subsection (f) of this section.

(2) The cost of submitting documents/plans and specifications shall be borne by the sender.

(3) Once the department has determined that the submission required in paragraph (1) of this subsection is complete, the department will assign an application number to the project that must be referenced on all documents and correspondence related to the project. Final construction documents will be reviewed in the chronological order received.

(4) All deficiencies noted in the final plan review shall be satisfactorily resolved before approval of project for construction will be granted.

(5) Construction shall not begin until the hospital owner/operator of the facility receives written notification from the department that the final construction documents have been approved.

(c) Feasibility conference. A hospital owner/operator or representative may request a feasibility conference. A feasibility conference is an informal meeting between a member of the department's Architectural Review Group staff and the hospital owner/operator or representative to determine the feasibility of a project, for consultation and informational purposes, and to facilitate and establish understanding of compliance with the rules and codes.

(1) A feasibility conference is not a substitute for plan review.

(2) A hospital owner/operator or representative may schedule a feasibility conference by calling the department's Architectural Review Group, telephone number (512) 834-6649.

(3) The hospital owner/operator or representative shall provide at the feasibility conference the items in subsection (b)(1)(A)-(C) of this section and a set of preliminary plans or final construction documents.

(4) The hospital owner/operator or representative is responsible for recording conference notes and shall submit the notes to the department.

(d) Functional program narrative. The hospital owner/operator shall submit a functional program narrative to the department with each new project in accordance with subsection (b)(1)(C) of this section. The functional program narrative shall be presented on facility letterhead, signed by hospital administration, include the functional description of each space, and the following:

(1) departmental relationships, number of patient beds in each category, and other basic information relating to the fulfillment of the facility's objectives;

(2) a description of each function to be performed, approximate space needed for these functions, occupants of the various spaces, projected occupant load, types of equipment required, interrelationship of various functions and spaces, and any special design features;

(3) energy conservation measures, included in building, mechanical and electrical designs;

(4) a description of the type of asepsis control in diagnostic and treatment areas;
and

(5) the type of construction (existing or proposed) as stated in Table 18.1.6.2 of National Fire Protection Association 101, Life Safety Code, 2003 edition (NFPA 101), published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following

address and telephone number: Post Office Box 9101, 1 Batterymarch Park, Quincy, Massachusetts 02269-9101, (800) 344-3555.

(e) Preliminary documents. The department may request preliminary documents. If requested by the department, the submission shall consist of the items in subsection (b)(1)(A)-(C) of this section, preliminary plans, and outline specifications. The documents shall contain sufficient information to establish the project scope, description of functions to be performed, project location, required fire safety and exiting requirements, building construction type, compartmentation showing fire and smoke barriers, bed count and services, and the usage of all spaces, areas, and rooms on every floor level.

(f) Final construction documents. Final construction documents and specifications shall be submitted to the department for review and approval prior to start of construction. All final documents and specifications shall be appropriately sealed and signed by the project registered architect and professional engineer(s) licensed by the state of Texas.

(1) Submission of final construction documents. The hospital owner/operator shall submit to the department for review and approval the items in subsection (b)(1)(A)-(C) of this section (if not previously submitted with preliminary documents) and one set of final construction documents and specifications covering the construction of new buildings or alterations, additions, conversions, modernizations, or renovations to existing buildings.

(2) Preparation of final construction documents. Construction documents shall be well-prepared so that clear and distinct prints may be obtained, shall be accurately and adequately dimensioned, and shall include all necessary explanatory notes, schedules, and legends and shall be adequate for contract purposes. Compliance with model building codes and this chapter shall be indicated. The type of construction, as classified by National Fire Protection Association 220, Standard on Types of Building Construction, 1999 edition, shall be provided for existing and new facilities. Final plans shall be drawn to a sufficiently large-scale to clearly illustrate the proposed design but not less than one-eighth inch equals one foot. All spaces shall be identified by usage (using the names of spaces used in this chapter) on all plans (architectural, fire safety, mechanical, electrical, etc.) submitted. Separate drawings shall be prepared for each of the following branches of work.

(A) Architectural plans. Architectural drawings shall include the following:

(i) a map of the area within a two-mile radius of the facility site shall be provided and any hazardous and undesirable location noted in §133.162(a) of this title (relating to New Construction Requirements) shall be identified;

(ii) site plan showing all new topography, newly established levels and grades, existing structures on the site (if any), new buildings and structures, roadways, parking, walks, easement, overhead or underground utilities or service lines, and the extent of the areas to be landscaped. All structures which are to be removed under the construction contract and improvements shall be shown. A general description of the immediate area surrounding the site shall be provided;

(iii) plan of each floor and roof to include fire and smoke separation, means of egress, and identification of all spaces;

(iv) schedules of doors, windows, and finishes;

(v) elevations of each facade;

(vi) sections through building; and

(vii) scaled details as necessary.

(B) Fire safety plans. These drawings shall be provided for all newly constructed buildings, conversions of existing buildings for facilities, additions to existing licensed facilities, and remodeled portions of existing buildings containing licensed facilities. Fire safety plans shall be of a sufficiently large-scale to clearly illustrate the proposed design but not less than one-sixteenth inch equals one foot and shall include the following information:

(i) separate fire safety plans (preferably one floor plan per sheet) shall indicate location of fire protection rated walls and partitions, location and fire resistance rating of each fire damper, and the required means of egress (corridors, stairs, exits, exit passageways);

(I) when a new building is to contain a proposed facility, when an existing building is converted to a facility, or when an addition is made to an existing facility building, plans of each floor and roof shall be provided;

(II) when a portion of a building is remodeled or when a new service is added, only the plan of the floor where the remodeling will take place or new service will be introduced and the plan of the floor of discharge shall be provided;

(ii) designated smoke compartments with floor areas of each compartment, location and fire resistance rating (one or two hour) of each smoke partition, location, type and fire resistance rating of each smoke damper;

(iii) location of all required fire alarm devices, including all fire alarm control panels, manual pull stations, audible and visual fire alarm signaling devices, smoke detectors (ceiling and duct-mounted), fire alarm annunciators, fire alarm transmission devices, fire sprinkler flow switches and control valve supervisory switches on each of the floor plans; and

(iv) areas protected with fire sprinkler systems (pendant, sidewall or upright, normal or quick response, and temperature rating shall be indicated), stand pipe system risers and sizes with valves and inside and outside fire department connections, fire sprinkler risers and sizes, location and type of portable fire extinguishers.

(C) Equipment drawings. Equipment drawings shall include the following:

(i) all equipment necessary for the operation of the facility as planned. The design shall indicate provisions for the installation of large and special items of equipment and for service accessibility;

(ii) fixed equipment (equipment which is permanently affixed to the building or which must be permanently connected to a service distribution system designed and installed during construction for the specific use of the equipment). The term "fixed equipment" includes items such as laundry extractors, walk-in refrigerators, communication systems, and built-in casework (cabinets);

(iii) movable equipment (equipment not described in clause (ii) of this subparagraph as fixed). The term "moveable equipment" includes wheeled equipment, plug-in type monitoring equipment, and relocatable items; and

(iv) equipment which is not included in the construction contract but which requires mechanical or electrical service connections or construction modifications. The equipment described in this clause shall be identified on the drawings to ensure its coordination with the architectural, mechanical, and electrical phases of construction.

(D) Structural drawings. Structural drawings shall include:

- (i) plans for foundations, floors, roofs, and all intermediate levels;
- (ii) a complete design with sizes, sections, and the relative location of the various members;
- (iii) a schedule of beams, girders, and columns;
- (iv) dimensioned floor levels, column centers, and offsets;
- (v) details of all special connections, assemblies, and expansion joints; and
- (vi) special openings and pipe sleeves dimensioned or otherwise noted for easy reference.

(E) Mechanical drawings. Mechanical drawings shall include:

- (i) complete ventilation systems (supply, return, exhaust), all fire and smoke partitions, locations of all dampers, registers, and grilles, air volume flow at each device, and identification of all spaces (e.g. corridor, patient room, operating room);
- (ii) boilers, chillers, heating and cooling piping systems (steam piping, hot water, chilled water), and associated pumps;

(iii) cold and warm water supply systems, water heaters, storage tanks, circulating pumps, plumbing fixtures, emergency water storage tank(s) (if provided), and special piping systems such as for deionized water;

(iv) nonflammable medical gas piping (oxygen, compressed medical air, vacuum systems, nitrous oxide), emergency shutoff valves, pressure gages, alarm modules, gas outlets;

(v) drain piping systems (waste and soiled piping systems, laboratory drain systems, roof drain systems);

(vi) fire protection piping systems (sprinkler piping systems, fire standpipe systems, water or chemical extinguisher piping system for cooking equipment);

(vii) piping riser diagrams, equipment schedules, control diagrams or narrative description of controls, filters, and location of all duct-mounted smoke detectors; and

(viii) laboratory exhaust and safety cabinets.

(F) Electrical drawings. Electrical drawings shall include:

(i) electrical service entrance with service switches, service feeders to the public service feeders, and characteristics of the light and power current including transformers and their connections;

(ii) location of all normal electrical system and essential electrical system conduits, wiring, receptacles, light fixtures, switches and equipment which require permanent electrical connections, on plans of each building level:

(I) light fixtures marked distinctly to indicate connection to critical or life safety branch circuits or to normal lighting circuits; and

(II) outlets marked distinctly to indicate connection to critical, life safety or normal power circuits;

(iii) telephone and communication, fixed computers, terminals, connections, outlets, and equipment;

(iv) nurses calling system showing all stations, signals, and annunciators on the plans;

(v) in addition to electrical plans, single line diagrams prepared for:

(I) complete electrical system consisting of the normal electrical system and the essential electrical system including the on-site generator(s), transfer switch(es), emergency system (life safety branch and critical branch), equipment system, panels,

subpanels, transformers, conduit, wire sizes, main switchboard, power panels, light panels, and equipment for additions to existing buildings, proposed new facilities, and remodeled portions of existing facilities. Feeder and conduit sizes shall be shown with schedule of feeder breakers or switches;

(II) complete nurses calling system with all stations, signals, annunciators, etc. with room number noted by each device and indicating the type of system (nurses regular calling system, nurses emergency calling system, or staff emergency assistance calling system);

(III) a single line diagram of the complete fire alarm system showing all control panels, signaling and detection devices and the room number where each device is located; and

(vi) schedules of all panels indicating connection to life safety branch, critical branch, equipment system or normal system, and connected load at each panel.

(3) Construction document changes. Any changes to the final construction documents which affect or change the function, design, or designated use of an area shall be submitted to the department for approval prior to authorization of the modifications.

(g) Special submittals.

(1) Self-certification.

(A) In an effort to shorten the plan review and approval process, the hospital owner/operator or representative may request approval of final construction documents under the self-certification review process.

(i) The owner/operator shall submit the items in subsection (b)(1)(A)-(D) of this section and a completed self-certification form, signed by the hospital owner/operator, architect of record, and engineer(s) of record attesting that the plans and specifications are based upon and comply with the requirements of this chapter.

(ii) By signing and submitting the self-certification form, the hospital owner/operator accepts the following conditions.

(I) The department retains the right to review the final construction documents, conduct inspections of the project, and withdraw its approval.

(II) The hospital owner/operator has a continuing obligation to make any changes the department requires to comply with the licensing rules whether or not physical plant construction or alterations have been completed.

(III) The hospital owner/operator is ultimately responsible for compliance with the Texas Hospital Licensing Law (Health and Safety Code, Chapter 241) and this chapter.

(B) The department will review the request for self-certification and notify the hospital owner/operator if the request is approved or denied. If denied, the department will review the final construction documents in the chronological order in which the documents were received. Construction may not begin until the final construction documents have been reviewed and approved.

(2) Fast-track project. At the discretion of the department, projects for new hospitals or major new additions may be allowed to be submitted under the fast-track project in not more than three separate packages. A fast-track project shall be requested in writing on facility letterhead, signed by hospital administration, with a brief written description and narrative of the proposed project. Construction may not begin until the first package has been approved by the department.

(A) First package. The first package shall include:

(i) the items in subsection (b)(1)(A)-(C) of this section;

(ii) a map showing the location of the proposed facility site and adjacent surrounding area at least two miles in radius identifying any hazardous and undesirable location noted in §133.162(a) of this title;

(iii) preliminary architectural plans and a detailed building site plan showing all adjacent streets, site work, underslab mechanical, electrical, and plumbing work, and related specifications; and

(iv) foundation and structural plans.

(B) Second package. The second package shall include complete architectural plans and details with specifications and fire safety plans as described in subsection (f)(1) and (2)(A)-(D) of this section.

(C) Third package. The third package shall include complete mechanical, electrical, equipment and furnishings, and plumbing plans and specifications, as described in subsection (f)(1) and (2)(E) and (F) of this section. Package three may be submitted with the second package.

(3) Minor project. If a hospital owner/operator believes that a proposed project is a minor project as described in §133.161(a)(2)(C) of this title (relating to Requirements for Buildings in which Existing Licensed Hospitals are Located), the hospital owner/operator shall provide to the department a brief written description of the proposed project and floor plans of the areas of work.

(A) If it is determined that the proposed project is a minor project, the department will notify the hospital owner/operator of the approval, and state the number of inspections that will be required. A minimum of one inspection will be conducted.

(B) The department will notify the hospital owner/operator that a proposed project is not approved as a minor project if the project involves any of the following:

(i) remodeling or alterations which involve alterations to load bearing members or partitions;

(ii) a change in functional operation;

(iii) affects fire safety (e.g. modifications to the fire, smoke, and corridor walls);

(iv) adds beds or services for which the hospital is not currently licensed; and

(v) significantly changes the mechanical, electrical, plumbing, fire protection, or piped medical system.

(C) The hospital owner/operator shall submit final construction documents in accordance with subsection (f) of this section if the department determines the project is not a minor project.

(4) Fire sprinkler systems.

(A) When the sole purpose of a project is installation of a sprinkler system, whether a partial or complete system, the hospital owner/operator shall submit to the department for approval the items in subsection (b)(1)(A)-(C) of this section and sprinkler documents.

(B) Fire sprinkler systems shall comply with the requirements of National Fire Protection Association 13, Standard for the Installation of Sprinkler systems, 2002 edition (NFPA 13), and shall be designed or reviewed by an engineer who is registered by the Texas Board of Professional Engineers in fire protection specialty or is experienced in hydraulic design and fire sprinkler system installation. A short resume shall be submitted if registration is not in fire protection specialty.

(i) Fire sprinkler working plans, complete hydraulic calculations and water supply information shall be prepared in accordance with NFPA 13, §§14.1, 14.2 and 14.3, for new fire sprinkler systems, alterations of and additions to existing ones.

(ii) One set of fire sprinkler working plans, calculations and water supply information shall be forwarded to the department together with the professional engineer's (P.E. licensed in the state of Texas) certification letter stating that the sprinkler system design complies with the requirements of NFPA 13. Certification of the fire sprinkler system shall be submitted prior to system installation.

(iii) Upon completion of the fire sprinkler system installation and any required corrections, written certification by the engineer, stating that the fire sprinkler

system is installed in accordance with NFPA 13 requirements, shall be submitted prior to or with the written request for the final construction inspection of the project.

(h) Retention of drawings, manuals and design data.

(1) As built drawings. Upon occupancy of the building or portion thereof, the owner shall retain as part of the hospital's permanent records, a complete set of legible architectural plans of each building level, fire safety plans as described in subsection (f)(2)(B) of this section for each floor reflecting fire safety requirements, and all single line diagrams described in subsection (f)(2)(F)(v) of this section, drawings for fixed equipment, and mechanical and electrical systems, as installed or built.

(2) Manuals. Upon completion of the contract, the owner shall retain as part of the hospital's permanent records a complete set of manufacturers' operating, maintenance, and preventive maintenance instructions; parts lists; and procurement information with numbers and a description for each piece of equipment. Facility staff shall also be provided with instructions on how to properly operate systems and equipment. Required information shall include energy ratings as needed for future conservation calculations.

(3) Design data. The owner shall retain in the hospital's permanent records complete design data for the facility. This shall include structural design loadings; summary of heat loss assumption and calculations; estimated water consumption; medical gas outlet listing; list of applicable codes; and electric power requirements of installed equipment. All such data shall be supplied to facilitate future alterations, additions, and changes, including, but not limited to, energy audits and retrofit for energy conservation.

§133.168. Construction, Inspections, and Approval of Project.

(a) Construction.

(1) Major construction. Construction, of other than minor alterations, shall not commence until the final plan review deficiencies have been satisfactorily resolved, the appropriate plan review fee according to the plan review schedule in §133.26 of this title (relating to Fees) has been paid, and the department has issued a letter granting approval to begin construction. Such authorization does not constitute release from the requirements contained in this chapter. If the construction takes place in or near occupied areas, adequate provision shall be made for the safety and comfort of occupants.

(2) Construction commencement notification. The architect of record or the hospital owner/operator shall provide written notification to the department when construction will commence. The department shall be notified in writing of any change in the completion schedules.

(3) Completion. Construction shall be completed in compliance with the construction documents including all addenda or modifications approved for the project.

(b) Construction inspections. All hospitals including those which maintain certification under Title XVIII of the Social Security Act (42 United States Code, §1395 et seq), and those which maintain accreditation by a Centers for Medicare and Medicaid Services-approved organization are subject to construction inspections.

(1) Number of construction inspections. A minimum of two construction inspections of the project is generally required for the purpose of verifying compliance with subchapters H and I of this chapter and the approved plans and specifications. The final plan approval letter will inform the architect of record and the owner as to the minimum number of inspections required for the project.

(2) Requesting an inspection. The architect of record or the hospital owner/operator shall request an inspection by submitting, at least three weeks in advance of the requested inspection date, an Application for Inspection and the construction inspection fee in accordance with §133.26(d) of this title for each intermediate inspection, final inspection, and reinspection requested. Inspection requests by contractors will not be honored.

(A) The architect of record or the hospital owner/operator shall request an intermediate construction inspection to occur at approximately 80% completion. All major work above the ceiling shall be completed at the time of the intermediate inspection, however ceilings shall not be installed.

(B) The architect of record or the hospital owner/operator shall request a final construction inspection at 100% completion. One hundred percent completion means that the project is completed to the extent that all equipment is operating in accordance with specifications, all necessary furnishings are in place, and patients could be admitted and treated in all areas of the project.

(3) Reinspections. Depending upon the number and nature of the deficiencies cited during the final inspection, the inspector may require that a reinspection be conducted to confirm correction of all deficiencies cited. The inspector may also require a reinspection if he determines that the project was not sufficiently complete to warrant a final inspection. The request for reinspection shall be submitted in accordance with paragraph (2) of this subsection.

(c) Approval of project. Patients and staff shall not occupy a new structure or remodeled or renovated space until approval has been received from the local building and fire authorities and the department.

(1) Documentation requirements. The hospital owner/operator shall submit the following documents to the department before the project will be approved:

(A) written approval of the project by the fire authority;

(B) a certificate of occupancy for the project issued by the local building authority;

(C) a copy of a letter or certification from a professional engineer (P.E.) licensed in the state of Texas indicating the fire sprinkler working plans, hydraulic calculation, the testing and field inspection of the installation of the new or modified sprinkler system is in compliance with the requirements of NFPA 13, Standard for the Installation of Sprinkler Systems, 2002 edition, if applicable. A copy of a letter or certification of changes in existing fire sprinkler system is not required when relocation of not more than twenty sprinkler heads and hydraulic calculation is not involved;

(D) fire alarm system certification (form FML-009 040392 of the Office of the State Fire Marshal), if applicable;

(E) a signed copy of a letter of certification from a qualified certification agency or individual for the piped-in medical gas system that was installed or modified and verification inspection testing in this project in accordance with §133.162 (d)(4)(A)(iii)(IV), (X) and (XI) of this title (relating to New Construction Requirements), if applicable;

(F) a copy of the test and a letter from the electrical contractor certifying that the electrical system was tested and complies with the standards of NFPA 99, Health Care Facilities, 2002 edition, §4.3.2.2.8 (Special Grounding) and §4.3.3.1 (Grounding System Testing), if applicable to the project;

(G) a copy of documentation indicating the flame spread rating and the smoke development rating of any wall covering installed in this project. Provide a signed letter or statement corroborating the installation of the product in the project;

(H) a copy of documentation indicating that draperies, curtains (including cubicle curtains), and other similar loosely hanging furnishings and decorations are flame-resistant as demonstrated by passing both the small and large-scale tests of NFPA 701, Standard Methods of Fire Tests for Flame-Resistant Textiles and Films, 1999 edition as required by NFPA 101, §18-7.5, and provide a signed letter or statement corroborating the installation of the product in the project;

(I) a written plan of correction signed by the hospital owner/operator for any deficiencies noted during the final inspection;

(J) a Final Construction Approval form signed by the hospital owner/operator; and

(K) any other documentation or information required or requested due to the type of the project.

(2) Temporary occupancy approval

(A) If, during the final inspection, the inspector finds only a few minor deficiencies that do not jeopardize patient health, safety and welfare, the inspector may grant temporary approval for occupancy contingent upon the documents listed in paragraph (1)(A)-(E)

of this subsection being provided to and approved by the inspector at the time of the final inspection.

(B) Temporary approval for occupancy allows the hospital owner/operator to occupy the project. However, the hospital owner/operator must submit the documents required in paragraph (1)(F)-(K) of this subsection before the project receives final approval.

(3) Final approval. Upon its receipt and acceptance of the documents required in paragraph (1) of this subsection, the department will issue written final approval of the project.

(a) Table 1. Sound transmission limitations in hospitals.

Figure: 25 TAC §133.169(a)

**TABLE 1
SOUND TRANSMISSION LIMITATIONS IN HOSPITALS**

	Airborne Sound Transmission Class (STC) ^A	
	Partitions	Floors
New construction		
Patient room to patient room	45	40
Public space to patient room ^B	55	40
Service areas to patient room ^C	65	45
Patient room access corridor ^D	45	45
Existing construction		
Patient room to patient room	35	40
Public space to patient room ^B	40	40
Service areas to patient room ^C	40	40

^A Sound transmission class (STC) shall be determined by tests in accordance with methods set forth in ASTM E90 and ASTM E4 13. Where partitions do not extend to the structure above, sound transmission through ceilings and composite STC performance must be considered.

^B Public space includes corridors (except patient room access corridors), lobbies, dining rooms, recreation rooms, treatment rooms, and similar space.

^C Service areas include kitchens, elevators, elevator machine rooms, laundries, garages, maintenance rooms, boiler and mechanical equipment rooms, and similar spaces of high noise. Mechanical equipment located on the same floor or above patient rooms, offices, nurses stations, and similar occupied space shall be effectively isolated from the floor.

^D Patient room access corridors contain composite walls with door/windows and have direct access to patient rooms. Junctions and joints of walls and partitions shall be sealed to prevent sound leakage under, over, or through the separation. Outlets shall be insulated and separated. Openings around ducts, conduits and pipes shall be sealed to minimize sound transmission.

Types of wall construction and the associated STC ratings are given in Fire Resistance Design Manual available from Gypsum Association, 810 First Street NE, #510, Washington, DC 20002.

NOTE: The listed STC rating requirements are for a reasonable degree of privacy. Rooms requiring confidentiality, such as psychiatric examination rooms and rooms with extraordinary noise sources, may require additional sound insulation including acoustical doors and seals.

**TABLE 2
FLAME SPREAD AND SMOKE PRODUCTION LIMITATIONS
FOR INTERIOR FINISHES**

		Flame Spread Rating	Smoke Development Rating
Walls and Ceilings¹	Exit Access, Storage Rooms, and Areas of Unusual Fire Hazard	Class A² NFPA 255	450 or less NFPA 258³
	All other Areas	Class B² NFPA 255	450 or less NFPA 258³
Floors⁴		No requirements	No requirements

¹ Textile materials having a napped, tufted, looped, woven, nonwoven, or similar surface shall not be applied to walls or ceilings unless such materials have a Class A rating and are installed in rooms or areas protected by an approved automatic sprinkler system. Cellular or foamed plastic materials shall not be used as interior wall and ceiling finishes.

² Products required to be tested in accordance with National Fire Protection Association 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 edition, shall be Class A (flame spread 0-25) or Class B (flame spread 26-75).

³ Smoke development rating, an average of flaming and nonflaming values as determined by National Fire Protection Association 258, Standard Research Test Method for Determining Smoke Generation of Solid Materials, 2001 Edition.

⁴ See §133.162(d)(1)(D) of this title for requirements relative to carpeting in areas that may be subject to use by handicapped individuals. Such areas include offices and waiting spaces as well as corridors that might be used by handicapped employees, visitors, or staff.

TABLE 3
VENTILATION REQUIREMENTS FOR HOSPITALS AND OUTPATIENT FACILITIES ¹

Area Designation	Air movement relationship to adjacent areas ^{2,16}	Minimum air changes of outdoor air per hour ³	Minimum total air changes per hour ⁴	All air exhausted directly to outdoors ⁵	Recirculated by means of room units ⁶	Relative humidity ⁷ (%)	Design temperature ⁸ (degrees F)
SURGERY AND CRITICAL CARE							
Operating/Surgical, cystoscopic rooms ^{9,16}	Out	4	20	----	No	30-60	68-73 ¹⁷
Airborne infection isolation surgical rooms	In	4	15	Yes	No	30-60	68-73
Isolation anteroom (surgery)	In/Out ²⁰	----	10	Yes	No	----	----
Delivery room ⁹	Out	3	15	----	No	30-60	68-73
Recovery room ⁹	----	2	6	----	No	30-60	70-75
Critical and intensive care	----	2	6	----	No	30-60	70-75
Treatment room ¹⁰	----	----	6	----	----	----	75
Trauma room ¹⁰	Out	3	15	----	No	30-60	70-75
Anesthesia gas storage	In	----	8	Yes	----	----	----
Endoscopy	Out	2	6	----	No	30-60	68-73
Bronchoscopy	In	2	12	Yes	No	30-60	68-73
Intermediate care	----	2	6 ¹⁸	----	No	30-60	70-75
Newborn intensive care	----	2	6	----	No	30-60	72-78
Emergency suite waiting	In	2	12	Yes ¹⁹	----	----	70-75
Triage	In	2	12	Yes ¹⁹	----	----	70-75
Radiology waiting	In	2	12	Yes ¹⁹	----	----	70-75
Procedure room	Out	4	20	----	No	30-60	70-75
Laser eye room	Out	4	20	----	No	30-60	70-75
X-ray (Surgical/Critical care, catheterization)	Out	3	15	----	No	30-60	70-75
NURSING							
Patient room	----	2	6 ¹⁸	----	----	----	70-75
Toilet room	In	----	10	Yes	----	----	70-75
Newborn nursery suite	----	2	6	----	No	30-60	72-78
Protective environment room ¹¹	Out	2	12	----	No	----	70-75
Protective environment anteroom ¹¹	In/In ²¹	----	10	----	No	----	----
Airborne infection isolation room ¹²	In	2	12	Yes	No	----	70-75
Isolation alcove or anteroom ¹²	In/Out ²⁰	----	10	Yes	No	----	----
Labor, delivery, recovery (LDR)	----	2	6 ¹⁸	----	----	----	70-75
Labor, delivery, recovery, postpartum(LDRP)	----	2	6 ¹⁸	----	----	----	70-75
Patient corridor	----	----	2	----	----	----	----

TABLE 3
VENTILATION REQUIREMENTS FOR HOSPITALS AND OUTPATIENT FACILITIES ¹
(Continued)

Area Designation	Air movement relationship to adjacent areas ^{2,16}	Minimum air changes of outdoor air per hour ³	Minimum total air changes per hour ⁴	All air exhausted directly to outdoors ⁵	Recirculated by means of room units ⁶	Relative humidity ⁷ (%)	Design temperature ⁸ (degrees F)
ANCILLARY							
Radiology ¹³ X-ray (diagnostic and treatment)	----	----	6	----	----	----	75
Darkroom	In	----	10	Yes	No	----	----
Fluoroscopy	In	2	6	----	----	----	75
Laboratory General ¹³	----	2	6	----	----	----	75
Bacteriology	In	2	6	Yes	No	----	75
Biochemistry ¹³	In	2	6	Yes	No	----	75
Cytology	In	2	6	Yes	No	----	75
Glass washing	In	----	10	Yes	----	----	75
Histology	In	2	6	Yes	No	----	75
Microbiology ¹³	In	2	6	Yes	No	----	75
Nuclear medicine	In	2	6	Yes	No	----	75
Pathology	In	2	6	Yes	No	----	75
Serology	In	2	6	Yes	No	----	75
Sterilizing	In	----	10	Yes	No	----	75
Media transfer	Out	2	4	----	----	----	----
Autopsy room	In	----	12	Yes	No	----	----
Nonrefrigerated body-holding room	In	----	10	Yes	----	----	70
Pharmacy	Out	----	4	----	----	----	75
Preparation/anteroom	Out	2	6	----	No	----	75
IV hood room	Out	2	6	----	No	----	75
Chemotherapy room-fume hoods	In	2	6	Yes	No	----	75
DIAGNOSTIC AND TREATMENT							
Examination room	----	----	6	----	----	----	75
Medication room	Out	----	4	----	----	----	75
Treatment room	----	----	6	----	----	----	75
Physical therapy and hydrotherapy	In	----	6	----	----	----	75
Soiled workroom or holding	In	----	10	Yes	No	----	----
Clean workroom or holding	Out	----	4	----	----	----	----
STERILIZING AND SUPPLY							
EO sterilizer room ¹⁵	In	----	10	Yes	No	30-60	75
Sterilizer equipment room ²	In	----	10	Yes	No	----	----

TABLE 3
VENTILATION REQUIREMENTS FOR HOSPITALS AND OUTPATIENT FACILITIES ¹
(Continued)

Area Designation	Air movement relationship to adjacent areas ^{2,16}	Minimum air changes of outdoor air per hour ³	Minimum total air changes per hour ⁴	All air exhausted directly to outdoors ⁵	Recirculated by means of room units ⁶	Relative humidity ⁷ (%)	Design temperature ⁸ (degrees F)
STERILIZING AND SUPPLY (Continued)							
Central medical and surgical supply							
Soiled or decontamination room	In	----	6	Yes	No	----	68-73
Clean workroom	Out	----	4	----	No	30-60	75
Sterile storage	Out	----	4	----	----	70 Max	----
Equipment storage	----	----	2	----	----	----	----
SERVICE							
Food preparation center ¹⁴	----	----	10	----	No	----	----
Ware washing	In	----	10	Yes	No	----	----
Dietary day storage	In	----	2	----	----	----	----
Laundry, general	----	----	10	Yes	----	----	----
Soiled linen (sorting and storage)	In	----	10	Yes	No	----	----
Clean linen storage	Out	----	2	----	----	----	----
Soiled linen and trash chute room	In	----	10	Yes	No	----	----
Bedpan room	In	----	10	Yes	----	----	----
Bathroom	In	----	10	Yes	----	----	75
Janitor's closet	In	----	10	Yes	No	----	----
ADMINISTRATIVE AND SUPPORT SERVICE							
Administrative and support service	----	----	2	----	----	30 Min	68-73

**Notes applicable to Table 3:
“Ventilation Requirements for Hospitals and Outpatient Facilities”**

¹ The ventilation rates in this table cover ventilation for comfort, as well as for asepsis and odor control in areas of acute care hospitals that directly affect patient care and are determined based on health care facilities being predominantly "No Smoking" facilities. Where smoking may be allowed, ventilation rates will need adjustment. Areas where specific ventilation rates are not given in the table shall be ventilated in accordance with American Society of Heating Refrigeration and Air-Conditioning Engineers (ASHRAE) Standard 62.1, 2004 edition, Ventilation for Acceptable Indoor Air Quality, and American Society of Heating Refrigeration and Air-Conditioning Engineers, Handbook of Applications, 2003 edition. Specialized patient care areas, including organ transplant units, burn units, specialty procedure rooms, etc. shall have additional ventilation provisions for air quality control as may be appropriate. Occupational Safety and Health Administration (OSHA) standards and/or National Institute for Occupational Safety and Health (NIOSH) criteria require special ventilation requirements or employee health and safety within health care facilities.

² Design of the ventilation system shall provide air movement which is generally from clean to less clean areas. If any form of variable air volume or load shedding system is used for energy conservation, it must not compromise the corridor-to-room pressure balancing relationships or the minimum air changes required by the table. Except where specifically permitted by exit corridor plenum provisions of NFPA 90A, 2002 edition, the volume of infiltration or exfiltration shall be the volume necessary to maintain a minimum of 0.01 inch water gauge.

³ To satisfy exhaust needs, replacement air from the outside is necessary. Table 3 does not attempt to describe specific amounts of outside air to be supplied to individual spaces except for certain areas such as those listed. Distribution of the outside air, added to the system to balance required exhaust, shall be as required by good engineering practice. Minimum outside air quantities shall remain constant while the system is in operation. In variable volume systems, the minimum outside air setting on the air handling unit shall be calculated using the ASHRAE Standard 62.1, 2004 edition.

⁴ Number of air changes may be reduced when the room is unoccupied if provisions are made to ensure that the number of air changes indicated is reestablished any time the space is being utilized. Adjustments shall include provisions so that the direction of air movement shall remain the same when the number of air changes is reduced. Areas not indicated as having continuous directional control may have ventilation systems shut down when space is unoccupied and ventilation is not otherwise needed, if the maximum infiltration or exfiltration permitted in Note 2 is not exceeded and if adjacent

**Notes applicable to Table 3:
“Ventilation Requirements for Hospitals and Outpatient Facilities”
(Continued)**

pressure balancing relationships are not compromised. Air quantity calculations must account for filter loading such that the indicated air change rates are provided up until the time of filter change-out. The minimum total air change requirements shall be based on the supply air quantity in positive pressure rooms and the exhaust air quantity in negative pressure rooms. Air change requirements indicated are minimum values. Higher values shall be used when required to maintain indicated room conditions (temperature and humidity, based on the cooling load of the space: lights, equipment, people, exterior walls and windows, etc.).

⁵ Air from areas with contamination and/or odor problems shall be exhausted to the outside and not recirculated to other areas. Note that individual circumstances may require special consideration for air exhaust to the outside, e.g. in intensive care units in which patients with pulmonary infection are treated, and rooms for burn patients.

⁶ Recirculating room heating, ventilating, and air conditioning (HVAC) units refers to those local units that are used primarily for heating and cooling of air, and not disinfection of air. Because of cleaning difficulty and potential for buildup of contamination, recirculating room units shall not be used in areas marked "No." However, for airborne infection control, air may be recirculated within individual isolation rooms if filters with a maximum efficiency rating value of 17 or higher are used. The maximum efficiency rating value (MERV) is a standard of ASHRAE, Standard 52.2, 1999 edition. Isolation and intensive care unit rooms may be ventilated by reheat induction units in which only the primary air supplied from a central system passes through the reheat unit. Gravity-type heating or cooling units such as radiators or convectors shall not be used in operating rooms and other special care areas. Recirculating devices with 99.97% efficiency filters may have potential uses in existing facilities as interim, supplemental environmental controls to meet requirements for the control of airborne infectious agents. Limitations in design must be recognized. The design of either portable or fixed systems should prevent stagnation and short circuiting of airflow. The supply and exhaust locations should direct clean air to areas where health care workers are likely to work, across the infectious source, and then to the exhaust, so the health care worker is not in a position between the infectious source and the exhaust location. The design of such systems should also allow for easy access for scheduled preventive maintenance and cleaning.

⁷ The ranges listed are the minimum and maximum limits where control is specifically needed. The maximum and minimum limits are not intended to be independent of a space's associated temperature. The relative humidity is expected to be at the lower end of the range when the temperature is at the higher end, and vice versa.

**Notes applicable to Table 3:
“Ventilation Requirements for Hospitals and Outpatient Facilities”
(Continued)**

⁸ Where temperature ranges are indicated, the systems shall be capable of maintaining the rooms at any point within the range. A single figure indicates a heating or cooling capacity of at least the indicated temperature. This is usually applicable when patients may be undressed and require a warmer environment. Additional heating may be required in these areas to maintain temperature range. Nothing in these rules shall be construed as precluding the use of temperatures lower than those noted when the patients' comfort and medical conditions make lower temperatures desirable. Unoccupied areas such as storage rooms shall have temperatures appropriate for the function intended.

⁹ NIOSH Criteria Documents regarding Occupational Exposure to Waste Anesthetic Gases and Vapors, and Control of Occupational Exposure to Nitrous Oxide indicate a need for both local exhaust (scavenging) systems and general ventilation of the areas in which the respective gases are utilized.

¹⁰ The term trauma room as used here is the operating room space in the emergency department or other trauma reception area that is used for emergency surgery. The first aid room and/or "emergency room" used for initial treatment of accident victims may be ventilated as noted for the "treatment room." Treatment rooms used for bronchoscopy shall be treated as bronchoscopy rooms. Treatment rooms used for cryosurgery procedures with nitrous oxide shall contain provisions for exhausting waste gases.

¹¹ The protective environment airflow design specifications protect the patient from common environmental airborne infectious microbes (i.e., Aspergillus spores). These special ventilation areas shall be designed to provide directed airflow from the cleanest patient care area to less clean areas. These rooms shall be protected with filters with a MERV rating of 17 or higher in the supply airstream. These interrupting filters protect patient rooms from maintenance-derived release of environmental microbes from the ventilation system components. Recirculation 99.97% efficiency filters can be used to increase the equivalent room air exchanges. Constant volume airflow is required for consistent ventilation for the protected environment. If the facility determines that airborne infection isolation is necessary for protective environment patients, an anteroom shall be provided. Rooms with reversible airflow provisions for the purpose of switching between protective environment and airborne infection isolation functions are not acceptable.

¹² The infectious disease isolation room described here is to be used for isolating the airborne spread of infectious diseases, such as measles, varicella, or tuberculosis. The

**Notes applicable to Table 3:
“Ventilation Requirements for Hospitals and Outpatient Facilities”
(Continued)**

design of airborne infection isolation rooms should include the provision for normal patient care during periods not requiring isolation precautions. Supplemental recirculating devices may be used in the patient room, to increase the equivalent room air exchanges; however, such recirculating devices do not provide the outside air requirements. Air may be recirculated within individual isolation rooms if filters with a MERV rating of 17 or higher are used. Exhaust systems for infectious isolation rooms shall exhaust no other areas or rooms. Rooms with reversible airflow provisions for the purpose of switching between protective environment and AII functions are not acceptable.

¹³ When required, appropriate hoods and exhaust devices for the removal of noxious gases or chemical vapors shall be provided. Laboratory hoods shall meet the following general standards.

1. Have an average face velocity of at least 75 feet per minute.
2. Be connected to an exhaust system to the outside which is separate from the building exhaust system.
3. Have an exhaust fan located at the discharge end of the system.
4. Have an exhaust duct system of noncombustible corrosion-resistant material as needed to meet the planned usage of the hood.

Laboratory hoods shall meet the following special standards:

1. Fume hoods and their associated equipment in the air stream, intended for use with perchloric acid and other strong oxidants, shall be constructed of stainless steel or other material consistent with special exposures, and be provided with a water wash and drain system to permit periodic flushing of duct and hood. Electrical equipment intended for installation within the duct shall be designed and constructed to resist penetration by water. Lubricants and seals shall not contain organic materials. When perchloric acid or other strong oxidants are only transferred from one container to another, standard laboratory fume hoods and associated equipment may be used in lieu of stainless steel construction. Fume hood intended for use with radioactive isotopes shall be constructed of stainless steel or other material suitable for the particular exposure and shall comply with National Fire Protection Association 801, Facilities for Handling Radioactive Materials, 2003 edition (NFPA 801).

NOTE: RADIOACTIVE ISOTOPES USED FOR INJECTIONS, ETC. WITHOUT PROBABILITY OF AIRBORNE PARTICULATES OR GASES MAY BE PROCESSED IN A CLEAN WORKBENCH-TYPE HOOD WHERE ACCEPTABLE TO THE NUCLEAR REGULATORY COMMISSION.

**Notes applicable to Table 3:
“Ventilation Requirements for Hospitals and Outpatient Facilities”
(Continued)**

2. In new installations and construction or major renovation work, each hood used to process infectious or radioactive materials shall have a minimum face velocity of 150 feet per minute with suitable static pressure operated dampers and alarms to alert staff of fan shutdown. Each hood shall have filters with an efficiency of 99.97% (based on the dioctyl-phthalate test method) in the exhaust stream, and be designed and equipped to permit the removal, disposal, and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination. Hoods that process radioactive materials shall meet the requirements of the Nuclear Regulatory Agency.

¹⁴ Food preparation centers shall have ventilation systems whose air supply mechanisms are interfaced appropriately with exhaust hood controls or relief vents so that exfiltration or infiltration to or from exit corridors does not compromise the exit corridor restrictions of NFPA 90A, 2002 edition, the pressure requirements of NFPA 96, 2001 edition, or the maximum defined in the table. The number of air changes may be reduced or varied to any extent required for odor control when the space is not in use.

¹⁵ The space that houses ethylene oxide (EO) sterilizers shall be designed to:

1. provide a dedicated local exhaust system with adequate capture velocity of 200 feet per minute to allow for the most effective installation of an air handling system, i.e., exhaust over sterilizer door, atmospheric exhaust vent for safety valve, exhaust at sterilizer, drain and exhaust for the aerator, and multiple load station;
2. provide exhaust in EO source areas such as service/aeration areas;
3. ensure that general airflow is away from sterilizer operator(s);
4. provide a dedicated exhaust duct system for EO. The exhaust outlet to the atmosphere should be at least 25 feet away from any air intake; and
5. meet OSHA requirements.

¹⁶ Differential pressure shall be a minimum of 0.01 inch water gauge. If alarms are installed, allowances shall be made to prevent nuisance alarms of monitoring devices.

¹⁷ Some surgeons may require room temperatures that are outside of the indicated range. All operating room design conditions shall be developed in consultation with surgeons, anesthesiologists, infection control and nursing staff.

**Notes applicable to Table 3:
“Ventilation Requirements for Hospitals and Outpatient Facilities”
(Continued)**

¹⁸ Total air changes per room for patient rooms, intermediate care, labor/delivery/recovery rooms, and labor/delivery/recovery/postpartum rooms may be reduced to four when supplemental heating and/or cooling systems (radiant heating and cooling, baseboard heating, etc.) are used.

¹⁹ In a ventilation system that recirculates air, filters with a MERV rating of 17 or higher can be used in lieu of exhausting the air from these spaces to the outside. In this application, the return air shall be passed through the HEPA filters before it is introduced into any other space.

²⁰ Air movement shall be IN to the isolation anteroom from the adjacent corridor and OUT from the anteroom to the adjacent isolation room.

²¹ Air movement shall be IN to the protective environment anteroom from the adjacent corridor and IN to the anteroom from the adjacent protective environment room.

(d) Table 4. Filter efficiencies for central ventilation and air conditioning systems.

TABLE 4
FILTER EFFICIENCIES FOR CENTRAL VENTILATION
AND AIR CONDITIONING SYSTEMS

Area Designation	Number of Filter Beds	Filter Bed No. 1 (Percent, MERV*)	Filter Bed No. 2 (Percent, MERV*)
Orthopedic and organ transplant operating rooms	2	25, 7	99.97, 17
Protective environment rooms	2	25, 7	99.97, 17
IV preparation and chemo-hood rooms	2	25, 7	99.97, 17
General procedure operating rooms, delivery rooms, nurseries, critical care units, patient care areas and treatment, diagnostic and related areas	2	25, 7	90, 14
Laboratories and sterile storage	1	80, 13	----
Administrative, bulk storage, soiled holding areas, food preparation areas, and laundries	1	30, 7	----

* MERV – Minimum efficiency rating value (American Society of Heating Refrigeration and Air-Conditioning Engineers (ASHRAE) Standard 52.2, 1999 edition.

NOTES:

- Additional roughing or prefilters should be considered to reduce maintenance required for filters with efficiency higher than 75%.
- The filtration efficiency ratings are based on ASHRAE Standard 52.1, 1992 edition.

**TABLE 5
HOT WATER USE**

	Clinical	Dietary	Laundry
Gallons per hour per bed ¹	3	2	2
Temperature (F degrees)	105-120 ²	140 ³	160 ⁴

¹ Quantities indicated for design demand of hot water are for general reference minimums and shall not substitute for accepted engineering design procedures using actual number and types of fixtures to be installed. Design will also be affected by temperatures of cold water used for mixing, length of run, and insulation relative to heat loss. As an example, total quantity of hot water needed will be less when temperature available at the outlet is very nearly that of the source tank, and cold water used for tempering is relatively warm.

² Hot water temperature at point of use for hand washing and bathing.

³ Provisions shall be made to provide 180 degrees Fahrenheit rinse water at the ware washer (may be by separate booster) unless a chemical rinse is provided.

⁴ Provisions shall be made to provide 160 degrees Fahrenheit hot water at the laundry equipment when needed. (This may be by steam jet or separate booster heater.) However, it is emphasized that this does not imply that all water used will be at this temperature. Water temperatures required for acceptable laundry results shall vary according to type of cycle, time of operation, and formula of soap and bleach as well as type and degree of soil. Lower temperatures may be adequate for most procedures in many facilities but the higher 160 degrees Fahrenheit should be available when needed for special conditions.

TABLE 6
STATION OUTLETS FOR OXYGEN, VACUUM, AND MEDICAL AIR SYSTEMS

Location	Station Outlets		
	Oxygen see notes 1, 4	Vacuum see notes 1, 4	Medical Air see notes 1, 2, 3, 4
Patient rooms (medical and surgical care)	1/bed	1/bed	---
Patient rooms (psychiatric and chemical dependency care)	---	---	---
Seclusion rooms	---	---	---
Isolation rooms – infectious and protective (medical and surgical)	1/bed	1/bed	---
Examination/treatment (medical, surgical care and postpartum)	1/room	1/room	---
Pediatric and adolescent patient rooms	1/bed	1/bed	1/bed
Pediatric nursery	1/bassinet	1/bassinet	1/bassinet
Critical care unit (general)	3/bed	3/bed	1/bed
Coronary critical care unit	3/bed	2/bed	1/bed
Pediatric critical care unit	3/bed	3/bed	1/bed
Isolation room for each type critical unit	3/bed	3/bed	1/bed
Preoperative preparation and holding	1/bed	1/bed	---
Operating room (general, cardio-vascular, neurological and orthopedic surgery)	2/room	3/room	1/room
Operating room (cystoscopic and endoscopic surgery)	1/room	3/room	---
Post-anesthetic care unit	1/bed	3/bed	1/bed
Phase II recovery (note 12)	1/bed	3/bed	---
Special procedure rooms	2/room	2/room	1/room
Special procedure recovery	1/bed	1/bed	---
Cardiac catheterization lab	2/room	2/room	2/room
Endoscopic procedure room	2/room	2/room	1/room
Endoscopy work room	---	1	1 (note 3)
Decontamination room (part of sterile processing)	---	1	1 (note 3)
Cesarean section delivery/delivery room (emergency)	2/room	3/room	1/room
Infant resuscitation station in each cesarean section, delivery, LDR, and LDRP room (see note 8)	1/bassinet	1/bassinet	1/bassinet
Labor room	1/room	1/room	1/room
Labor/delivery/recovery (LDR)	1/bed	1/bed	---
Labor/delivery/recovery/postpartum (LDRP) room (see note 11)	1/bed	1/bed	---
Newborn nursery (full-term) (see note 10)	1/4 bassinets	1/4 bassinets	1/4 bassinets
Continuing care nursery	1/bassinet	1/bassinet	1/bassinet
Neonatal critical care unit	3/bassinet	3/bassinet	3/bassinet
Room-in nursery program (postpartum and LDRP)	1/bassinet	1/bassinet	1/bassinet
Obstetrical recovery room	1/bed	3/bed	1/bed
Obstetrical Triage room	1/bed	1/bed	---
Antepartum patient rooms	1/bed	1/bed	---
Postpartum patient rooms	1/bed	1/bed	---

TABLE 6
STATION OUTLETS FOR OXYGEN, VACUUM, AND MEDICAL AIR SYSTEMS
(Continued)

Location	Station Outlets		
	Oxygen see notes 1, 4	Vacuum see notes 1, 4	Medical Air see notes 1, 2, 4
MRI	1/room	1/room	1/room
Anesthesia workroom	1 /workstation	---	1/workstation
Holding/observation area/room	1/bed	1/bed	---
Definitive emergency care holding/observation area/room	1/bed	1/bed	---
Definitive emergency care exam/treatment room	1/bed	1/bed	1/bed
Trauma/cardiac room	2/bed	3/bed	1/bed
Orthopedic and cast room	1/room	1/room	---
Initial emergency management	1/bed	1/bed	---
Triage area (definitive emergency care)	1/station	1/station	---
Decontamination room (definitive emergency care)	1/station	1/station	---
Respiratory therapy clean room	1	---	1
Skilled nursing patient rooms	1/bed	1/bed	---
Intermediate care patient rooms	2/bed	2/bed	1/bed
Universal care patient rooms	3/bed	3/bed	1/bed
Autopsy room	---	1/workstation	---
Laboratory (note 9)	(notes 4,5,7)	(notes 5,6)	(notes 4,5,7)

Notes:

1. Prohibited uses of medical gases include fueling torches, blowing down or drying any equipment such as lab equipment, endoscopy or other scopes, or any other purposes. Also prohibited is using the oxygen or medical air to raise, lower, or otherwise operate booms or other devices in operating rooms (ORs) or other areas.
2. Medical air sources shall be connected to the medical air distribution system only and shall be used only for air in the application of human respiration, and calibration of medical devices for respiratory application. The medical air piping distribution system shall support only the intended need for breathable air for such items as intermittent positive pressure breathing (IPPB) and long-term respiratory assistance needs, anesthesia machines, and so forth. The system shall not be used to provide engineering, maintenance, and equipment needs for general hospital support use. The life safety nature of the medical air system shall be protected by a system dedicated solely for its specific use.

TABLE 6
STATION OUTLETS FOR OXYGEN, VACUUM, AND MEDICAL AIR SYSTEMS
(Continued)

3. Instrument air shall be used for purposes such as the powering of medical devices unrelated to human respiration (e.g., surgical tools, ceiling arms). Medical air and instrument air are distinct systems for mutually exclusive applications. Nitrogen shall be allowed for Decontamination and Endoscopy workroom uses if provided with reducing regulator. This shall be supplied from existing medical gas support nitrogen system and installed in accordance to NFPA 99, 2002 edition.
4. Central supply systems for oxygen, medical air, nitrous oxide, carbon dioxide, nitrogen and all other medical gases shall not be piped to, or used for, any other purpose except patient care applications.
5. Primary NFPA reference documents regarding laboratories shall be as follows:
Laboratory in a building with inpatients – NFPA 99, 2002 edition.
Laboratory in a building with outpatients incapable of self-preservation – NFPA 99, 2002 edition.
Laboratory in a building with outpatients capable of self-preservation – NFPA 45, 2000 edition.
6. Any laboratory (such as for analysis, research, or teaching) in a hospital that is used for purposes other than direct support of patient therapy should preferably have its own self-supporting vacuum system, independent of the medical-surgical vacuum system. Where only one set of vacuum pumps is available for a combined medical-surgical vacuum system and an analysis, research, or teaching laboratory vacuum system, such laboratories shall be connected separately from the medical-surgical system directly to the receiver tank through its own isolation valve and fluid trap located at the receiver. Between the isolation valve and fluid trap, a scrubber shall be permitted to be installed. A small laboratory in patient care areas used in direct support of patient therapy should not be required to be connected directly to the receiver or have fluid traps, scrubbers, and so forth, separate from the rest of the medical-surgical system.
7. Laboratory gas piping systems should not be used to pipe gas for use by hospital patients. This applies to piping systems intended to supply gas to patients within a laboratory facility. Such a system should not be used to supply laboratory equipment other than that directly involved with the patient procedure.
8. When infant resuscitation takes place in a room such as cesarean section/delivery or LDRP, then the infant resuscitation services must be provided in that room in addition to the minimum service required for the mother.

TABLE 6
STATION OUTLETS FOR OXYGEN, VACUUM, AND MEDICAL AIR SYSTEMS
(Continued)

9. Laboratory is a building, space, room, or group of rooms intended to serve activities involving procedures for investigation, diagnosis, or treatment in which flammable, combustible, or oxidizing materials are to be used.
10. Four bassinets may share one outlet that is accessible to each bassinet.
11. One outlet for mother and one for bassinet.
12. If Phase II recovery area is a separate area from the PACU, only one vacuum per bed or station shall be required.

**TABLE 7
NURSES CALLING SYSTEM**

LOCATION	NURSES REGULAR CALLING SYSTEM		EMERGENCY CALLING SYSTEM		STAFF EMERGENCY ASSISTANCE CALLING SYSTEM (Code Blue)	
	CALL	Annunciate	CALL ⁴	Annunciate	CALL	Annunciate
Administration & Public Suite	-	-	-	-	-	-
Cart Cleaning & Sanitizing Unit	-	-	-	-	-	-
Central Sterile Supply Suite	-	-	-	-	-	-
Critical Care Unit - see specific unit	-	-	-	-	-	-
CCU	X	Note 1	X	Note 1	X ¹⁰	Note 2, 3
CCCU	X	Note 1	X	Note 1	X ¹⁰	Note 2, 3
PCCU	X	Note 1	X	Note 1	X ¹⁰	Note 2, 3
Dietary Suite	-	-	-	-	-	-
Emergency Suite	-	Note 1	X	Note 1	-	Note 2, 3
Triage, Trauma	-	-	-	-	X	-
Exam, Treatment	X ⁶	-	-	-	X	-
Holding and Observations Rooms/Area	X ⁶	-	-	-	X ¹⁰	-
Multiple Purpose Room	-	-	-	-	X	-
Patient Decontamination/Shower	-	-	-	-	X	-
Employees Suite	-	-	-	-	-	-
Engineering Suite & Equipment Areas	-	-	-	-	-	-
General Stores	-	-	-	-	-	-
Hospital-based Skilled Nursing Units - see Nursing Unit	-	-	-	-	-	-
Hyperbaric Suite	-	Note 1	X	Note 1	-	Note 2, 3
Holding Area	X ⁶	-	-	-	-	-
Patient Dressing Room	-	-	X	-	-	-
Treatment	-	-	-	-	X	-
Imaging Suite	-	Note 1	X	Note 1	-	Note 2, 3
Holding, Prep, Recovery	X ⁶	-	-	-	-	-
Patient Dressing Room	-	-	X	-	-	-
Imaging Procedure Room	-	-	-	-	X ⁵	-
Intermediate Care Suite	-	Note 1	X	Note 1	-	Note 2, 3
Patient Room	X ⁶	-	-	-	X ¹⁰	-
Patient Bathroom	-	-	X	-	-	-
Laboratory Suite	-	-	-	-	-	-
Specimen Collection Room (remote location only)	-	-	X	Note 8 Note 1	-	-
Laundry Suite	-	-	-	-	-	-
Medical Records Suite	-	-	-	-	-	-
Mental Health and Chemical Dependency Nursing Suite ⁷	-	-	-	-	-	-
Morgue	-	-	-	-	-	-
Nuclear Medicine Suite	-	Note 1	X	Note 1	-	Note 2, 3
Holding, Observation, Exam	X ⁶	-	-	-	-	-
Patient Dressing Room, Dose Administration	-	-	X	-	-	-
Nuclear Medicine Procedure Room, Exam	-	-	-	-	X	-

**TABLE 7
NURSES CALLING SYSTEM**

LOCATION	NURSES REGULAR CALLING SYSTEM		EMERGENCY CALLING SYSTEM		STAFF EMERGENCY ASSISTANCE CALLING SYSTEM (Code Blue)	
	CALL	Annunciate	CALL ⁴	Annunciate	CALL	Annunciate
Nursing Unit	-	Note 1	X	Note 1	-	Note 2, 3
Patient Room	X	-	-	-	-	-
Patient Bathroom	-	-	X	-	-	-
Central Bathing Facility Room	-	-	X	-	X	-
Exam, Treatment	-	-	-	-	X	-
Obstetrical Suite	-	Note 1	X	Note 1	-	Note 2,3
Obstetric Triage	-	-	-	-	X	-
Preoperative Rooms	X ⁶	-	-	-	-	-
Labor, Recovery, LDR and LDRP Room	X ⁶	-	-	-	X	-
Operating, Delivery, Infant Resuscitation Area/Room, Birthing Room, Full-Term Nursery	-	-	-	-	X	-
Continuing Care Nursery, NCCU	-	-	-	-	X ¹⁰	Note 2, 3
Outpatient Suite	-	-	X	Note 1	-	Note 2, 3
Treatment, Diagnostic, and Observation Rooms, Secondary Recovery Lounge	-	-	-	-	X ¹⁰	-
Stress Test Room/Lab	-	-	-	-	X	-
Pediatric and Adolescent Nursing Unit	-	Note 1	-	Note 1	-	Note 2, 3
Patient Suite with bed(s)	X ⁹	-	X	-	X	-
Exam, Treatment	-	-	-	-	X	-
Pharmacy Suite	-	-	-	-	-	-
Radiotherapy Suite	-	Note 1	-	Note 1	-	Note 2, 3
Holding	X ⁶	-	-	-	-	-
Patient Dressing Room	-	-	X	-	-	-
Exam, Treatment	-	-	-	-	X	-
Rehabilitation Nursing Unit - see Nursing Unit	-	-	-	-	-	-
Rehabilitation Therapy Suite	-	-	X	Note 1	-	Note 2, 3
Exam, Treatment	-	-	-	-	X	-
Hydrotherapy Tub	-	-	X	-	X	-
Patient Dressing Room	-	-	X	-	-	-
Renal Dialysis Suite (Acute & Chronic)	-	Note 1	X	Note 1	-	Note 2, 3
Treatment	X ⁶	-	-	-	X	-
Respiratory Therapy Suite	-	-	X	Note 1	-	-
Special Procedure Suite	-	Note 1	X	Note 1	-	Note 2, 3
Preoperative, Holding Area	X ⁶	-	-	-	-	-
Recovery	X ⁶	-	-	-	X ¹⁰	-
Special Procedure, Treatment Room, Bronchoscopy, Cardiac Catheterization Lab.	-	-	-	-	X	-
Surgical Suite	-	Note 1	X	Note 1	-	Note 2, 3
Preoperative	X ⁶	-	-	-	-	-
PACU, Recovery, Holding Area	X ⁶	-	-	-	X ¹⁰	-
Operating, Special Procedure Room	-	-	-	-	X	-

**TABLE 7
NURSES CALLING SYSTEM**

LOCATION	NURSES REGULAR CALLING SYSTEM		EMERGENCY CALLING SYSTEM		STAFF EMERGENCY ASSISTANCE CALLING SYSTEM (Code Blue)	
	CALL	Annunciate	CALL ⁴	Annunciate	CALL	Annunciate
Universal Care Suite	X	Note 1	X	Note 1	X	Note 2, 3
Exam, Treatment	-	-	-	-	X	Note 2, 3
Patient Toilet, Shower, Bath	-	-	X	Note 1	-	-
Patient Dressing Room	-	-	X	Note 1	-	-
Mobile Units - see specific requirements for type of suite provided	-	-	-	-	-	-

Notes to TDSHS Nurses Calling Systems Table:	
1	Nurse Station, Clean Work Room, Soiled Work Room, Medication Room, Charting Room, Clean Linen Storage, Nourishment Room, Equipment Storage
2	Nurse Station, Clean Work Room, Soiled Work Room, Medication, Room, Charting Room, Clean Linen Storage, Nourishment Room, Equipment Storage, Exam and Treatment Rooms
3	The system shall have voice communication capabilities between the point of alarm and the nurse station so that the type of emergency or help required may be specified.
4	All toilets, showers, baths and dressing rooms used by all patients
5	Device(s) for MRI to be in adjacent Control Room
6	In areas under constant visual surveillance, the nurses regular calling system may be limited to a bedside call button or station that activates a signal readily seen at the control station.
7	System is not required. When provided, refer to §133.163(q)(5)(A) for requirements.
8	Call to annunciate in the nearest unit or suite
9	Each patient bed shall be provided with a bedside call button. Consideration should be given to the age of the patient(s) so that voice communication is available as needed.
10	One code blue station may be shared between two beds, cribs, bassinets, or gurneys in a multiple type bed ward.

**TABLE 8
MULTIPLE BED ROOM CONFIGURATIONS**

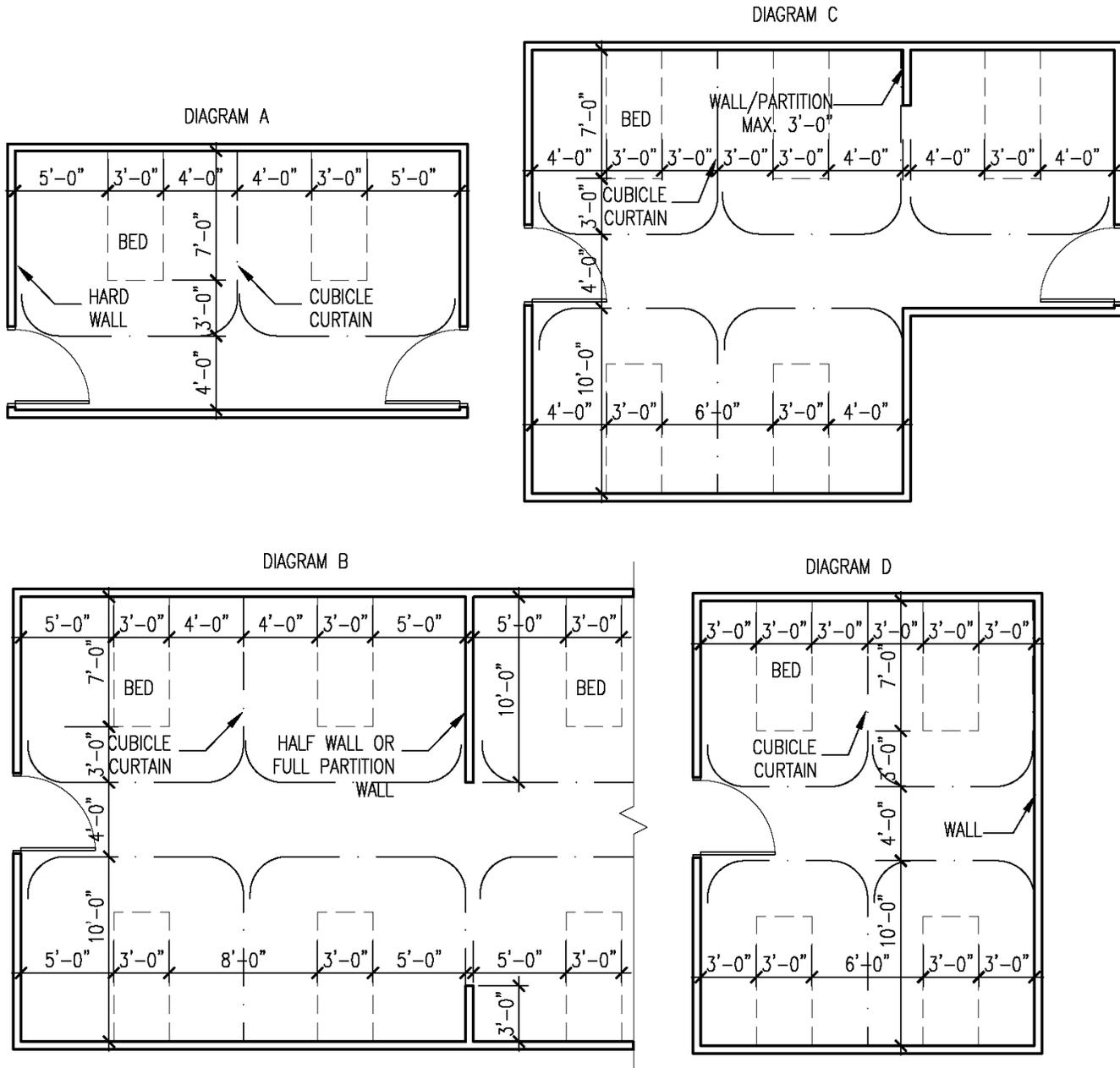


TABLE 8
MULTIPLE BED ROOM CONFIGURATIONS
(Continued)

DIAGRAM E

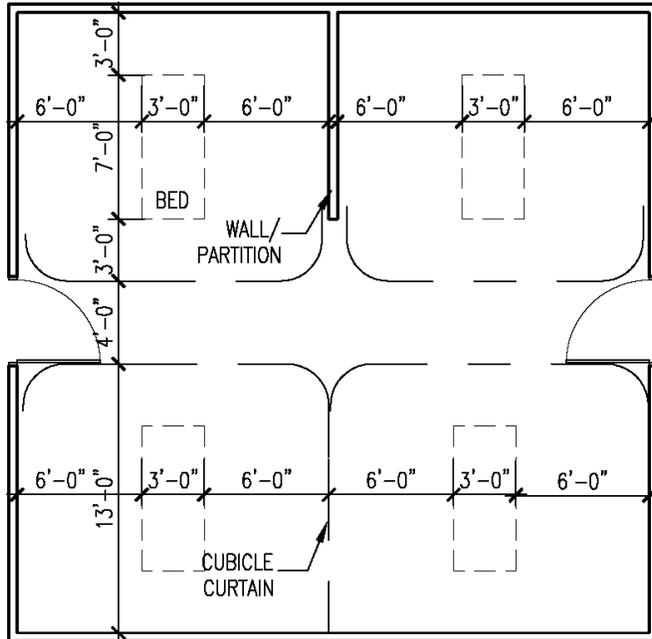


DIAGRAM G

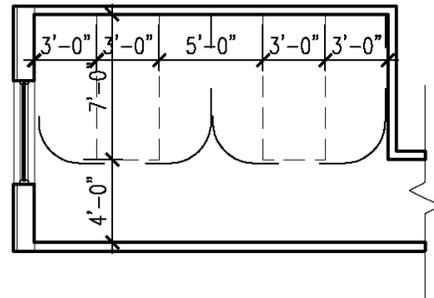


DIAGRAM H

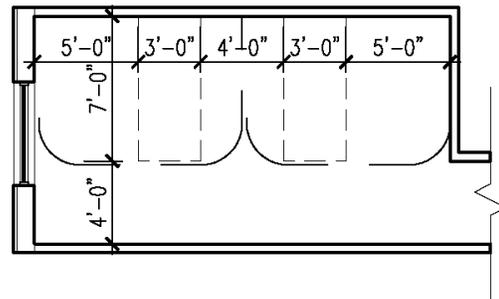


DIAGRAM F

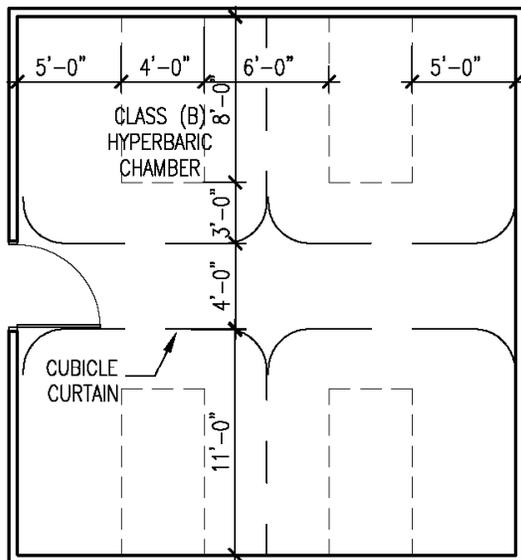


TABLE 8
MULTIPLE BED ROOM CONFIGURATIONS
(Continued)

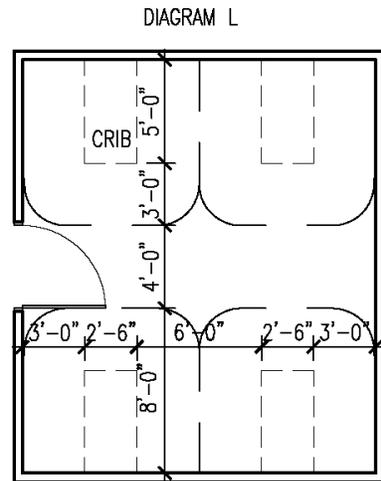
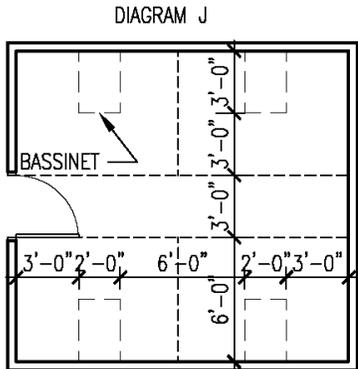
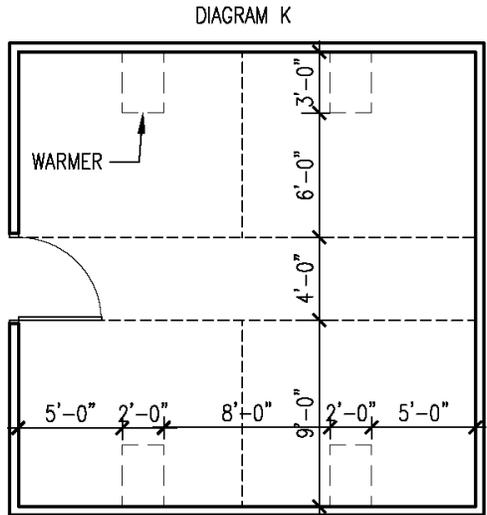
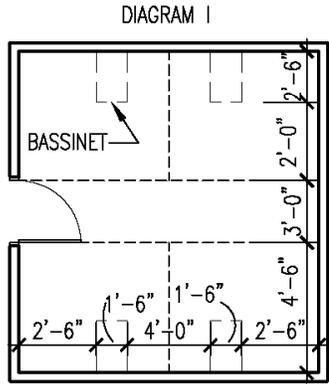


TABLE 8
MULTIPLE BED ROOM CONFIGURATIONS
(Continued)

