



**DEPARTMENT OF
STATE HEALTH SERVICES
FACILITY LICENSING GROUP**

**TITLE 25
TEXAS ADMINISTRATIVE CODE
CHAPTER 135
AMBULATORY SURGICAL CENTERS
LICENSING RULES**

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Chapter 135. AMBULATORY SURGICAL CENTERS

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§135.1. Scope and Purpose.

(a) The purpose of these sections is to implement Health and Safety Code, Chapter 243 which requires ambulatory surgical centers to be licensed by the Department of State Health Services.

(b) These sections provide minimum standards for ambulatory surgical center licenses and procedures for granting, denying, suspending, and revoking a license and licensure fees. The sections under this heading primarily cover the licensing procedures and standards for operation, and the remaining sections of this chapter primarily cover the requirements concerning construction design and the life safety code.

(c) The standards pertaining to the construction and design, the qualifications of the professional staff and other personnel, the equipment essential to the health and welfare of the patients, sanitary and hygienic conditions, and the quality assurance program may not exceed the minimum standards for certification under the Social Security Act, Title XVIII, 42 United States Code (U.S.C.) §1395 et seq. Should the state standards exceed the federal requirements in these areas, the federal requirements will control.

§135.2. Definitions.

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

(1) Act--Texas Ambulatory Surgical Center Licensing Act, Health and Safety Code, Chapter 243.

(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) Administrator--A person who is a physician, registered nurse, has a baccalaureate or postgraduate degree in administration or a health-related field, or has one year of administrative experience in a health care setting.

(4) Advanced Practice Nurse (APN)--A registered nurse, currently licensed in the State of Texas, or under a multi-state licensure privilege with another compact state, who has been approved by the Board of Nurse Examiners for the State of Texas (board) to practice as an advanced practice nurse based on completing an advanced educational program of study acceptable to the board. The term includes a nurse practitioner, nurse-midwife, nurse anesthetist, and a clinical nurse specialist.

(5) 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.

(6) Ambulatory Surgical Center (ASC)--A facility that primarily provides surgical services to patients who do not require overnight hospitalization or extensive recovery, convalescent time or observation. The planned total length of stay for an ASC patient shall not exceed 23 hours. Patient stays of greater than 23 hours must be the result of an unanticipated medical condition and shall occur infrequently. The 23-hour period begins with the induction of anesthesia.

(7) Autologous blood units--Units of blood or blood products derived from the recipient.

(8) Available--Able to be physically present in the facility to assume responsibility for the delivery of patient care services within five minutes.

(9) Certified registered nurse anesthetist (CRNA)--A currently licensed registered nurse who has current certification from the Council on Certification of Nurse Anesthetists and who is currently authorized to practice as an Advanced Practice Nurse by the Board of Nurse Examiners.

(10) Change of ownership--

(A) A sole proprietor who transfers all or part of the ASC's ownership to another person or persons;

(B) The removal, addition, or substitution of a person or persons as a general, managing, or controlling partner in an ASC owned by a partnership and the tax identification number of that ownership changes; or

(C) A corporation that transfers all or part of the corporate stock which represents the ASC's ownership to another person or persons and the tax identification number of that ownership changes.

(11) Dentist--A person who is currently licensed under the laws of this state to practice dentistry.

(12) Department--The Department of State Health Services.

(13) Disposal--The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharge into any waters, including ground waters.

(14) Electronic Signature--Signature produced or generated on a computer.

(15) Extended observation--The period of time that a patient remains in the facility following recovery from anesthesia and discharge from the post anesthesia care unit, during which additional comfort measures or observation may be provided.

(16) FDA-approved blood bank--A facility that has been licensed in accordance with the Food and Drug Administration requirements in the preparation of blood and blood products.

(17) Health care practitioners (Qualified Medical Personnel)--Individuals currently licensed under the laws of this state who are authorized to provide services in an ASC.

(18) 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.

(19) 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.

(20) Medicare-approved reference laboratory--A facility that has been certified and found eligible for Medicare reimbursement, and includes hospital laboratories which may be Joint Commission on Accreditation of Healthcare Facilities or American Osteopathic Association accredited or nonaccredited Medicare approved hospitals, Medicare certified independent laboratories.

(21) Physician--A person who is currently licensed under the laws of this state to practice medicine and who holds a doctor of medicine or a doctor of osteopathy degree.

(22) Person--Any individual, firm, partnership, corporation, or association.

(23) Premises--A building where patients receive outpatient surgical services.

(24) Prescriber--A person who is legally authorized to write an order or prescription for a health care service, medical device, or drug.

(25) Registered nurse (RN)--A person who is currently licensed by the Board of Nurse Examiners 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.

(26) 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 as listed under §135.27 of this title (relating to Patient Safety Program). 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.

(27) Title XVIII--Title XVIII of the United States Social Security Act, 42 U.S.C. §1395 et seq.

§135.3. Fees.

(a) Initial license fee. The fee for an initial license (includes change of ownership or relocation) is \$5,200. The license term is two years.

(b) Renewal license fee. The fee for a renewal license is \$5,200. The license term is two years.

(c) Official submission. The department will not consider an application as officially submitted until the applicant pays the application fee and submits the application form.

(d) Nonrefundable. Fees paid to the department are not refundable.

(e) Payment of fees. All fees shall be paid to the Department of State Health Services.

(f) Fee schedule review. The department shall make periodic reviews of its fee schedule and make any adjustments necessary to provide funds to meet its expenses without creating an unnecessary surplus. Such adjustments shall be through section amendments.

(g) Other fees. The department is authorized to collect subscription and convenience fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online, in accordance with Texas Government Code, §2054.111.

§135.4. ASC Operation.

(a) The ASC must have a governing body that sets policy and assumes full legal responsibility for the total operation of the ASC.

(b) The governing body shall be responsible for assuring that medical staff bylaws are current and on file.

(c) The governing body shall address and is fully responsible, either directly or by appropriate professional delegation, for the operation and performance of the ASC. Governing body responsibilities include, but are not limited to:

(1) determining the mission, goals, and objectives of the ASC;

(2) assuring that facilities and personnel are adequate and appropriate to carry out the mission;

(3) establishing an organizational structure and specifying functional relationships among the various components of the ASC;

(4) adopting bylaws or similar rules and regulations for the orderly development and management of the ASC;

(5) adopting policies or procedures necessary for the orderly conduct of the ASC;

(6) assuring that the quality of care is evaluated and that identified problems are addressed;

(7) reviewing all legal and ethical matters concerning the ASC and its staff and, when necessary, responding appropriately;

(8) maintaining effective communication throughout the ASC;

(9) establishing a system of financial management and accountability that includes an audit appropriate to the ASC;

(10) developing, implementing, and enforcing a policy on the rights of patients;

(11) approving all major contracts or arrangements affecting the medical care provided under its auspices, including, but not limited to, those concerning:

(A) the employment of health care practitioners;

(B) an effective procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the ASC. The ASC must have a written transfer agreement with a hospital or all physicians performing surgery at the ASC must have admitting privileges at a local hospital;

(C) the use of external laboratories;

(D) an effective procedure for obtaining emergency laboratory, radiology, and pharmaceutical services if laboratory, X-ray, and pharmacy services are not provided on-site;

(E) the provision of education to students and postgraduate trainees if the ASC participates in such programs;

(12) formulating long-range plans in accordance with the mission, goals, and objectives of the ASC;

(13) operating the ASC without limitation because of race, creed, sex, or national origin;

(14) assuring that all marketing and advertising concerning the ASC does not imply that it provides care or services which it is not capable of providing; and

(15) developing a system of risk management appropriate to the ASC including, but not limited to:

(A) periodic review of all litigation involving the ASC, its staff, and health care practitioners regarding activities in the ASC;

(B) periodic review of all incidents reported by staff and patients;

(C) review of all deaths, trauma, or adverse reactions occurring on premises; and

(D) evaluation of patient complaints.

(d) The governing body shall provide for full disclosure of ownership to the department.

(e) The governing body shall meet at least annually and keep such minutes or other records as may be necessary for the orderly conduct of the ASC.

(f) If the governing body elects, appoints, or employs officers and administrators to carry out its directives, the authority, responsibility, and functions of all such positions shall be defined.

(g) When a majority of its members are physicians, the governing body, either directly or by delegation, shall make (in a manner consistent with state law and based on evidence of the education, training, and current competence of the physician) initial appointments, reappointments, and assignment or curtailment of medical privileges. When a majority of the members of the governing body are not physicians, the ASC's bylaws or similar rules and regulations shall specify a procedure for establishing medical review for the purpose of making (in a manner consistent with state law and based on evidence of the education, training, and current competence of the physician) initial appointments, reappointments, and assignment or curtailment of medical privileges.

(h) The governing body shall provide (in a manner consistent with state law and based on evidence of education, training, and current competence) for the initial appointment, reappointment, and assignment or curtailment of privileges and practice for nonphysician health care personnel and practitioners.

(i) The governing body shall encourage personnel to participate in continuing education that is relevant to their responsibilities within the ASC.

(j) The governing body shall adopt, implement and enforce a written policy to ensure accurate billing for services and supplies. The policy shall include a procedure for addressing complaints related to billed services and supplies.

(k) The governing body shall adopt, implement and enforce written policies to ensure compliance with applicable state laws.

(l) Informed consent for abortion. An ASC that performs abortions shall adopt, implement and enforce a policy to ensure compliance with Health and Safety Code, Chapters 171 and 245, Subchapters A and B (relating to Abortion and Informed Consent).

§135.5. Patient Rights.

(a) Patients shall be treated with respect, consideration, and dignity.

(b) Patients shall be provided appropriate privacy.

(c) Patient records shall be treated confidentially and, except when authorized by law, patients shall be given the opportunity to approve or refuse their release.

(d) Patients shall be provided, to the degree known, appropriate information concerning their diagnosis, treatment, and prognosis. When it is medically inadvisable to give such information to a patient, the information shall be provided to a person designated by the patient or to a legally authorized person.

(e) Patients shall be given the opportunity to participate in decisions involving their health care, except when such participation is contraindicated for medical reasons.

(f) Information shall be available to patients and staff concerning:

(1) patient rights, including those specified in subsections (a)-(e) of this section;

(2) patient conduct and responsibilities;

(3) services available at the ASC;

(4) provisions for after-hours and emergency care;

(5) fees for services;

(6) payment policies;

(7) patient's right to refuse to participate in experimental research; and

(8) methods for expressing complaints and suggestions to the ASC.

(g) Marketing or advertising regarding the competence and/or capabilities of the organization shall not be misleading to patients.

§135.6. Administration.

(a) Administrative policies, procedures, and controls shall be established and implemented to assure the orderly and efficient management of the ASC. Administrative responsibilities shall include, but are not limited to:

- (1) enforcing policies delegated by the governing body;
- (2) employing qualified management personnel;
- (3) long-range and short-range planning for the needs of the ASC, as determined by the governing body;
- (4) using methods of communicating and reporting, designed to assure the orderly flow of information within the ASC;
- (5) controlling the purchase, maintenance, and distribution of the equipment, materials, and facilities of the ASC;
- (6) establishing lines of authority, accountability, and supervision of personnel;
- (7) establishing controls relating to the custody of the official documents of the ASC; and
- (8) maintaining the confidentiality, security, and physical safety of data on patients and staff.

(b) Personnel policies shall be established and implemented to facilitate attainment of the mission, goals, and objectives of the ASC. Personnel policies shall:

- (1) define and delineate functional responsibilities and authority;
- (2) require the employment of personnel with qualifications commensurate with job responsibilities and authority, including appropriate licensure or certification;
- (3) require periodic appraisal of each person's job performance;
- (4) specify responsibilities and privileges of employment;
- (5) be made known to employees at the time of employment; and
- (6) provide adequate orientation and training to familiarize all personnel with the ASC's policies, procedures, and facilities.

(c) The ASC shall periodically assess patient satisfaction with services and facilities provided by the ASC. The findings shall be reviewed by the governing body.

(d) When students and postgraduate trainees are present, their status shall be defined in the ASC's personnel policies.

(e) All employee categories shall be included in personnel policies and appropriate job descriptions shall be developed.

§135.7. Quality of Care.

(a) All health care practitioners shall have the necessary and appropriate training and skills to deliver the services provided by the ASC.

(b) Health care practitioners shall practice in accordance with applicable state law and conform to the standards and ethics of their professions.

(c) Patient care responsibilities shall be delineated in accordance with recognized standards of practice.

(d) There shall be qualified medical personnel available for emergency treatment whenever there is a patient in the ASC who has received services.

(e) The provision of quality health care services shall be demonstrated by at least the following:

(1) accessible and available health services;

(2) appropriate and timely diagnostic procedures;

(3) treatment that is consistent with clinical impression or working diagnosis;

(4) appropriate and timely consultation;

(5) absence of clinically unnecessary diagnostic or therapeutic procedures;

(6) provision for services when the ASC is not open;

(7) appropriate, accurate, and complete medical record entries; and

(8) adequate transfer of information when patients are transferred to and from other health care providers.

(f) When clinically indicated, patients shall be contacted as quickly as possible for follow-up regarding significant problems and/or abnormal laboratory or radiologic findings that have been identified.

(g) When the need arises, patients shall be transferred from the care of one health care practitioner to another.

(1) Adequate specialty consultation services shall be made available by prior arrangement.

(2) Referral to another health care practitioner shall be clearly outlined to the patient and arranged with the accepting health care practitioner prior to transfer.

(h) Concern for the appropriateness of care shall be governed by the following:

(1) the relevance of health care services to the needs of the patients;

(2) the absence of duplicative diagnostic procedures;

(3) the appropriateness of treatment frequency; and

(4) the use of ancillary services that are consistent with patients' needs.

(i) Education activities shall relate, in part, to the findings as quality assurance activities and shall include cardiopulmonary resuscitation training.

§135.8. Quality Assurance.

(a) Quality assurance includes the selection of professional personnel prior to engagement for service, ongoing review of clinical responsibilities and authority, and peer review and supervision of all professional and technical activities of personnel.

(b) The professional and administrative staff shall understand, support, and participate in the quality assurance program.

(c) The quality assurance program shall address clinical, administrative, and cost effective issues. Exclusive concentration on administrative cost effective issues does not fulfill this requirement.

(d) Quality assurance activities shall be conducted by the Quality Assurance Committee, which is composed of specific clinical disciplines within the ASC (individual medical specialties, nursing, etc.) and shall be consistent with the characteristics of the overall quality assurance program and the services provided by the ASC.

(e) Problem identification and resolution activities shall be conducted as part of an ongoing, organized quality assurance program in which all practitioners in all clinical disciplines have an opportunity to participate. A variety of self-assessment methodologies may be used to implement the quality assurance program. Assessment techniques shall examine the structure, process, or outcome of care, and shall be assessed prospectively, concurrently, or retrospectively.

(f) Quality assurance activities shall address the following.

(1) Important problems or concerns in the care of patients shall be identified. Although the medical record is an important data source for identifying previously unrecognized problems, any sources may be used. Problems concerning accessibility, medical-legal issues, and wasteful practices shall be considered, as well as concerns previously recognized by patients and staff but inadequately addressed.

(2) The frequency, severity, and source of suspected problems or concerns shall be assessed.

(A) Health care practitioners shall participate in the development and application of the criteria used to evaluate the care they provide.

(B) Health care practitioners shall participate in the evaluation of the problems or concerns identified.

(C) A record shall be maintained of all fires, patient deaths, and all transfers from the ASC to the hospital.

(3) Measures shall be implemented to resolve important problems or concerns that have been identified. Health care practitioners as well as administrative staff shall participate in the resolution of the problems or concerns that are identified.

(4) The problems or concerns shall be reassessed to determine objectively whether or not the measures have achieved and sustained the desired result, and if not, why not.

(5) Through the ASC's designated mechanisms, quality assurance activities shall be reported, as appropriate, to the proper personnel, and the governing body.

(g) Quality assurance activities described in subsection (f) of this section shall encompass, but are not limited to:

(1) the clinical performance of health care practitioners;

(2) the standards for medical records;

(3) quality controls for and the use of radiology, pathology, and medical laboratory services;

(4) other professional and technical services provided; and

(5) studies of patient satisfaction.

(h) The quality assurance program shall be a well-defined organized program designed to enhance patient care through the ongoing objective assessment of important aspects of patient care and the associated or identified problems. The responsibilities for quality assurance activities shall be clearly delineated.

(1) Qualified medical staff shall participate in assessment of medical services by health care practitioners and shall be accomplished by a specified member(s) of the medical staff or by staff as a group.

(2) Nursing service shall be represented by one or more qualified registered nurses in quality assurance activities.

§135.9. Medical Records.

(a) The ASC shall develop and maintain a system for the collection, processing, maintenance, storage, retrieval, and distribution of patient medical records.

(b) An individual medical record shall be established for each person receiving care.

(c) All clinical information relevant to a patient shall be readily available to health care practitioners involved in the care of that patient.

(d) Except when otherwise required by law, any record that contains clinical, social, financial, or other data on a patient shall be strictly confidential and shall be protected from loss, tampering, alteration, destruction, and unauthorized or inadvertent disclosure.

(e) A person shall be designated to be in charge of medical records whose responsibilities include, but are not limited to:

(1) the confidentiality, security, and safe storage of medical records;

(2) the timely retrieval of individual medical records upon request;

(3) the specific identification of each patient's medical record;

(4) the supervision of the collection, processing, maintenance, storage, retrieval, and distribution of medical records; and

(5) the maintenance of a predetermined organized medical record format.

(f) Policies concerning medical records shall follow current statute in regard to retention of active records, retirement of inactive records and the release of information contained in the record.

(g) Except when otherwise required by law, the content and format of medical records, including the sequence of information, shall be uniform.

(h) Reports, histories and physicals, progress notes, and other patient information (such as laboratory reports, x-ray readings, and consultation) shall be incorporated into the medical record in a timely manner.

(i) Medical records shall be available to authorized health care practitioners any time the ASC is open to patients.

(j) The ASC record shall include the following:

(1) patient identification;

(2) allergies and untoward reactions to drugs recorded in a prominent and uniform location;

(3) all pre-operative, post-operative medications administered and drug/dose/route/frequency/quantity of all post-operative drugs dispensed to the patient by the ASC and entered on the patient's record;

(4) significant medical history and results of physical examination;

(5) preop diagnostic studies entered before surgery, if required by policy or ordered by a physician or advanced practice nurse;

(6) findings and techniques of the operation (operative report);

(7) pathology report on all tissues removed during surgery except those exempted by the governing body;

(8) anesthesia administration record that includes either general, local, or regional anesthetic;

(9) documentation of a properly executed informed consent;

(10) evidence of evaluation of the patient by a physician or advanced practice nurse prior to dismissal;

(11) evidence that the patient left the facility in the company of a responsible adult unless a physician or advanced practice nurse writes an order that the patient may leave the facility without the company of a responsible adult; and

(12) for patients with a length of stay greater than eight hours, an evaluation of nutritional needs and evidence of how identified needs were met.

(k) Appropriate medical advice given to a patient by telephone shall be entered in the patient's medical record and appropriately signed or initialed.

(l) Entries in patients' medical records shall be legible to clinical personnel and shall be accurate and completed promptly.

(m) Any notation in a patient's medical record indicating diagnostic or therapeutic intervention as part of clinical research shall be clearly contrasted with entries regarding the provision of nonresearch related care.

(n) When necessary for assuring continuity of care, summaries of records of a patient who was treated elsewhere (such as by another physician, hospital, ambulatory surgical center, nursing home, or consultant) shall be obtained.

(o) When necessary for assuring continuity of care, summaries or photocopies of the patient's record shall be transferred to the health care practitioner to whom the patient was referred and, if appropriate, to the facility where future care will be rendered.

(p) Certain repetitive procedures are suitable for pre-printed operative notes. These operative notes are suitable as long as they are approved by the governing body and signed by the surgeon and transmit to a knowledgeable reader the events of the surgical procedure.

(q) All final tissue and abnormal cytology reports from the Medicare approved reference laboratory shall be signed by a pathologist.

§135.10. Facilities and Environment.

(a) The ASC shall have the necessary personnel, equipment, and procedures to handle medical emergencies that may arise in connection with services sought or provided. At a minimum, the ASC shall provide:

(1) periodic instruction of all personnel in the proper use of safety, emergency, and fire extinguishing equipment;

(2) procedures, including adequate surveillance techniques, that minimize sources and transmission of infections;

(3) a comprehensive emergency plan to address internal and external emergencies, including:

(A) a provision for the safe evacuation of patients during an internal emergency, especially patients who have difficulty walking;

(B) a provision for the most efficient use of available facilities and services during an external emergency; and

(C) a requirement for at least four drills a year of the internal emergency plan.

(b) Hazards that might lead to slipping, falling, electrical shock, burns, poisoning, or other trauma shall be eliminated.

(c) Facilities shall be clean and properly maintained.

(d) An emergency call system shall be provided and readily accessible to staff and patients in all areas of the facility.

(e) All equipment, including emergency equipment, shall be properly maintained and periodically tested.

(f) There shall be a system for the proper identification, management, handling, transport, treatment, and disposition of hazardous materials and wastes whether solid, liquid, or gas.

(1) This system shall include, but is not limited to, infectious, radioactive, chemical, and physical hazards.

(2) The system shall provide for the protection of patients, staff, and the environment.

(g) An ambulatory surgical center shall meet the requirements set forth by the department in §§1.131 et seq., of this title (relating to Definition, Treatment, and Disposition of Special Waste from Health Care Related Facilities).

(h) Sufficient space, equipment, and supplies shall be provided to perform the volume of work with optimal accuracy, precision, efficiency, and safety in the laboratory and x-ray. The ASC shall furnish equipment for basic diagnostic purposes, depending on the extent of services provided. Dressing area(s) shall be required, depending on services provided, with convenient access to toilets and may be shared with patient changing/preop rooms.

§135.11. Anesthesia and Surgical Services.

(a) Anesthesia services.

(1) Anesthesia services provided in the ASC shall be limited to those that are approved by the governing body, which may include the following.

(A) Topical anesthesia--an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce transient and reversible loss of sensation to the circumscribed area.

(B) Local anesthesia--administration of an agent that produces a transient and reversible loss of sensation to a circumscribed portion of the body.

(C) Regional anesthesia--injection of an anesthetic agent to the nerves supplying a region of the body that results in a loss of sensation.

(D) Minimal sedation (anxiolysis)--a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

(E) Moderate sedation/analgesia ("conscious sedation")--a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained (reflex withdrawal from a painful stimulus is NOT considered a purposeful response).

(F) Deep sedation/analgesia--a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. (Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.)

(G) General anesthesia--a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

(2) The anesthesia department shall be under the medical direction of a physician approved by the governing body upon the recommendation of the ASC medical staff.

(3) The medical staff shall develop written policies and practice guidelines for the anesthesia service, which shall be approved, implemented and enforced by the governing body. The policies and guidelines must include consideration of the applicable practice standards and guidelines of the American Society of Anesthesiologists, the American Association of Nurse Anesthetists, and the licensing rules and standards applicable to those categories of licensed professionals qualified to administer anesthesia.

(4) Administration of anesthesia or sedation.

(A) The following practitioners may administer all categories of anesthesia and sedation, in accordance with their education and training:

(i) an anesthesiologist;

(ii) a physician, dentist, oral surgeon or podiatrist who is qualified under state law and has education, training and experience in the type of anesthesia being performed; and

(iii) a certified registered nurse anesthetist practicing in accordance with the Nursing Practice Act and the rules and regulations promulgated by the Board of Nurse Examiners.

(B) A qualified registered nurse (RN) who is not a certified registered nurse anesthetist (CRNA), in accordance with the orders of the operating surgeon or an anesthesiologist, may administer topical anesthesia, local anesthesia, minimal sedation and moderate sedation, in accordance with all applicable rules, polices, directives and guidelines issued by the Board of Nurse Examiners for the State of Texas. When an RN who is not a CRNA administers sedation, as permitted in this paragraph, the facility must:

(i) verify that the registered nurse has the requisite training, education and experience;

(ii) maintain documentation to support that the registered nurse has demonstrated competency in the administration of sedation;

(iii) with input from the facility's qualified anesthesia providers, develop, implement and enforce detailed, written policies and procedures to guide the registered nurse; and

(iv) ensure that, when administering sedation during a procedure, the registered nurse has no other duties except to monitor the patient.

(5) Anesthesia shall not be administered unless the operating surgeon or anesthesiologist has evaluated the patient immediately prior to surgery to assess the risk of the anesthesia relative to the surgical procedure to be performed.

(6) The anesthesiologist or the operating surgeon shall be available until all of his or her patients operated on that day have been discharged from the post-anesthesia care unit.

(7) Patients who have received anesthesia shall be evaluated for proper anesthesia recovery by the operating surgeon or the person administering the anesthesia prior to discharge from the post-anesthesia care unit using criteria approved by the medical staff.

(8) Patients who remain in the facility for extended observation following discharge from the post-anesthesia care unit shall be evaluated immediately prior to leaving the facility by a physician, the person administering the anesthesia or a registered nurse acting in accordance with physician's orders and written policies, procedures and criteria developed by the medical staff.

(9) A physician shall be on call and able to respond physically or by telephone within 30 minutes until all patients have been discharged from the ASC.

(10) Emergency equipment and supplies appropriate for the type of anesthesia services provided shall be maintained and accessible to staff at all times.

(A) Functioning equipment and supplies which are required for all facilities include:

(i) suctioning equipment, including a source of suction and suction catheters in appropriate sizes for the population being served;

(ii) source of compressed oxygen;

(iii) basic airway management equipment, including oral and nasal airways, face masks, and self-inflating breathing bag-valve set;

(iv) blood pressure monitoring equipment; and

(v) emergency medications specified by the medical staff and appropriate to the type of surgical procedures and anesthesia services provided by the facility.

(B) In addition to the equipment and supplies required under subparagraph (A) of this paragraph, facilities which provide moderate sedation/analgesia, deep sedation/analgesia, regional analgesia and/or general anesthesia must provide the following:

(i) intravenous equipment, including catheters, tubing, fluids, dressing supplies, and appropriately sized needles and syringes;

(ii) advanced airway management equipment, including laryngoscopes and an assortment of blades, endotracheal tubes and stylets in appropriate sizes for the population being served;

(iii) a mechanism for monitoring blood oxygenation, such as pulse oximetry;

(iv) electrocardiographic monitoring equipment;

(v) cardiovertor-defibrillator; and

(vi) pharmacologic antagonists as specified by the medical staff and appropriate to the type of anesthesia services provided.

(b) Surgical services.

(1) Surgical procedures performed in the ASC shall be limited to those procedures that are approved by the governing body upon the recommendation of qualified medical personnel.

(2) Adequate supervision of surgery conducted in the ASC shall be a responsibility of the governing body, shall be recommended by qualified medical personnel, and shall be provided by appropriate personnel.

(3) Surgical procedures shall be performed only by health care practitioners who are licensed to perform such procedures within Texas and who have been granted privileges to perform those procedures by the governing body of the ASC, upon the recommendation of qualified medical personnel and after medical review of the practitioner's documented education, training, experience, and current competence.

(4) Surgical procedures to be performed in the ASC shall be reviewed periodically as part of the peer review portion of the ASC's quality assurance program.

(5) An appropriate history, physical examination, and pertinent preoperative diagnostic studies shall be incorporated into the patient's medical record prior to surgery.

(6) The necessity or appropriateness of the proposed surgery, as well as any available alternative treatment techniques, shall be discussed with the patient prior to scheduling the patient for surgery.

(7) Licensed nurses and other personnel assisting in the provision of surgical services shall be appropriately trained and supervised and shall be available in sufficient numbers for the surgical care provided.

(8) Each operating room shall be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all persons in the area.

(A) If flammable agents are present in an operating room the room shall be constructed and equipped in compliance with standards established by the National Fire Protection Association (NFPA 99, Annex 2, Flammable Anesthetizing Locations, 1999) and with applicable state and local fire codes.

(B) If nonflammable agents are present in an operating room the room shall be constructed and equipped in compliance with standards established by the National Fire Protection Association (NFPA 99, Chapters 4 and 8, 1999) and with applicable state and local fire codes.

(9) With the exception of those tissues exempted by the governing body after medical review, tissues removed during surgery shall be examined by a pathologist, whose signed report of the examination shall be made a part of the patient's medical record.

(10) A description of the findings and techniques of an operation shall be accurately and completely written or dictated immediately after the procedure by the health care practitioner who performed the operation. If the description is dictated, an accurate written summary shall be immediately available to the health care practitioners providing patient care

and becomes a part of the patient's medical record. Refer to §135.9(p) of this title (relating to Medical Records).

(11) A safe environment for treating surgical patients, including adequate safeguards to protect the patient from cross-infection, shall be assured through the provision of adequate space, equipment, and personnel.

(A) Provisions shall be made for the isolation or immediate transfer of patients with communicable diseases.

(B) All persons entering operating rooms shall be properly attired.

(C) Acceptable aseptic techniques shall be used by all persons in the surgical area.

(D) Only authorized persons shall be allowed in the surgical area.

(E) Suitable equipment for rapid and routine sterilization shall be available to assure that operating room materials are sterile.

(F) Environmental controls shall be implemented to assure a safe and sanitary environment.

(G) Operating rooms shall be appropriately cleaned before each operation.

(12) Written policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies shall be developed, implemented and enforced. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

(A) Policies and procedures shall be developed following standards, guidelines and recommendations issued by the Association of Operating Room Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), the Centers for Disease Control and Prevention (CDC) and, if applicable, the Society of Gastroenterology Nurses and Associates (SGNA). Standards, guidelines, and recommendations of these organizations are available for review at the Department of State Health Services, Exchange Building, 8407 Wall Street, Austin, Texas. Copies may also be obtained directly from each organization, as follows: AORN, 2170 South Parker Road, Suite 300, Denver CO, 80231, (800) 755-2676; APIC, 1275 K Street, NW, Suite 1000, Washington, DC, 20005, (202) 789-1890; CDC, National Center for Infectious Disease, Mailstop C-14, 1600 Clifton Road, Atlanta, GA, 30333; SGNA, 401 North Michigan Avenue, Chicago, IL, 60611.

(B) Policies and procedures shall also address proper use of external chemical indicators and biological indicators.

(C) Performance records for all sterilizers shall be maintained for a period of 6 months.

(D) Preventive maintenance of all sterilizers shall be completed according to manufacturers recommendations on a scheduled basis. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least one year and shall be available for review to the facility within two hours of request by the department.

(13) Emergency power adequate for the type of surgery performed shall be available in the operative and post operative recovery areas.

(14) Periodic calibration and/or preventive maintenance of all equipment shall be provided in accordance with manufacturer's guidelines.

(15) The informed consent of the patient or, if applicable, of the patient's legal representative, shall be obtained before an operation is performed.

(16) A written procedure shall be established for observation and care of the patient during the preoperative preparation and postoperative recovery period.

(17) Written protocols shall be established for instructing patients in self-care after surgery, including written instructions to be given to patients who receive conscious sedation, regional and general anesthesia.

(18) Patients who have received anesthesia shall only be allowed to leave the facility in the company of a responsible adult unless the operating surgeon, a physician or an advanced practice nurse writes an order that the patient may leave without the company of a responsible adult.

(19) An effective written procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the ASC shall be developed. The ASC must have a written transfer agreement with a hospital or all physicians on staff at the ASC must have admitting privileges at a local hospital.

§135.12. Pharmaceutical Services.

(a) The ASC shall provide drugs and biologicals in a safe and effective manner in accordance with professional practices and shall be in compliance with all state and federal laws and regulations. The ASC shall be licensed as required by the Texas State Board of Pharmacy and comply with 25 Texas Administrative Code §291.76 (relating to Class C Pharmacies Located in a Freestanding Ambulatory Surgical Center).

(b) Pharmaceutical services may be made available by the ASC through a contractual agreement and must be provided in accordance with the same ethical and professional practices

and legal requirements that would be required if such services were provided directly by the ASC.

§135.13. Pathology and Medical Laboratory Services.

Pathological and clinical services shall be provided or made available when appropriate to meet the needs of the patients and adequately support the ASC's clinical capabilities.

(1) Pathology and clinical laboratory services shall include, but are not limited to:

(A) conducting laboratory procedures that are appropriate to the needs of the patients;

(B) performing tests in a timely manner;

(C) distributing test results within 24 hours after completion of a test and maintaining a copy of the results in the laboratory; and

(D) performing and documenting appropriate quality assurance procedures, including, but not limited to, calibrating equipment periodically and validating test results through use of standardized control specimens or laboratories.

(2) Preoperative laboratory procedures may be required as follows.

(A) It shall be at the discretion of the governing body to require pre-operative laboratory orders.

(B) If specific pre-operative laboratory work is required, the medical staff shall approve them in accordance with the medical staff by-laws. Other lab work shall be performed only on the order of a physician, podiatrist, dentist or advanced practice nurse and written on the patient's chart.

(C) These services shall be provided either directly within or through an effective contract arrangement with a Medicare-approved reference laboratory.

(D) The contractual agreement with the Medicare-approved reference laboratory shall provide for routine and stat work to include pathology, clinical, and blood bank services, if blood is authorized by the ASC, and shall be available for review.

(3) The patient may be instructed to go directly to the Medicare-approved reference laboratory or the specimen may be collected on the ambulatory surgical center's premises and then referred to the Medicare-approved reference laboratory.

(4) If the specimens are collected on the premises only, the following shall be maintained:

(A) procedures and policies governing the Medicare reference laboratory specimen requirements; identifying, collection, labeling, storage, and transportation of the specimen, and preventive maintenance of equipment used in processing and storage of specimen;

(B) a log book which shall include patient name and identification number, doctor's name, date the specimen was drawn and sent to the Medicare-approved reference laboratory, laboratory tests ordered, date the final report came back from the reference laboratory, and condition of the specimen. The final report shall be on the patient chart, with copies kept in the ASC's laboratory.

(5) If laboratory tests are performed on the premises, the following shall be maintained:

(A) procedures governing identification, collection, labeling, and storage of specimens;

(B) a log book, which shall include patient name and identification number, practitioner's name, date the specimen was drawn, test ordered, and results;

(C) procedures for each test procedure performed by the laboratory, including source of reagents, standards, and calibration procedures, and information concerning the basis for the tested normal ranges;

(D) procedures and documentation of performed maintenance on equipment used to process laboratory work;

(E) dated reports of all examinations performed and made a part of the patient's medical record; and

(F) proficiency testing.

(6) Quality control of the laboratory shall be monitored through the Quality Assurance Committee.

(7) If the ASC designates its laboratory to perform as an independent laboratory, it shall be surveyed according to 42 Code of Federal Regulations, Part 405, Subpart M, §§405.1310-405.1317.

(8) The ASC can allow laboratory work to be performed and brought in from other Medicare-approved reference laboratories or practitioners' offices and the reports shall be on the patient's charts before surgery.

(A) Written criteria describing the length of time tests can be done prior to surgery shall be developed by the medical staff and approved by the governing body.

(B) Laboratory work shall be performed in a Medicare-approved reference laboratory or in the patient's healthcare practitioner's office. This shall be written in a policy accepted by the medical staff and governing body.

(9) If it is the ASC's policy to administer blood, policies shall be developed on administration of blood transfusions to include autologous blood units in accordance with the ASC's operative procedures. If the operative procedure(s) performed in the ASC requires or may require the necessity for transfusions, policies and procedures shall include provisions for stat and routine transfusions. These policies and procedures shall include, but are not limited to, collection, labeling, and transportation of specimen in accordance with the ASC or contract service policies. All patient results shall appear in the patient's chart.

(10) If the ASC performs surgery which incorporates the removal of a tissue specimen or the freezing of a tissue specimen, the specimen shall be submitted to a Medicare-approved reference laboratory. The following shall be maintained:

(A) procedures governing the Medicare-approved reference laboratory specimen requirements, identification, collection, labeling, storage, and transportation of the specimen;

(B) documentation to include patient name and identification number, practitioner's name, date the tissue specimen was collected and referred to the Medicare-approved reference laboratory, and date the final report came back from the Medicare-approved reference laboratory. Final copies shall be placed in the patient's chart, with copies kept in the ASC; and

(C) the medical staff bylaws may exempt tissue specimens from pathology exam and the list of exemptions shall be available for review. The exemptions shall be based on the following criteria.

(11) The medical staff bylaws shall define those specimens for macroscopic pathology examination only and both macroscopic and microscopic pathology examinations.

(12) The original pathology report shall be included in the patient's chart.

(13) Pathology tissue reports and positive cytology reports shall have the authorized signature of the pathologist interpreting the report.

§135.14. Radiology Services.

(a) Radiology services shall be provided or made available when appropriate to meet the needs of the patients and adequately support the ASC's clinical capabilities. Policy and procedures shall be available for emergency and/or routine radiological procedures.

(b) A radiologist shall authenticate all examination reports, except reports of specific procedures that may be authenticated by physicians who are not radiologists, but who have been granted privileges by the governing body or its designee to authenticate such reports.

(c) Services shall be provided either directly within or through a Medicare-approved facility and the contracts shall be available for review. If services are provided by an outside x-ray firm coming into the ASC, this portable x-ray firm must be Medicare certified according to 42 Code of Federal Regulations Part 405, Subpart N, §§405.1411 - 405.1416.

(d) If x-ray services are performed within the ASC, the x-ray department will be surveyed according to 42 Code of Federal Regulations Part 405, Subpart J, §405.1029.

(e) Procedure manuals shall include procedures for all examinations performed, infection control in the ASC and operating rooms to include dress code of personnel and cleaning of equipment.

(f) Policies shall address the quality aspects of radiology services, including, but not limited to:

(1) performing radiology services only upon the written order of a physician, dentist, advanced practice nurse or other authorized healthcare practitioner (such orders must be accompanied by a concise statement of the reason for the examination); and

(2) limiting the use of any radioactive sources in the ASC to physicians who have been granted privileges for such use on the basis of their training, experience, and current competence.

(g) Policies shall address the safety aspects of radiology services, including, but not limited to:

(1) regulation of the use, removal, handling, and storage of any radioactive material which is required to be licensed by the Department of State Health Services, Radiation Control;

(2) precautions against electrical, mechanical, and radiation hazards;

(3) proper shielding where radiation sources are used;

(4) acceptable monitoring devices for all personnel who might be exposed to radiation (monitoring devices shall be worn by such personnel in any area with a radiation hazard);

(5) maintenance of radiation exposure records on personnel; and

(6) authenticated, dated reports of all examinations performed shall be made a part of the patient's medical record.

(h) Laser equipment shall be licensed as required by the Department of State Health Services, Radiation Control. Policies and procedures shall be established and implemented for laser technology which include laser safety programs, education and training of laser personnel, credentialing for each specific laser and a requirement for all personnel working with lasers to be adequately trained in the safety and use of each type of laser utilized.

§135.15. Nursing Services.

(a) Nursing services.

(1) There shall be an organized nursing service under the direction of a qualified registered nurse (RN). The ASC shall be staffed to assure that the nursing needs of all patients are met.

(2) There shall be a written plan of administrative authority for all nursing services with responsibilities and duties of each category of nursing personnel delineated and a written job description for each category. The scope of nursing service shall include, but is not limited to, nursing care rendered to patients preoperatively, intraoperatively, and postoperatively.

(A) The responsible individual for nursing services shall be a qualified RN whose responsibility and authority for nursing service shall be clearly defined and includes supervision of both personnel performance and patient care.

(B) There shall be a written delineation of functions, qualifications, and patient care responsibilities for all categories of nursing personnel.

(C) Surgical technicians and licensed vocational nurses may be permitted to serve as the scrub nurse under the direct supervision of an RN; they shall not be permitted to function as circulating nurses in the operating rooms, except in ASCs where no general anesthesia is administered and when there is an adequate number of RNs immediately available for an emergency situation. Licensed vocational nurses and surgical technicians may assist in circulatory duties under the direct supervision of a qualified RN during general anesthesia cases.

(D) Nursing services shall be provided in accordance with current recognized standards or recommended practices.

(3) There shall be an adequate number of RNs on duty to meet the following minimum staff requirements: director of the department (or designee), and supervisory and staff personnel for each service area to assure the immediate availability of an RN for emergency care or for any patient when needed.

(A) An RN shall assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the preparation and qualifications of the nursing staff available.

(B) There shall be other nursing personnel in sufficient numbers to provide nursing care not requiring the service of an RN.

(4) An RN qualified, at a minimum, with current certification in basic cardiac life support, shall be on duty and on the premises at all times whenever patients are present in the facility.

(b) Additional staffing requirements. In addition to meeting the requirements for nursing staff under subsection (a) of this section, facilities must comply with the following minimum staffing requirements.

(1) Facilities that provide only topical anesthesia, local anesthesia and/or minimal sedation are required to have a second individual on duty on the premises who is trained and currently certified in basic cardiac life support until all patients have been discharged from the facility.

(2) Facilities that provide moderate sedation/analgesia are required to have the following additional staff:

(A) a second individual on duty on the premises who is trained and currently certified in basic cardiac life support until all patients have been discharged from the facility; and

(B) an individual trained and currently certified in advanced cardiac life support and, if surgery is performed on pediatric patients, pediatric advanced life support, must be available until all patients have been discharged from the post anesthesia care unit.

(3) Facilities that provide deep sedation/analgesia, general anesthesia, and/or regional anesthesia must have the following additional staff:

(A) a second individual on duty on the premises who is trained and currently certified in basic cardiac life support until all patients have been discharged from the facility; and

(B) an individual who is trained and currently certified in advanced cardiac life support and, if surgery is performed on pediatric patients, pediatric advanced life support, must be on duty on the premises and sufficiently free of other duties to enable the individual to respond rapidly to emergency situations until all patients have been discharged from the post anesthesia care unit.

§135.16. Teaching and Publication.

(a) Policies concerning teaching activities shall be developed, implemented, and enforced which address:

(1) the terms and conditions of reimbursement or other compensation;

(2) the reasonableness of the time spent away from direct patient care and administrative activities; and

(3) the training of all students and postgraduate trainees, including the extent of their involvement in patient care activities.

(b) A policy concerning the provision of health care by personnel in any student or postgraduate trainee status shall be developed, implemented, and enforced and provide for close and adequate supervision and for informing the patient of the status of the provider.

(c) A policy shall be developed, implemented, and enforced concerning publishing activities. The policy shall address:

(1) the need for governing body approval when the views, policies, and procedures expressed in the publication are attributed to the ASC; and

(2) the terms and conditions of compensation from publication and the cost of publication.

§135.17. Research Activities.

(a) Research activities shall be performed in accordance with ethical and professional practices and legal requirements, and these activities shall be periodically monitored by the governing body.

(b) The protocols for conducting research shall be approved by the governing body or its designee after medical and legal review.

(c) Any research activities carried out within the ASC shall be appropriate to the expertise of staff and the resources in the ASC.

(d) Individuals engaged in research shall be provided with adequate facilities.

(e) Provisions shall be made to assure that the rights and welfare of all research subjects are adequately protected and that the informed consent of the subject, in the language spoken by him or her, is obtained by adequate and appropriate methods.

(f) All professional staff shall be informed of the ASC's research policies.

§135.18. Unlicensed Ambulatory Surgical Center.

(a) If the department has reason to believe that a person or facility may be providing ambulatory surgical services without a license as required by the Act, the person or facility shall be so notified in writing by certified mail, return receipt requested, and shall submit to the department the following information within 20 days of receipt of the notice:

(1) an application for a license and the license fee, which is nonrefundable;

(2) a claim for exemption under §135.19 of this title (relating to Exemptions); or

(3) any and all documentation necessary to establish that ambulatory surgical services are not being provided. Documentation shall include a notarized statement attesting to the fact that ambulatory surgical services are not provided and a statement of the type(s) of service(s) that are provided.

(b) If the person or facility has submitted an application for a license, the application will be processed in accordance with §135.20 of this title (relating to Initial Application and Issuance of License).

(c) If the person or facility submits a claim for exemption, the exemption claim will be processed in accordance with §135.19 of this title (relating to Exemptions).

(d) If the person or facility submits sufficient documentation to establish that ambulatory surgical services are not provided, the department shall so notify the person or facility in writing within 30 days that no license is required. If the documentation submitted is determined to be insufficient by the department, the person or facility shall be so notified in writing and shall have 10 days to respond. Following receipt of the response, if any, the department shall then notify the person or facility in writing within 10 days of the determination.

§135.19. Exemptions.

(a) The following facilities are not required to be licensed under the Act:

(1) an office or clinic of a licensed physician, dentist, or podiatrist;

(2) a licensed nursing home; or

(3) a licensed hospital.

(b) If a person or facility is uncertain about whether or not licensing under the Act is required, a written claim for exemption, including all documentation supporting the exemption claim, may be submitted to the department.

(c) The department shall evaluate the claim for exemption and notify the person or facility in writing of the proposed decision within 30 days following receipt of the claim for exemption.

(d) If the proposed decision is to grant the claim for exemption, the department will provide written notice according to subsection (c) of this section.

(e) If the claim for exemption is proposed to be denied, the person or facility so affected shall have the right to appeal the determination to the department by written letter with the reasons supporting exemption within 10 days following receipt of the proposed denial.

(f) If the person or facility does not request an appeal as provided in subsection (e) of this section, the right to appeal is deemed to be waived and the denial of the exemption becomes final 30 days following the person or facility's receipt of the proposed denial.

(g) The person or facility must submit a completed application and nonrefundable licensing fee to the department within 20 days following the final denial of exemption.

§135.20. Initial Application and Issuance of License.

(a) All first-time applications for licensing, including those from unlicensed operating ASCs and licensed ASCs for which a change of ownership or relocation is anticipated, are applications for an initial license.

(b) Upon written or verbal request, the department shall furnish a person with an application form for an ASC license. The applicant shall submit to the department a completed original application and the nonrefundable license fee.

(1) The applicant shall provide:

(A) the name and address of the owner of the ASC or a list of names and addresses of persons who own an interest in the ASC;

(B) the name, Texas license number, and license expiration date of the medical chief of staff;

(C) the number of physicians, dentists, podiatrists and advanced practice nurses on staff at the ASC;

(D) the name, Texas license number, and license expiration date of the director of nursing of the ASC;

(E) whether the ASC has applied for certification under Title XVIII of the Social Security Act; and

(F) number of surgery suites.

(2) Upon receipt of the application, the department shall review the application to determine whether it is complete. All documents submitted to the department must be originals. The address provided on the application must be the address at which the ASC is operating.

(3) If the department determines that the application for an unlicensed ASC is complete and correct, a representative of the department shall schedule a presurvey conference

with the applicant in order to inform the applicant of the standards for the operation of the ASC. A presurvey conference, may at the department's discretion, be waived for an applicant of a licensed ASC for which a change of ownership is anticipated.

(4) After a presurvey conference has been held or waived at the department's discretion and the facility has received an approved Life Safety Code inspection conducted by the department, the department may issue a license to an ASC to provide ambulatory surgical services in accordance with these sections.

(c) Issuance of license. When it is determined that the facility is in compliance with subsection (b) of this section, the department shall issue the license to the applicant.

(1) Effective date. The license shall be effective on the date the facility is determined to be in compliance with subsection (b) this section.

(2) Expiration date.

(A) For initial licenses issued prior to January 1, 2005.

(i) If the effective date of the license is the first day of a month, the license expires on the last day of the 11th month after issuance.

(ii) 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 12th month after issuance.

(B) For initial licenses issued January 1, 2005, or after.

(i) 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.

(ii) 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.

(d) Withdrawal of application. If an applicant decides not to continue the application process for a license the application may be withdrawn. The applicant shall submit a written request to withdraw to the department. The department shall acknowledge receipt of the request to withdraw.

(e) During the initial licensing period, the department shall conduct a survey of the ASC to ascertain compliance with the provisions on the Health and Safety Code, Chapter 243, and this chapter.

(1) The ASC shall request that an on-site survey be conducted after the ASC has provided services to a minimum of one patient.

(2) The ASC shall be providing services at the time of the survey.

(3) If the ASC has applied to participate in the federal Medicare program, the Medicare survey may be conducted in conjunction with the licensing survey.

(4) The initial licensing survey may be waived if the ASC provides documented evidence of accreditation by the Joint Commission of Accreditation of Health Care Organization, the Accreditation Association for Ambulatory Health Care or the American Association for Accreditation of Ambulatory Surgery Facilities and Medicare deemed status.

§135.21. Inspections.

(a) The department shall conduct an on-site inspection to evaluate the ASC's compliance with the standards for licensing set forth in these sections.

(1) The department will evaluate the ASC on a standard-by-standard basis before the first renewal license is issued, unless waived in accordance with §135.20(e)(4) of this title (relating to Initial Application and Issuance of License).

(2) An on-site licensing inspection may be conducted once every three years.

(3) The department may make any survey or investigation that it considers necessary. A department representative(s) may enter the premises of a facility at any reasonable time to make a survey or an investigation to ensure compliance with or prevent a violation of HSC, Chapter 243 of this chapter, 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 in §135.27 of this title (relating to Patient Safety Program).

(b) If an on-site inspection is conducted at an ASC and deficiencies are cited, the surveyor shall request the applicant or person in charge to sign the statement of deficiencies as an acknowledgment of receipt of a copy of the statement of deficiencies. Signing the statement of deficiencies does not indicate agreement with any deficiencies. If the applicant or person in charge declines to sign the form, the surveyor shall note the declination on the statement of deficiencies and the name of the person so declining. The surveyor shall leave a copy of the statement of deficiencies at the ASC and, if the person in charge is not the applicant, mail a copy of the statement of deficiencies to the applicant.

(c) After an inspection is completed, the surveyor shall prepare a survey report which contains the following:

(1) a completed survey report form;

(2) a statement of which standards were evaluated;

(3) a statement of deficiencies, if any, and the signature of the applicant or person in charge;

(4) a plan of correction which has been provided by the ASC and the date(s) by which correction(s) will be made; and

(5) any comments by the applicant or person in charge concerning the survey.

(d) The survey report form shall be submitted as follows.

(1) The surveyor shall submit the survey report to their supervisor for evaluation and decision.

(2) A license shall be issued to an ASC that is in compliance with minimum standards in accordance with these sections at the time of the on-site inspection.

(3) If deficiencies are cited and the plan of correction is acceptable, written notice will be sent to the applicant acknowledging same.

(4) If deficiencies are cited and the plan of correction is not acceptable, the department will notify the applicant in writing and request that the plan of correction be resubmitted. Upon resubmission of the acceptable plan of correction, written notice will be sent to the applicant acknowledging same.

(5) The ASC shall come into compliance at least 30 days prior to the expiration date of the temporary or annual license.

(6) The department shall verify the correction of deficiencies by mail or by an on-site inspection.

(7) If the ASC does not timely come into compliance, the department may take action in accordance with §135.24 of this title (relating to Enforcement).

§135.22. Renewal of Annual License.

(a) The department will send written notice of expiration of an annual license to an applicant at least 60 days before the expiration date. If the applicant has not received notice, it is the duty of the applicant to notify the department and request a renewal application.

(b) Renewal license. The department shall issue a renewal license to an ASC that meets the minimum standards for a license set forth in these sections.

(1) The ASC shall submit the following to the department no later than 30 days prior to the expiration date of the license:

(A) a completed renewal application form;

(B) a nonrefundable license fee; and

(C) if the ASC is accredited by JCAHO, AAAHC or AAAASF, documented evidence of current accreditation status.

(2) Renewal licenses issued prior to January 1, 2005, will be valid for 12 months.

(3) Renewal licenses issued January 1, 2005, through December 31, 2005, will be valid for either 12 months or 24 months, to be determined by the department prior to the time of license renewal.

(4) Renewal licenses issued January 1, 2006, or after will be valid for 24 months.

(c) If the applicant fails to timely submit an application and fee in accordance with subsection (b) of this section, the department shall notify the applicant that the ASC must cease providing ambulatory surgical services. If the ASC can provide the department with sufficient evidence that the submission was completed in a timely manner and all dates were adhered to, the cease to perform will be dismissed. If the ASC cannot provide sufficient evidence, the ASC shall immediately thereafter return the license by certified mail. If the applicant wishes to provide ambulatory surgical services after the expiration date of the license, the applicant must reapply for an annual license under §135.20 of this title (relating to Initial Application and Issuance of License).

§135.23. Conditions of Licensure.

(a) An ASC license is issued only for the premises and person or governmental unit named on the application.

(b) An ASC license is issued for a single physical location, and shall not include multiple buildings or offsite locations.

(c) Multiple ASCs may share a single building, provided that:

(1) each ASC is separately licensed; and

(2) no part of the building may be dually licensed by more than one ASC.

(d) No license may be transferred or assigned from one person to another person. If a change of ownership of a licensed ASC is anticipated, in order to ensure continuity of patient services, the department shall be informed in writing and the applicant shall submit a license application and nonrefundable fee at least 30 days prior to the change of ownership of each ASC. The procedure shall be handled in accordance with §135.20 of this title (relating to Initial Application and Issuance of License), with the exception of the presurvey conference and the on-site inspection, unless deemed necessary by the department. A license will be issued for the

newly acquired ASC effective on the date the ownership changed. The previous license will be void on the date of acquisition.

(e) No license may be transferred from one ASC location to another. If an ASC is relocating, the ASC shall complete and submit a license application and non-refundable fee at least 30 days prior to the relocation of the ASC. The procedure shall be handled in accordance with §135.20 of this title, with the exception of the presurvey conference, unless deemed necessary by the department. An initial license will be issued for the relocated ASC effective on the date the relocation occurred. The previous license will be void on the date of relocation.

(f) Written notice to the department of any change in telephone number must be received within 30 days after the number has changed.

(g) If the name of an ASC is changed, the department must be notified in writing within 30 days after the effective date of the name change.

§135.24. Enforcement.

(a) Reasons for enforcement action.

(1) The Department of State Health Services (department) may deny, suspend, or revoke an ASC's license in accordance with Health and Safety Code (HSC), §243.011 if the applicant or licensee:

(A) fails to comply with any provision of the Act;

(B) fails to comply with any provision of this chapter or any other applicable laws;

(C) fails to comply with a special license condition;

(D) fails to comply with an order of the commissioner or another enforcement procedure under the statute;

(E) has a history of noncompliance with the rules adopted under this chapter relating to patient health, safety, and rights which reflects more than nominal noncompliance;

(F) has aided, committed, abetted or permitted the commission of an illegal act;

(G) fails to provide an adequate application or renewal information;

(H) fails to timely pay assessed administrative penalties in accordance with the Act;

(I) fails to comply with applicable requirements within a designated probation period;

(J) fails to submit an acceptable plan of correction for cited deficiencies;
or

(K) if the facility is participating under Title XVIII, and the Centers for Medicare and Medicare Services terminates the ASC's Medicare provider agreement.

(2) The department may suspend or revoke an existing valid license or disqualify a person from receiving a license because of a person's conviction of a felony or misdemeanor if the crime directly relates to the duties and responsibilities of the ownership or operation of an ambulatory surgical center.

(A) In determining whether a criminal conviction directly relates, the department shall consider the provisions of Texas Occupations Code, Chapter 53.

(B) The following felonies and misdemeanors directly relate because these criminal offenses indicate an ability or a tendency for the person to be unable to own or operate an ambulatory surgical center:

- (i) a misdemeanor violation of the statute;
- (ii) a misdemeanor or felony involving moral turpitude;
- (iii) a conviction relating to deceptive business practices;
- (iv) a misdemeanor of practicing any health-related profession without a required license;
- (v) a conviction under any federal or state law relating to drugs, dangerous drugs, or controlled substances;
- (vi) an offense 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 offense under various titles of the TPC, as follows:

- (I) Title 5 concerning offenses against the person;
- (II) Title 7 concerning offenses against property;
- (III) Title 9 concerning offenses against public order and decency;

(IV) Title 10 concerning offenses against public health, safety, and morals; or

(V) Title 4 concerning offenses of attempting or conspiring to commit any of the offenses in this subsection; and

(viii) other misdemeanors and felonies which indicate an inability or tendency for the person to be unable to own or operate an ambulatory surgical center.

(C) Upon a licensee's felony conviction, felony probation revocation, revocation of parole, or revocation of mandatory supervision, the license shall be revoked.

(3) If the department proposes to deny, suspend, or revoke a license, the department shall give the applicant written notification of the reasons for the proposed action and offer the applicant an opportunity for a hearing. The applicant may request a hearing within 30 days after the date the applicant receives notice. The request must be in writing and submitted to the department as instructed in the notice of violation letter. A hearing shall be conducted pursuant to the Government Code, Chapter 2001, Administrative Procedure Act, and §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures). If a hearing is not requested in writing within 30 days after receiving notice of the proposed action, the applicant is deemed to have waived the opportunity for a hearing and the proposed action shall be taken.

(4) If the department finds that a violation of the standards or licensing requirements prescribed by the Act creates an immediate threat to the health and safety of patients of an ASC, the department may petition the district court for a temporary restraining order to restrain continuing violations.

(5) The provisions of Texas Occupations Code, Chapter 53, Consequences of Criminal Conviction, apply to an ASC.

(6) If a person violates the licensing requirements or the standards prescribed by the Act, the department may petition the district court for an injunction to prohibit the person from continuing the violation or to restrain or prevent the establishment or operation of an ASC without a license issued under the Act.

(b) Emergency Suspension of a License. The department may issue an emergency order to suspend a license issued under this chapter if the department has reasonable cause to believe that the conduct of a license holder creates an immediate danger to the public health and safety.

(1) An emergency suspension is effective immediately without a hearing on notice to the license holder.

(2) On written request of the license holder, the department shall conduct a hearing not earlier than the 10th day or later than the 30th day after the date the hearing request is received to determine if the emergency suspension is to be continued, modified, or rescinded.

The hearing and any appeal are governed by the department's rules for a contested case hearing and Government Code, Chapter 2001.

(c) Probation. In lieu of denying, suspending or revoking the license under subsection (a) of this section, the department may schedule the ASC for a probation period of not less than thirty days if the ASC's noncompliance does not endanger the health and safety of the public.

(1) The department shall provide notice of the probation to the ASC not later than the 10th day before the date the probation begins. The notice will include the items of noncompliance that resulted in placing the ASC on probation, and will designate the period of the probation.

(2) During the probationary period, the ASC must correct the items of noncompliance and provide a written report to the department that describes the corrective actions taken.

(3) The department may verify the corrective actions through an onsite inspection.

(d) Administrative penalty. The department may impose an administrative penalty on a person licensed under this chapter who violates the Act, this chapter, or order adopted under this chapter.

(1) A penalty collected under this section shall be deposited in the state treasury in the general revenue fund.

(2) A proceeding to impose the penalty is considered to be a contested case under Government Code, Chapter 2001.

(3) The amount of the penalty may not exceed \$1,000 for each violation, and each day a violation continues or occurs is a separate violation for purposes of imposing a penalty. The total amount of the penalty assessed for a violation continuing or occurring on separate days under this paragraph may not exceed \$5,000.

(4) In determining the amount of an administrative penalty assessed under this section, the department shall consider:

(A) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation;

(B) the threat to health or safety caused by the violation;

(C) the history of previous violations;

(D) the amount necessary to deter a future violation;

(E) whether the violator demonstrated good faith, including when applicable whether the violator made good faith efforts to correct the violation; and

(F) any other matter that justice may require.

(5) Report and notice of violation and penalty. If the department initially determines that a violation occurred, the department shall give written notice of the report by certified mail to the person alleged to have committed the violation following the survey exit date. The notice must include:

(A) a brief summary of the alleged violation;

(B) a statement of the amount of the recommended penalty; and

(C) a statement of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both.

(6) Penalty to be paid or hearing requested. Within 20 days after the date the person receives the notice under subsection (c) of this section, the person in writing may:

(A) accept the determination and recommended penalty of the department;

or

(B) make a request for a hearing on the occurrence of the violation, the amount of the penalty, or both.

(7) If the person accepts the determination and recommended penalty or if the person fails to respond to the notice, the commissioner of public health (commissioner) or the commissioner's designee by order shall approve the determination and impose the recommended penalty.

(8) Hearing. If the person requests a hearing, the commissioner shall refer the matter to the State Office of Administrative Hearings (SOAH). The hearing shall be conducted in accordance with the Government Code, Chapter 2001, and all applicable SOAH and department rules.

(9) Decision by commissioner. Based on the proposal for decision made by the administrative law judge under paragraph (8) of this subsection, the commissioner by order may find that a violation occurred and impose a penalty, or may find that a violation did not occur. The commissioner or the commissioner's designee shall give notice of the commissioner's order under paragraph (1) of this subsection to the person alleged to have committed the violation in accordance with Government Code, Chapter 2001. The notice must include:

(A) a statement of the right of the person to judicial review of the order;

(B) separate statements of the findings of fact and conclusions of law; and

(C) the amount of any penalty assessed.

(10) Within 30 days after the date an order of the commissioner under subsection (f)(1) of this section that imposes an administrative penalty becomes final, the person shall:

(A) pay the penalty; or

(B) appeal the penalty by filing a petition for judicial review of the commissioner's order contesting the occurrence of the violation, the amount of the penalty, or both.

(11) Stay of enforcement of penalty. Within the 30-day period prescribed by paragraph (10) of this subsection, a person who files a petition for judicial review may:

(A) stay enforcement of the penalty by:

(i) paying the penalty to the court for placement in an escrow account; or

(ii) giving the court a supersedeas bond that is approved by the court for the amount of the penalty and that is effective until all judicial review of the commissioner's order is final; or

(B) request the court to stay enforcement of the penalty by:

(i) filing with the court a sworn affidavit of the person stating that the person is financially unable to pay the penalty and is financially unable to give the supersedeas bond; and

(ii) sending a copy of the affidavit to the commissioner by certified mail.

(C) If the commissioner receives a copy of an affidavit under paragraph (11)(B) of this subsection, the commissioner may file with the court, within five days after the date the copy is received, a contest to the affidavit. In accordance with Health and Safety Code, §243.016(c), the court shall hold a hearing on the facts alleged in the affidavit as soon as practicable and shall stay the enforcement of the penalty on finding that the alleged facts are true. The person who files an affidavit has the burden of proving that the person is financially unable to pay the penalty or to give a supersedeas bond.

(12) Collection of penalty. If the person does not pay the penalty and the enforcement of the penalty is not stayed, the department may refer the matter to the attorney general for collection of the penalty. As provided by the Health and Safety Code, §243.016(d), the attorney general may sue to collect the penalty.

(13) Decision by court. A decision by the court is governed by Health and Safety Code, §243.016(e) and (f), and provides the following.

(A) If the court sustains the finding that a violation occurred, the court may uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty.

(B) If the court does not sustain the finding that a violation occurred, the court shall order that a penalty is not owed.

(14) Remittance of penalty and interest and release of supersedeas bond. The remittance of penalty and interest is governed by Health and Safety Code, §243.016(g) and provides the following.

(A) If the person paid the penalty and if the amount of the penalty is reduced or the penalty is not upheld by the court, the court shall order, when the court's judgement becomes final, that the appropriate amount plus accrued interest be remitted to the person within 30 days after the date that the judgment of the court becomes final.

(B) The interest accrues at the rate charged on loans to depository institutions by the New York Federal Reserve Bank.

(C) The interest shall be paid for the period beginning on the date the penalty is paid and ending on the date the penalty is remitted.

(15) Release of bond. The release of supersedeas bond is governed by Health and Safety Code, §243.016(h), and provides the following.

(A) If the person gave a supersedeas bond and the court does not uphold the penalty, the court shall order, when the court's judgment becomes final, the release of the bond.

(B) If the person gave a supersedeas bond and the amount of the penalty is reduced, the court shall order the release of the bond after the person pays the reduced amount.

§135.25. Complaints.

(a) In response to a complaint, the department or its authorized representative may enter the premises of an ASC during normal business hours as necessary to assure compliance with the Act and these sections. The investigation may be conducted on-site, unannounced or announced, or may be investigated by phone or mail.

(b) All licensed ambulatory surgical centers are required to provide the patient and his/her guardian at time of admission a written statement identifying the department as the responsible agency for ambulatory surgical centers complaint investigations. The statement shall inform persons to direct complaint to the Department of State Health Services, Facility Licensing

Group, 1100 West 49th Street, Austin, Texas 78756, telephone (888) 973-0022. This information must also be prominently and conspicuously posted for display in an area of the facility that is readily available to patients, families and visitors. Complaints may be registered with the department by phone or in writing. A complainant may provide his/her name, address, and phone number to the department. Anonymous complaints may be registered. All complaints are confidential.

(c) The department will evaluate all complaints against all ambulatory surgical centers. Only those allegations determined to be relevant to the Act will be authorized for investigation.

(d) Conduct of the investigation will include, but is not limited to:

(1) a conference prior to commencing the on-site inspection for the purpose of explaining the nature and scope of the inspection between the department's authorized representative and the person who is in charge of the ASC;

(2) inspection of the ASC;

(3) inspection of medical and personnel records, including administrative files, reports, records, or working papers;

(4) an interview with any willing recipient of ambulatory surgical center services at the ASC or in the recipient's home if the recipient grants permission in writing;

(5) an interview with any health care practitioner or ambulatory surgical center personnel who care for the recipient of ambulatory surgical services;

(6) a conference at the conclusion of the inspection between the department's representative and the person who is in charge of the ASC.

(A) The department's representative will identify any records that have been reproduced.

(B) Any records that are removed from an ASC (other than those reproduced) shall be removed only with the consent of the ASC. The ASC shall furnish copies of all records pertinent to the investigation at the department's request.

(e) The department will review the report of the investigation and determine the validity of the complaint.

§135.26 Reporting Requirements.

(a) The ambulatory surgical center must make a report of the following incidents to the department. A written letter of explanation with supporting documents must be mailed to the department within 10 business days of the incident. The mailing address is Department of State Health Services, Facility Licensing Group, 1100 West 49th Street, Austin, Texas 78756.

- (1) The death of a patient while under the care of the ASC;
- (2) The transfer of a patient to a hospital;
- (3) Patient development of complications within 24 hours of discharge from the ASC resulting in admission to a hospital; and
- (4) A patient stay exceeding 23 hours.

(b) On an annual basis, the ASC must report the types and numbers of procedures performed and the average length of stay during the previous 12-month period. The report will be made using a form to be prescribed by the department.

(c) Any theft of drugs and/or diversion of controlled drugs shall be reported to the local police agency, the State Board of Pharmacy, the Texas Department of Public Safety, and/or the Drug Enforcement Administration, and the Department of State Health Services.

(d) An ASC that performs abortions must comply with the reporting requirements specified in the Texas Health and Safety Code, §245.011.

(e) Occurrences of fire in the ASC shall be reported as specified under §135.41(2) of this title (relating to Fire Prevention, Protection, and Safety) and §135.42(1)(F) of this title (relating to Handling and Storage of Gases, Anesthetics, and Flammable Liquids).

§135.27. Patient Safety Program.

(a) General.

(1) The ASC 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 ASC'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;

report internally;

- (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;
- (v) consequences for failing to report events in accordance with ASC policy;
- (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.

(C) The ASC 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 subsection (a)(1)(B) of this section.

(2) The ASC 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 the root cause analysis and resulting action plans; and
- (D) serving as liaison among ASC departments and committees to ensure facility-wide integration of the PSP.

(3) Within 45 days of becoming aware of a reportable event specified under subsection (b)(1) of this section, the ambulatory surgery center 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 ASC 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 ASC must make the root cause analysis and action plan available for on-site review by department representatives.

(b) Reporting Requirements.

(1) Annual Events Report. On the renewal of the ASC's license, or annually based on the ASC's original licensing date, the ASC shall submit to the department a report that lists the number of occurrences at the ambulatory surgery center of each of the following events occurring during the preceding year. The ambulatory surgical center is not required to include any information other than the total number of occurrences of each of the events listed within this section.

(A) 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.

(B) The suicide of a patient in a setting in which the patient received care 24 hours a day.

(C) The sexual assault of a patient during treatment or while the patient was on the premises of the ASC.

(D) A hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities.

(E) 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.

(F) A surgical procedure on the wrong patient or on the wrong body part of a patient.

(G) A foreign object accidentally left in a patient during a procedure.

(2) Best Practices Report.

(A) On the renewal of the ASC's license, or annually based on the ASC's original licensing date, the ASC 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 ASC may submit a copy of a report submitted to a patient safety organization.

(C) Ambulatory surgical centers may voluntarily report additional best practices and safety measures.

§135.28. Confidentiality.

Request for information and access to records are governed by the Texas Public Information Act, Texas Government Code, Chapter 552.

(1) A written request for information is required. The request must sufficiently identify the information requested.

(2) The department may ask for a clarification if it cannot reasonably understand a particular request.

§135.29. Time Periods for Processing and Issuing a License.

(a) General.

(1) The date a license application is received is the date the application reaches the 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 §135.20 of this title (relating to Initial Application and Issuance of License).

(3) An application for an annual renewal license is complete when the department has received, reviewed and found acceptable the information described in §135.22 of this title (relating to Renewal of Annual License).

(b) Time Periods. An application from a facility for an initial license or a 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 license is issued, or if the application is received incomplete, the period ends on the date the facility 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 45 calendar days.

(2) The second time period begins on the date the last item necessary to complete the application is received and ends on the date the license is issued. The second time period is 45 calendar days.

(c) Reimbursement of fees.

(1) In the event the application is not processed in the time periods stated in subsection (b) of this section, the applicant has the right to request that the department 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 will 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 giving good cause for exceeding the established periods.

(d) Appeal. If the request for reimbursement as authorized by subsection (c) of this section is denied, the applicant may then appeal to the commissioner of health for a resolution of the dispute. The applicant shall give written notice to the commissioner requesting reimbursement of the fee paid because the application was not processed within the established 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 will make the final decision and provide written notification of the decision to the applicant and the director.

(e) Hearings. If a hearing is proposed during the processing of the application, the hearing shall be conducted pursuant to the Texas Government Code, Chapter 2001, Administrative Procedure Act (APA), the hearing procedures of the State Office of Administrative Hearings (Texas Government Code, Chapter 2003 and Rules of Procedure, 1 Texas Administrative Code, Chapter 155).

§135.41. Fire Prevention, Protection, and Safety.

An ambulatory surgical center (ASC) shall comply with the provisions of this section with respect to fire prevention, protection, and safety.

(1) Fire inspections. An ASC shall comply with local fire codes.

(2) Fire reporting. Except as required under §135.42(1)(F) of this title (relating to Handling and Storage of Gases, Anesthetics, and Flammable Liquids), an ASC shall report all occurrences of fire in writing no later than 10 calendar days following the occurrence to the department in care of the Facility Licensing Group (FLG), Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756 or fax to (512) 834-4514. Any fire occurrence

causing injury to a person shall be reported no later than the next business day to the department, FLG, by fax or overnight mail, to the address or fax number previously mentioned in this paragraph.

(3) Smoking policy. An ASC shall adopt, implement and enforce a written smoking policy. The policy shall include the minimum provisions of National Fire Protection Association 101, Life Safety Code, 2000 edition (NFPA 101), §20.7.4. 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.

(4) Fire extinguishing systems. An ASC shall adopt, implement, and enforce a written policy for periodic inspection, testing and maintenance of firefighting equipment, portable fire extinguishers, and when installed sprinkler systems. If installed, fire sprinkler systems shall comply with National Fire Protection Association 13, Standard for the Installation of Sprinkler Systems, 1999 edition (NFPA 13). Portable fire extinguishers shall comply with National Fire Protection Association 10, Standard for Portable Fire Extinguishers, 1998 edition (NFPA 10).

(5) Fire protection and evacuation plan. An ASC shall develop a written plan for the protection of patients in the event of fire and their evacuation from the building when necessary in accordance with NFPA 101, §20.7. Copies of the plan shall be made available to all staff.

(A) Posting requirements. An ASC shall prominently display evacuation floor plans in public areas, readily visible to patients, employees, and visitors.

(B) Annual training. An ASC shall conduct an annual training program to instruct all personnel in the location and use of firefighting equipment.

(6) Fire drills. An ASC shall conduct at least one fire drill per shift, per quarter. Each drill shall include activation of the fire alarm system, simulation of evacuation of patients and other occupants, and the use of firefighting equipment. Fire exit drills shall incorporate the minimum requirements of NFPA 101, §§20.7.1.2 through 20.7.2.3. The ASC shall maintain documentation of its compliance with this subsection.

(7) Fire alarm system. A fire alarm system shall be installed, maintained and tested, in accordance with National Fire Protection Association 72, National Fire Alarm Code, 1999 edition (NFPA 72) standard and NFPA 101, §20.3.4.

(8) Fire department access. Driveways shall be provided for access of fire fighting apparatus and rescue vehicles. Such driveways shall be maintained and kept free from all obstructions.

(9) Fire department protection. An ASC shall comply with local fire department access requirements. When an ASC is located outside of the service area of the public fire protection, arrangements shall be made for the nearest fire department to respond in case of an emergency.

(10) Safety officer. An ASC shall have a designated safety officer who is knowledgeable in safety practices of health care facilities. An ASC shall afford sufficient time to the safety officer to carry out the functions of the safety program. The ASC shall develop written safety policies and procedures which shall be approved by the governing body and medical staff and made available to all employees.

(11) Maintaining a fire safe environment. The building and premises shall be maintained free of accumulations of combustible and extraneous materials not necessary for the day-to-day operation of the center.

(12) Electrical systems. Electrical systems shall be installed and maintained in a safe condition in accordance with National Fire Protection Association 70, National Electrical Code, 1999 edition (NFPA 70).

§135.42. Handling and Storage of Gases, Anesthetics, and Flammable Liquids.

An ASC shall comply with the requirements of this section for handling and storage of gas, anesthetics, and flammable liquids.

(1) Flammable germicides. If flammable germicides, including alcohol-based products, are used for preoperative surgical skin preparation, the facility must:

(A) use only self-contained, single-use, pre-measured applicators to apply the surgical skin preparations;

(B) follow all manufacturer product safety warnings and guidelines;

(C) 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;

(D) 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 the use of the product;

(E) 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

(F) provide a written report of all occurrences of surgical suite fires within two business days to the department in care of the Facility Licensing Group, and complete an investigation of the occurrence and develop and implement a corrective action plan within 30 days.

(2) Flammable and nonflammable gases and liquids. The determination of flammability of liquids and gases shall be in accordance with the National Fire Protection Association 325, "Guide to Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids," 1994 edition (NFPA 325). 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) Nonflammable gases shall be stored and distributed in accordance with National Fire Protection Association 99 "Standard for Health Care Facilities," 1999 edition (NFPA 99), Chapter 4. Examples of nonflammable gases include, but are not limited to, oxygen and nitrous oxide. Medical gases and liquefied medical gases shall be handled in accordance with NFPA 99, Chapter 8, "Gas Equipment."

(B) Flammable gas systems intended for use in laboratories and piping systems for fuel gases shall comply with requirements of NFPA 99, §4-6.

(C) Flammable and combustible liquids intended for use in laboratories shall comply with NFPA 99, §10-7.

(D) Other flammable agents shall be stored in accordance with NFPA 99, Chapter 6 "Materials".

(3) Gas fired appliances. The installation, use, and maintenance of gas fired appliances and gas piping installations shall comply with the NFPA 54, National Fuel Gas Code, 1999 edition. The use of portable gas heaters and unvented open flame heaters is prohibited.

§135.51. Construction Requirements for an Existing Ambulatory Surgical Center.

(a) Compliance.

(1) A licensed ambulatory surgical center (ASC) which is licensed prior to the effective date of these rules is considered to be an existing licensed ASC and shall continue, at a minimum, to meet the licensing requirements under which it was originally licensed.

(2) In lieu of meeting the requirements in paragraph (1) of this subsection, an existing licensed ASC may, instead, comply with National Fire Protection Association (NFPA) 101, Life Safety Code 2000 Edition (NFPA 101), Chapter 21, "Existing Ambulatory Health Care Facilities".

(3) 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) Remodeling and additions. All remodeling, renovations, additions and alterations to or relocation of an existing ASC shall be done in accordance with the requirements for new construction in §135.52 of this title (relating to Construction Requirements for New Ambulatory Surgical Centers). When existing conditions make such changes impractical, the department may grant a conditional approval of minor deviations from the requirements of §135.52 of this title, if the intent of the requirements is met and if the care, safety and welfare of patients will not be jeopardized. The operation of the ASC, accessibility of individuals with disabilities, and safety of the patients shall not be jeopardized by a condition(s) which is not in compliance with these sections.

(1) Building equipment alterations or installations. Any alteration or any installation of new building equipment, such as mechanical, electrical, plumbing, fire protection, or piped medical gas system shall comply with the requirements for new construction and may not be replaced, materially altered, or extended in an existing ASC until complete plans and specifications have been submitted to the department, and the department has reviewed and approved the plans and specifications in accordance with §135.53 of this title (relating to Preparation, Submittal, Review and Approval of Plans).

(2) Minor remodeling or alterations. Minor remodeling or alterations within an existing ASC which do not involve alterations to load bearing members and partitions, change functional operation, affect fire safety, add or subtract services, or involve any of the major changes listed in paragraph (3) of this subsection are considered to be minor projects and require evaluation and approval by the department. An ASC shall submit a written request for evaluation, a brief description of the proposed changes, and sketches of the area being remodeled. Based on such submittal, the department will evaluate and determine whether any additional submittals or inspections are required. The department will notify the ASC of its decision. If not approved within 60 days after submission, the project may proceed subject to compliance with the regulations.

(3) Major remodeling or alterations. All remodeling or alterations which involve alterations to load bearing members or partitions, change functional operation, affect fire safety, or add or delete services, are considered major projects. An ASC shall comply with this paragraph prior to beginning construction of major projects.

(A) Submittal of plans. Plans shall be submitted in accordance with §135.53 of this title for all major remodeling or alterations.

(B) Phasing of construction in existing facilities. Projects involving alterations of or additions to existing buildings shall be programmed and phased so that on-site construction will minimize disruptions of existing functions.

(i) Access, exit access, fire protection and all necessary functions shall be maintained so that the safety of the occupants will not be jeopardized during construction.

(ii) Construction, dust, objectionable fumes and vapor barriers shall be provided to separate areas undergoing demolition and construction from occupied areas.

(iii) Temporary sound barriers shall be provided where intense, prolonged construction noises will disturb patients or staff in the occupied portions of the building

(c) Previously licensed ASCs. A previously licensed ASC which has been vacated or used for other purposes shall comply with all the requirements for new construction contained in §135.52 of this title in order to be licensed.

§135.52. Construction Requirements for New Ambulatory Surgical Centers.

(a) Ambulatory surgical center (ASC) location. An ASC may be a distinct separate part of an existing hospital, it may occupy an entire separate independent structure, or it may be located within another building such as an office building or commercial building.

(1) Accessibility. The location of a proposed new ASC shall be easily accessible for service vehicles and fire protection apparatus.

(2) Means of egress. An ASC shall have at least two exits remotely located in accordance with National Fire Protection Association (NFPA) 101, Life Safety Code, 2000 edition (NFPA 101), §20.2.4.1. When a required means of egress from the ASC is through another portion of the building, that means of egress shall comply with the requirements of NFPA 101 which are applicable to the occupancy of that other building. Such means of egress shall be open, available, unlocked, unrestricted, and lighted at all times during the ASC hours of operation. 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.

(3) Hazardous location.

(A) Underground and above ground hazards. A new ASC or an addition(s) to an existing ASC may not be constructed near a hazardous location. Hazardous locations include underground liquid butane or propane, liquid petroleum or natural gas transmission lines, high pressure lines, or under high voltage electrical lines.

(B) Fire hazards. A new ASC may 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 areas.

(C) Health and safety hazards. A new ASC may not be located in a building(s) which, because of its location, physical condition, state of repair, or arrangement of facilities, would be hazardous to the health or safety of the patients.

(4) Undesirable locations.

(A) Nuisance producing sites. A new ASC may not be located near nuisance producing sites such as industrial sites, feed lots, sanitary landfills, or manufacturing plants which produce excessive noise or air pollution.

(B) Flood plains. Construction of new ASCs shall be avoided in designated flood plains. Where such is unavoidable, access and required ASC components shall be constructed above the designated flood plain. This requirement also applies to new additions to existing ASCs or portions of facilities which have been licensed previously as ASCs, but which have been vacated or used for other purposes. This requirement does not apply to remodeling of existing licensed ASCs.

(b) ASC site. The ASC site shall include paved roads, walkways, and parking in accordance with the requirements set out in this subsection.

(1) Paved roads and walkways.

(A) Paved roads shall be provided within lot lines for access from public roads to the main entrance and to service entrances.

(B) Finished surface walkways shall be provided for pedestrians. When public transportation or walkways serve the site, finished surface walkways or paved roads shall extend from the public conveyance to the building entrance.

(2) Parking.

(A) Off street parking shall be provided at the minimum ratio of two spaces for each operating room, one space for each staff member and one visitor's space for each operating room.

(B) Handicapped parking. Parking spaces for handicapped persons shall be provided in accordance 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.

(c) 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 local governing building codes. Where there is no local governing building code, one of the following codes shall govern: Uniform Building Code, 1999 edition, published by the International Conference of Building Officials, 5360

Workman Mill Road, Whittier, California 90601, telephone (562) 699-0541; or the Standard Building Code, 1997 edition, published by the Southern Building Code Congress International, Inc., 900 Montclair Road, Birmingham, Alabama 35213-1206, telephone (205) 591-1853.

(1) General architectural requirements. All new construction, including conversion of an existing building to an ASC or establishing a separately licensed ASC within another existing building, shall comply with NFPA 101, Chapter 20, "New Ambulatory Health Care Facilities," and this section.

(A) Construction types for multiple building occupancy.

(i) When an ASC is part of a larger building which complies with NFPA 101, §20.1.6, "Minimum Construction Requirements" for (fire resistance) construction type, the designated ASC shall be separated from the remainder of the building with a minimum of 1-hour fire rated construction.

(ii) Multistory buildings. When an ASC is located in a multistory building of two or more stories, the entire building shall meet the construction requirements of NFPA 101, §20.1.6.3. An ASC may not be located in a multistory building which does not comply with the minimum construction requirements of NFPA 101, §20.1.6.3.

(iii) Single story buildings. When an ASC is part of a one-story building that does not comply with the construction requirements of NFPA 101, §20.1.6.2, the ASC must be separated from the remainder of the building with a 2-hour fire rated construction. The designated ASC portion shall have the construction type upgraded to comply with NFPA 101, §20.1.6.2.

(B) Special design provisions. Special provisions shall be made in the design of a facility if located in a region where local experience shows loss of life or extensive damage to buildings resulting from hurricanes, tornadoes, or floods.

(2) Foundations. Foundations shall rest on natural solid bearing if satisfactory bearing is available. Proper soil-bearing values shall be established in accordance with nationally recognized requirements. If solid bearing is not encountered at practical depths, the structure shall be supported on driven piles or drilled piers designed to support the intended load without detrimental settlement, except that one-story buildings may rest on a fill designed by a soils engineer. When engineered fill is used, site preparation and placement of fill shall be done under the direct full-time supervision of the soils engineer. The soils engineer shall issue a final report on the compacted fill operation and certification of compliance with the job specifications.

(3) Physical environment. A physical environment that protects the health and safety of patients, personnel, and the public shall be provided in each facility. The physical premises of the facility and those areas of the facility'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 the requirements of this chapter.

(4) State handicapped requirements. Special considerations benefiting handicapped staff, visitors, and patients shall be provided. Each ASC 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.

(5) Other regulations. Certain projects may be subject to other regulations, including those of federal, state, and local authorities. The more stringent standard or requirement shall apply when a difference in requirements exists.

(6) Exceeding minimum requirements. Nothing in these sections shall be construed to prohibit a better type of building construction, more exits, or otherwise safer conditions than the minimum requirements specified in these sections.

(7) Equivalency. Nothing in these sections 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 these sections, provided technical documentation which demonstrates equivalency is submitted to the department for approval.

(8) Separate freestanding buildings (not for patient use). Separate freestanding buildings for nonpatient use which are located at least 20 feet from the ASC building such as the heating plant, boiler plant, repair workshops, or general storage may be designed and constructed in accordance with other applicable occupancy classification requirements listed in NFPA 101.

(d) Spatial requirements.

(1) Administration and public areas.

(A) Entrance. Entrances shall be located at grade level, be accessible to individuals with disabilities, and protected against inclement weather from the point of passenger loading/unloading to the building entrance. When an ASC is located on a floor above grade level, elevators shall be accessible and shall meet the requirements of subsection (g) of this section.

(B) Waiting area. A waiting area or lobby shall be provided which includes having access to the following rooms and items:

(i) public toilet facilities;

(ii) telephone(s) for public use; and

(iii) access to potable drinking water.

(C) Reception area. A designated reception area with desk or counter shall be provided.

(D) Interview space(s). Space shall be provided for private interviews relating to social services, credit, or admission.

(E) General or individual office(s). An office(s) shall be provided for business transactions, records, and administrative and professional staff.

(F) Medical records area. Medical record storage space shall be located within a secure designated area under direct visual supervision of administrative staff.

(G) General storage room.

(i) A minimum of 50 square feet per operating room shall be provided exclusive of soiled holding, sterile supplies, clean storage, drug storage, locker rooms, and surgical equipment storage. General storage may be located in one or more rooms or closets and shall be located outside of the patient treatment areas.

(ii) General storage room(s) shall be separated from adjacent areas by fire-rated construction in accordance with the NFPA 101, §§38.3.2.1 and 38.3.2.2.

(H) Wheelchair storage space or alcove. Storage space for wheelchairs shall be provided and shall be out of the direct line of traffic.

(2) Engineering services and equipment areas. Equipment rooms with adequate space shall be provided for mechanical and electrical equipment. These areas shall be separate from public, patient, and staff areas.

(3) Janitor's closet. In addition to the janitor's closet exclusive to the surgery suite, a sufficient number of janitor's closets shall be provided throughout the facility to maintain a clean and sanitary environment. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(4) Laboratory.

(A) General. Laboratory services shall be provided within the ASC or through a contract or other arrangement with a hospital or accredited laboratory.

(B) Special requirements. When the laboratory is located on-site the following minimum items shall be provided:

(i) a room with work counter, utility sink, and storage cabinets or closet(s); and

(ii) specimen collection facilities. For dip stick urinalysis, urine collection rooms shall be equipped with a water closet and lavatory. Blood collection facilities shall have space for a chair, work counter and hand washing facilities.

(C) Code compliance. An on-site laboratory shall comply with the following codes.

(i) Construction for fire protection in laboratories employing quantities of flammable, combustible, or other hazardous material shall be in accordance with the National Fire Protection Association 99, Health Care Facilities, 1999 edition, (NFPA 99).

(ii) Laboratories shall comply with the requirements of NFPA 99, "Health Care Facilities," 1999 edition, Chapter 10, as applicable and the requirements of NFPA 45, "Standards on Fire Protection for Laboratories Using Chemicals," 1996 edition, as applicable.

(5) Laundry and linen processing area(s). Laundry and linen processing may be done within the center or off-site at a commercial laundry.

(A) On-site linen processing. When on-site linen processing is provided, soiled and clean processing operations shall be separated and arranged to provide a one-way traffic pattern from soiled to clean areas. The following rooms and items shall be provided:

(i) a soiled linen processing room which includes areas for receiving, holding, sorting, and washing;

(ii) a clean linen processing room which includes areas for drying, sorting, folding, and holding prior to distribution;

(iii) supply storage cabinets in the soiled and clean linen processing rooms;

(iv) hand washing facilities within the soiled linen processing room; and

(v) a storage room for clean linen located within the surgical suite. Clean linen storage may be combined with the clean work room.

(B) Off-site linen processing. When linen is processed off-site, the following rooms or items shall be provided:

(i) a storage room for clean linen located within the surgical suite. Clean linen storage may be combined with the clean work room; and

(ii) a soiled linen holding room or area located within the surgical suite. Soiled linen holding may be combined with the soiled workroom.

(6) Pharmacy. A pharmacy work room or alcove shall be provided and located separate from patient and public areas and under the direct supervision of staff. A work counter, refrigerator, medication storage and locked storage for biologicals and drugs shall be provided. Hand washing facilities shall be located in or convenient to the pharmacy room or alcove.

(7) Preoperative patient holding room.

(A) General. A preoperative holding area shall be provided and arranged in a one-way traffic pattern so that patients entering from outside the surgical suite can change, gown, and move directly into the restricted corridor of the surgical suite. The holding area shall be separate from the post-operative recovery suite and the restricted corridor.

(B) Patient station. A minimum of one patient station per operating room shall be provided.

(i) A minimum area of 60 square feet shall be provided for each patient station.

(ii) When a gurney or bed is used, the minimum clearance from the gurney or bed to a sidewall may not be less than three feet. A space of four feet shall be provided at the foot of the gurney or bed and the minimum clearance between gurneys or beds may not be less than four feet six inches.

(iii) Space shall be made available for storing and securing patient's personal effects.

(C) Patient toilet. A toilet room with handicapped accessible water closet and hand washing facilities shall be provided. The toilet room may be shared with the post-operative recovery suite, if conveniently located to both.

(D) Special requirements. Hand washing facilities and a counter or shelf space for writing shall be provided for staff use within or convenient to the preop area. Staff hand washing facilities shall be separate from and in addition to patient toilet accommodations.

(8) Radiology.

(A) Special requirements. When radiology services are provided on-site, the following minimum facilities shall be provided:

(i) film processing facilities, if used;

(ii) viewing capabilities;

(iii) storage facilities for exposed film, if used, located in rooms or areas constructed in accordance with the NFPA 101, §38.3.2.1 and §38.3.2.2; and

(iv) dressing area(s) shall be required, depending on services provided, with convenient access to toilets and may be shared with patient changing/preop rooms.

(B) Fluoroscopy room. When fluoroscopy services are provided on site in a dedicated fluoroscopy room, a toilet room with handicapped accessible water closet and hand washing facilities shall be directly accessible to the room.

(9) Post-operative recovery suite.

(A) General. A post-operative recovery suite shall be distinct and separate from preoperative areas. The post-operative recovery suite shall be arranged to provide a one-way traffic pattern from the restricted surgical corridor to the post-operative recovery suite and then to the extended observation rooms or discharge.

(B) Post anesthesia care unit. A minimum of one patient station per operating room, plus one additional station, shall be provided.

(i) When a gurney or bed is used, the minimum clearance from the gurney or bed to a sidewall may not be less than three feet. A space of not less than four feet shall be provided at the foot of each gurney or bed.

(ii) The minimum clearance between gurneys and beds may not be less than four feet six inches.

(C) Extended observation rooms. Separate supervised rooms or areas may be provided for patients who are sufficiently stabilized to leave the post anesthesia care unit, but require additional time in the facility for observation or comfort measures prior to being discharged.

(i) When individual rooms are provided, the rooms shall have an area of at least 60 square feet. When such rooms include a bed or recliner, a minimum clearance of three feet at the foot and on each side of the bed or recliner shall be provided.

(ii) When an open or ward area is provided, the minimum clearance from the bed or recliner to the side wall may not be less than three feet; and a space of four feet shall be provided at the foot of each bed or recliner. The minimum clearance between beds or recliners may not be less than three feet.

(D) Patient toilet. A toilet room with handicapped accessible water closet and hand washing facilities shall be provided. The toilet room may be shared with the preoperative patient holding area, if conveniently located to both.

(10) Staff clothing change area.

(A) General. The change area shall be designed to provide a one-way traffic pattern so that personnel entering from outside the surgical suite can change into scrub attire and move directly into the restricted corridor of the surgical suite.

(B) Staff changing area. A staff changing area shall include the following rooms and accommodations:

- (i) dressing room with lockers;
- (ii) toilet room(s) with water closet and hand washing facilities (may be shared if accessible to both male and female dressing rooms); and
- (iii) a shower located somewhere within the facility.

(C) Surgical lounge. When provided, a lounge for surgical staff shall be located to permit use without leaving the surgical suite. These facilities may be integrated with the staff changing areas.

(11) Soiled workroom. In addition to the soiled workroom provided in the surgical suite, a separate soiled workroom(s) shall be required when a treatment room is provided, except as allowed in subparagraph (B) of this paragraph.

(A) Special requirements. The workroom(s) shall contain a clinical sink or equivalent flushing type fixture, work counter, designated space for waste and linen receptacles, and hand washing facilities.

(B) Shared functions. The soiled workroom required in support of a treatment room may be combined with a surgical suite soiled work room with two means of entry. A separate door into the soiled workroom shall serve a treatment room located outside the surgical suite.

(12) Sterilizing facilities. A system for sterilizing equipment and supplies shall be provided. Sterilizing procedures may be done on-site or off-site, or disposables may be used to satisfy functional needs.

(A) Off-site sterilizing. When sterilizing is provided off-site and disposables and prepackage surgical supplies are used, the following rooms shall be provided near the operating room.

(i) Soiled holding room. A room for receiving contaminated/soiled material and equipment from the operating room shall be provided. The room shall be physically separate from all other areas of the suite. The room shall include a work counter(s) or a table(s), clinical sink or equivalent flushing type fixture, equipment for initial disinfection and preparation for transport to off-site sterilizing, and hand washing facilities. The soiled holding room may be combined with the surgical suite soiled workroom.

(ii) Clean workroom. A clean workroom shall be provided for the exclusive use of the surgical suite. The workroom shall contain a work counter, with space for receiving, disassembling and organizing clean supplies, storage cabinets or shelving, and hand washing facilities.

(iii) Sterilizer equipment. Sterilizer equipment shall be located in a separate room convenient to the operating room(s), in an alcove adjacent to the restricted corridor, or in the clean workroom.

(B) On-site sterilizing facilities. When sterilizing facilities are provided on-site they shall be located near the operating room and provide the following rooms.

(i) Receiving/decontamination room. The receiving/decontamination room shall be physically separate from all other areas of the surgical suite. The room shall include a work counter(s) or table(s), clinical sink or equivalent flushing type fixture, equipment for initial washing/disinfection, and hand washing facilities. Pass-through doors, windows, and washer/sterilizer decontaminators shall serve in delivering material to the clean workroom. The receiving/decontamination room may be combined with the surgical suite soiled workroom.

(ii) Clean/assembly workroom. The clean/assembly workroom shall include a counter(s) or table(s) with space for organizing, assembling, and packaging of medical/surgical supplies and equipment, equipment for terminal sterilizing, and hand washing facilities. Clean and soiled work areas shall be physically separated.

(iii) Sterile storage. A storage room for clean and sterile supplies shall be provided. The storage room shall have adequate areas and counters for breakdown of manufacturers' clean/sterile medical/surgical supplies. This room may be combined with the clean assembly/workroom.

(iv) Cart storage room or alcove. The storage space for distribution carts shall be adjacent to clean and sterile storage area(s) and close to main distribution points.

(13) Surgical suite. The surgical suite shall be arranged to preclude unrelated traffic through the suite. The surgical suite shall contain at least one operating room and all surgical service areas required under subparagraph (B) of this paragraph.

(A) Operating room. The operating room(s) shall have a clear floor area of at least 240 square feet exclusive of fixed or moveable cabinets, counters, or shelves. The minimum clear dimension between built-in cabinets, counters, and shelves shall be 14 feet.

(B) Surgical service areas.

(i) Restricted corridor. The restricted corridor shall serve as the primary passageway for staff and patients within the surgical suite. The following rooms and areas when provided or required by NFPA 101 shall have direct access to the restricted corridor:

(I) preoperative patient holding area;

(II) operating room(s);

- (III) post-operative recovery suite;
- (IV) soiled workroom;
- (V) clean workroom;
- (VI) janitor's closet;
- (VII) equipment storage;
- (VIII) sterilizing facilities;
- (IX) anesthesia workroom;
- (X) area for emergency crash cart; and
- (XI) emergency eyewash.

(ii) Soiled workroom. A soiled workroom shall be provided for the exclusive use of the surgical suite staff. The workroom shall contain a clinical sink or equivalent flushing type fixture, work counter, designated space for waste and linen receptacles, and hand washing facilities. The soiled workroom may not have direct connection with operating room(s) or other sterile activity room(s).

(iii) Clean linen storage. A storage room or alcove shall be provided for storing clean linen.

(iv) Scrub facilities. A scrub sink shall be provided near the entrance to each operating room. Scrub facilities shall be arranged to minimize incidental splatter on nearby personnel or carts. One scrub station with dual faucets and separate controls may serve two adjacent operating rooms.

(v) Janitor's closet. A janitor's closet shall be provided for the exclusive use of the surgical suite. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(vi) Equipment storage. A room, alcove, or designated area shall be provided for storing equipment and supplies used in the surgical suite. The storage room or area shall be a minimum of 50 square feet per operating room.

(vii) Medical gas storage room. When provided or required by NFPA 101, a medical gas storage room shall comply with the requirements of NFPA 99, 1999, Chapter 4 "Gas and Vacuum Systems".

(viii) Area for emergency crash cart. An area or alcove located out of traffic and convenient to the operating room(s) shall be provided for an emergency crash cart.

(ix) Stretcher storage area. An area or alcove shall be located convenient for use and out of the direct line of traffic for the storage of stretchers as required. Stored stretchers shall not encroach on corridor widths.

(14) Treatment room.

(A) A treatment room is not required, but when provided, it may be used only for minor procedures.

(B) If anesthesia is administered in the treatment room, the room must comply with NFPA requirements for an anesthetizing location.

(C) The treatment room shall have a clear floor area of at least 100 square feet exclusive of fixed or moveable cabinets, counters, or shelves.

(D) The treatment room shall contain an examination table, a counter for writing, and hand washing facilities.

(15) Examination room. An examination room is not required, but when provided, the room shall have:

(A) a minimum clear floor area of at least 80 square feet exclusive of fixed or moveable cabinets, counters, or shelves; and

(B) a work counter with space for writing and hand washing facilities.

(16) Medical waste processing. Space and facilities shall be provided for the safe storage and disposal of waste as appropriate for the material being handled and in compliance with all applicable rules and regulations.

(e) Details.

(1) Corridors.

(A) Public corridor. The minimum clear and unobstructed width of a public corridor shall be at least four feet.

(B) Communicating corridor. The communicating corridor shall be used to convey patients by stretcher, gurney, or bed.

(i) The communicating corridor shall link the preoperative holding area, operating room(s), and post-operative recovery suite, and shall be continuous to at least one exit.

(ii) The minimum clear and unobstructed width of the communicating corridor shall be eight feet.

(2) Doors and windows.

(A) Door types. Doors at all openings between corridors and rooms or spaces subject to occupancy shall be swing type. Elevator doors are excluded from this requirement.

(B) Door swing. Doors, except doors to spaces such as small closets which are not subject to occupancy, shall not swing into corridors in a manner that might obstruct traffic flow or reduce the required corridor width. Large walk-in type closets are considered as occupiable spaces.

(C) Patient access doors. The minimum width of doors for patient access to examination and consultation rooms shall be three feet. The minimum width of doors requiring access for beds and gurneys (preoperative holding area, operating room, post-operative recovery suite) shall be three feet eight inches.

(D) Emergency access. At least one door into a patient use toilet room shall swing outward or have hardware to permit access from the outside in an emergency.

(E) Labeled doors. Labeled fire doors shall be listed by an independent testing laboratory and shall meet the construction requirement for fire doors in NFPA 80, "Standard for Fire Doors and Fire Windows," 1999 edition. Reference to a labeled door shall be construed to include labeled frame and hardware.

(F) Glazing. Glass doors, sidelights, borrowed lights, and windows located within 12 inches of a door jamb or with a bottom-frame height of less than 18 inches above the finished floor 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 unless otherwise required for fire safety. Safety glass, tempered glass, or plastic glazing materials shall be used for shower doors, bath enclosures, interior windows, and doors (which have glazing).

(3) Ceiling heights. The minimum ceiling height shall be eight feet with the following exceptions.

(A) Rooms containing ceiling-mounted light fixtures or equipment. Operating rooms or other rooms containing ceiling-mounted light fixtures or equipment shall have ceiling heights of not less than nine feet. Additional ceiling height may be required to accommodate special fixtures or equipment.

(B) Minor rooms. Ceilings in storage rooms, toilet rooms, and other minor rooms shall be not less than seven feet six inches.

(C) Special requirements. Suspended tracks, rails, pipes, signs, lights, door closures, exit signs, and other fixtures that protrude into the path of normal traffic shall be not less than six feet eight inches above the finished floor.

(4) Toilet room accessories. Grab bars shall be provided at water closets and showers in accordance with the ADA.

(5) 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 controls shall be provided in each examination room, preoperative area, post-operative recovery suite, soiled utility room, fluoroscopy room, clean work room, and toilet room. 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 conveniently located for staff use in rooms and areas noted under spacial requirements in subsection (d) of this section and throughout the center where patient care services are provided.

(6) Hand drying. Provisions for hand drying shall be included at all hand washing facilities except scrub sinks. Hot air dryers or individual paper units shall be provided and must be enclosed in such a way as to provide protection against dust or soil. Paper dispensing units shall provide for single unit dispensing.

(7) Radiation protection. Shielding shall be designed, tested, and approved by a medical physicist licensed under the Medical Physics Act, Occupations Code, Chapter 602. The ASC must obtain a certificate of registration issued by the Bureau of Radiation Control to use radiation machines.

(8) Rooms with heat producing equipment. Rooms containing heat producing equipment such as mechanical and electrical equipment and laundry rooms shall be insulated and ventilated to prevent floors of any occupied room located above it from exceeding a temperature differential of 10 degrees Fahrenheit above the ambient room temperature.

(f) Finishes.

(1) Floor finishes.

(A) General. Floor materials shall be easily cleanable, wear resistant, and appropriate for the location involved. In areas subject to frequent wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. Floors that are subject to traffic while wet, such as shower areas and certain work areas, shall have nonslip surfaces.

(B) Operating rooms and sterilizing facility(ies).

(i) Floor finishes shall be seamless, be tightly sealed to the wall without voids, and be impervious to water.

(ii) Base materials shall be coved and integral with the floor.

(iii) Welded joint flooring is acceptable.

(C) Threshold and expansion joint covers. Thresholds at doorways may not exceed 3/4 inch in height for exterior sliding doors or 1/2 inch for other type doors. Raised thresholds and floor level changes at accessible doorways shall be beveled with a slope no greater than 1:2. Expansion joint covers may not exceed 1/2 inch in height and shall have beveled edges with a slope no greater than 1:2.

(2) Wall finishes. Wall finishes shall be smooth, washable, moisture resistant, and cleanable by standard housekeeping practices. Wall finishes shall be in compliance with the requirements of NFPA 101, §38.3.3, relating to flame spread.

(A) Finishes at plumbing fixtures. Wall finishes shall be water resistant in the immediate area of plumbing fixtures.

(B) Wet cleaning methods. Wall finishes in areas subject to frequent wet cleaning methods shall be impervious to water, tightly sealed; and without voids.

(3) Ceiling finishes.

(A) General. All occupied rooms and spaces shall be provided with finished ceilings, unless otherwise noted. Ceilings which are a part of a rated roof and ceiling assembly or a floor-ceiling assembly shall be constructed of listed components (by a nationally recognized testing laboratory) and installed in accordance with the listing.

(B) Monolithic ceilings. Ceilings in operating rooms and sterilizing facilities shall be monolithic from wall to wall, smooth and without fissures, open joints, or crevices and with a washable and moisture impervious finish.

(C) Special requirements. Finished ceilings may be omitted in mechanical and equipment spaces, shops, and similar spaces unless required for fire-resistive purposes.

(4) Floor, wall, and ceiling penetrations. Floor, wall, and ceiling penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of dirt particles, rodents, and insects. Joints of structural elements shall be similarly sealed.

(5) Cubicle curtains, draperies, and other hanging fabrics. Cubicle curtains, draperies, and other hanging fabrics shall be noncombustible or flame retardant and shall pass both the small scale and large scale test of NFPA 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.

(g) Elevators. All buildings that have patient services located on other than the main entrance floor shall have electric or electrohydraulic elevators. The elevators shall be installed in sufficient quantity, capacity, and speed to ensure that the average interval of dispatch time will not exceed one minute, and average peak loading can be accommodated.

(1) Requirements for new elevators. New elevators shall be installed in accordance with the requirements of Health and Safety Code, Chapter 754, Elevators, Escalators, and Related Equipment, and ASME A17.1, "Safety Code for Elevators and Escalators," 1996 latest edition, published by the American Society of Mechanical Engineers and the American National Standards Institute (ASME/ANSI A17.1). All new elevators shall conform to the Fire Fighters' Service Requirements of ASME/ANSI A17.1 requirements of NFPA 101, §9.4.3.1. 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.

(2) Requirements for existing elevators. Existing elevators shall comply with the ASME/ANSI A17.1, Safety Code for Elevators and Escalators, current edition, Part XII "Alterations, Repair, Replacements, and Maintenance" and ASME A17.3, 1995, "Safety Code for Existing Elevators and Escalators," current 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, §9.4.3.2.

(3) 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 with the capability to maintain an operating temperature during fire fighter service operations. 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. These requirements are not applicable to existing elevators.

(4) Elevator car size.

(A) Minimum elevator car size shall be five feet wide and five feet deep.

(B) When an operating room(s) is located on a different floor than the preoperative area or the post-operative recovery suite, a hospital-type elevator shall be provided. Cars of hospital-type elevators shall be at least five feet eight inches wide by eight feet five inches deep.

(5) Elevator and elevator shaft doors. When light beams are used for operating door opening devices, the beams shall be used in combination with door edge devices and shall be interconnected with a system of smoke detectors. The light control feature shall be disengaged when smoke is detected in any elevator lobby.

(A) The smallest elevator car door opening shall be at least three feet wide and seven feet high.

(B) The elevator car door opening for a hospital-type elevator shall be at least 44 inches wide and seven feet high.

(6) Type of controls and alarms. Elevator call buttons, controls, and door safety stops shall be of a type that will not be activated by heat or smoke.

(7) Leveling. All elevators shall be equipped with an automatic leveling device of the two-way automatic maintaining type with an accuracy of one-half inch.

(8) Operation. All elevators, except freight elevators, shall be equipped with a two-way key operated service switch permitting cars to bypass all landing button calls and be dispatched directly to any floor.

(9) Accessibility of controls and alarms. Elevator controls, alarm buttons, and telephones shall be accessible to wheelchair occupants in accordance with the Americans with Disabilities Act.

(10) Location. Elevators shall not open to an exit.

(11) Testing. An ASC shall have all elevators and escalators routinely and periodically inspected and tested in accordance with ASME/ANSI A17.1. 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, §7-4.8, "Elevator Testing".

(12) Certification. An ASC shall obtain a certificate of inspection evidencing that the elevators 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. The certificate of inspection shall be on record in each center.

(h) Mechanical requirements. This subsection contains requirements for mechanical systems; air-conditioning, heating and ventilating systems; steam and hot and cold water systems; plumbing fixtures; piping systems; and thermal and acoustical insulation.

(1) Cost. All mechanical systems shall be designed for overall efficiency and life cycle costing, including operational costs. Recognized engineering practices shall be followed to achieve the most economical and effective results except that in no case shall patient care or safety be sacrificed for conservation.

(2) Equipment location. Mechanical equipment may be located indoors or outdoors (when in a weatherproof enclosure), or in a separate building(s).

(3) 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.

(4) 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.

(A) Material lists. Upon completion of the contract, the owner shall obtain from the construction contractor parts lists and procurement information with numbers and description for each piece of equipment.

(B) Instructions. Upon completion of the contract, the owner shall obtain from the construction contractor instructions in the operational use and maintenance of systems and equipment as required.

(5) Heating, ventilating, and air conditioning (HVAC) systems.

(A) All central HVAC systems shall comply with and shall be installed in accordance with the requirements of NFPA 90A, "Standard for the Installation of Air Conditioning and Ventilating Systems," 1999 edition, or NFPA 90B, "Standard for the Installation of Warm Air Heating and Air-Conditioning Systems," 1999 edition, as applicable and the requirements contained in this subparagraph. Air handling units serving two or more rooms are considered to be central units.

(B) Non-central air handling systems, i.e., individual room units that are used for heating and cooling purposes (e.g., fan-coil units, heat pump units, and packaged terminal air conditioning units) shall be equipped with permanent (cleanable) or replaceable filters. The filters shall have an average efficiency of 25-30% and an average arrestance of 85% based on ASHRAE Test Standard 52.1-92. These units may be used as air recirculating units only. All outdoor air requirements shall be met by a separate central air handling system with the proper filtration, as required in Table 1 in §135.54(a) of this title (relating to Tables).

(C) Ventilation system requirements. All rooms and areas in the center 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 1 of §135.54(a) of this title shall be used only as minimum requirements since they do not preclude the use of higher rates that may be appropriate.

(i) Temperatures and humidities. The designed capacity of the systems shall be capable of providing the following ranges of temperatures and humidities.

(I) Operating room. The systems serving the operating room shall be capable of maintaining a temperature range between 68 and 75 degrees Fahrenheit and a relative humidity range between 45% and 60%.

(II) Post-operative recovery suite. The system serving the post-operative recovery suite shall be capable of maintaining a temperature of 75 degrees Fahrenheit and a relative humidity range between 45% and 60%.

(III) Other areas. The indoor design temperature in all other patient care areas shall be 75 degrees Fahrenheit with relative humidity of not less than 30%.

(ii) Thermometers and humidity gauges. Each operating room and post-operative recovery suite shall have temperature and humidity indicating devices mounted at eye level.

(iii) Air handling duct requirements. Fully ducted supply, return and exhaust air systems shall be provided for all patient care areas. Combination systems, utilizing both ducts and plenums for movement of air in these areas shall not be permitted. Ductwork access panels shall be labeled.

(I) X-ray protection. Ducts which penetrate construction intended for X-ray or other ray protection shall not impair the effectiveness of the protection.

(II) Protection of ducts penetrating fire and smoke partitions. Combination fire and smoke leakage limiting dampers (Class II) shall be installed in accordance with manufacturer's instructions for all ducts penetrating 1 and 2-hour rated fire and smoke partitions required by NFPA 101, §20.3.7 "Subdivision of Building Space" (not required in ASCs meeting the provisions of NFPA 101, §20.3.7.2, Exception No. 1).

(-a-) Fail-safe installation. Combination smoke and fire dampers shall close on activation of the fire alarm system by smoke detectors installed and located as required by NFPA 72, Chapter 5, "National Fire Alarm Code," 1999 edition; NFPA 90A, Chapter 4; and NFPA 101, §20.3.7; the fire sprinkler system; and upon loss of power. Smoke dampers shall not close by fan shut-down alone. This requirement applies to all existing and new installations.

(-b-) Interconnection of air handling fans and smoke dampers. Air handling fans and smoke damper controls shall be interlocked so that closing of smoke dampers will not damage the ducts.

(-c-) Frangible devices. The use of frangible (nonresetting) devices for shutting smoke dampers shall not be permitted.

(iv) Outside air intake locations.

(I) Outside air intakes shall be located at least 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum system outlets, plumbing vents, or areas which may collect vehicular exhaust or other noxious fumes. (Prevailing winds and proximity to other structures may require other arrangements).

(II) 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 to the air intake.

(III) The bottom of outside air intakes shall be located not less than six feet above ground level. The bottom of outside air intakes located on a roof shall be not less than three feet above the adjacent roof level.

(v) Air exhaust outlets. Exhaust outlets from areas containing ethylene oxide sterilizers and other contaminants, e.g. glutaraldehyde, shall terminate not less than eight feet above the roof level (or be appropriately labeled as "hazardous exhaust") and arranged to exhaust upward.

(vi) Pressure relationship. Ventilation systems shall be designed and balanced to provide pressure relationships contained in Table 1 of §135.54(a) of this title. For reductions and shut down of ventilation systems when a room is unoccupied, the provisions in Note 4 of Table 1 of §135.54(a) of this title shall be followed.

(vii) Air Distribution Devices. Supply diffusers grilles located in operating rooms and other anesthetizing locations shall be located on the ceiling or on a wall near the ceiling and bottoms of return air grilles in operating rooms and other anesthetizing locations shall be located not more than 12 inches above the finished floor nor less than six inches above the finished floor. At least two return air outlets shall be provided in each operating room on opposing walls or opposite corners.

(viii) Ventilation start-up requirements. Air handling systems shall not be operated without the proper installation of the filter in accordance with the manufacturer recommendation or instruction. This includes the 90% efficiency filters where required. Ducts shall be cleaned thoroughly by a National Air Duct Cleaner Association (NADCA) certified air duct cleaning contractor when the air handling systems have been operated without the required filters in place. This includes construction operations.

(ix) Humidifier location. When duct humidifiers are located upstream of the final filters, they shall be located at least 15 feet from the filters. Duct work 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 takeoffs should be sufficiently downstream of the humidifier to ensure complete moisture absorption. Reservoir-type water spray or evaporative pan humidifiers shall not be used.

(x) Filtration requirements. All air handling units shall be equipped with filters having efficiencies equal to, or greater than, those specified in Table 2 of §135.54(b)

of this title. Filter efficiencies shall be average dust spot efficiencies tested in accordance with American Society of Heating, Refrigerating, and Air-conditioning Engineers (ASHRAE), Inc., Standard 52, "Gravimetric and Dust Spot Procedures for Testing Air Cleaning Devices Used in General Ventilation for Removing Particulate Matter," 1992 edition. 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. 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) Location of multiple filters. When two filter beds are required by Table 2 of §135.54(b) of this title, filter bed No. 1 shall be located upstream of the air-conditioning equipment, and filter bed No. 2 shall be located downstream of the supply fan or blowers.

(II) Location of single filters. Where only one filter bed is required by Table 2 of §135.54(b) of this title, it shall be located upstream of the cooling and heating coils.

(III) Duct linings. Friable internal linings shall not be used in ducts, air terminal units, or other air system components supplying operating rooms and post anesthesia recovery rooms unless terminal filters of at least 90% efficiency are installed downstream of linings. This requirement shall not apply to air terminal units and sound attenuators that have approved nonfriable coverings, e.g., foil facing, over such linings.

(xi) Pressure monitoring devices. A manometer or draft gauge shall be installed across each filter bed having a required efficiency of 75% or more, including laboratory hoods requiring high efficiency particulate air (HEPA) filters.

(xii) Ventilation for anesthetizing locations. Ventilation for anesthetizing locations (defined in NFPA 99, §2-2) shall comply with NFPA 99, §5.4.1 and the requirements of subclauses (I) and (II) of this clause.

(I) Smoke removal systems for anesthetizing locations (surgical suites). Supply and exhaust systems for windowless anesthetizing locations shall be arranged to automatically exhaust smoke and products of combustion, prevent recirculation of smoke originating within the surgical suite, and prevent the circulation of smoke entering the system intakes, without in either case interfering with the exhaust function of the system as required by NFPA 99, §5-4.1.3.

(II) Smoke exhaust grilles. Exhaust grilles for smoke evacuation systems shall be ceiling-mounted or on the wall near the ceiling.

(D) Thermal and acoustical insulation for air handling systems. Asbestos containing insulation materials shall not be used.

(i) Thermal duct insulation. Air ducts and casings with outside surface temperature below the ambient dew point or temperature above 80 degrees Fahrenheit shall be provided with thermal insulation.

(ii) Insulation in air plenums and ducts. When installed, linings in air ducts and equipment shall meet the Erosion Test Method described in Underwriters' Laboratories, Inc., Standard 181, "Factory-Made Duct Materials and Air Duct Connectors." 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 2 and 3 and as determined by an independent testing laboratory in accordance with NFPA 255, A Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 edition.

(iv) Friable 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 or occupant discomfort.

(6) Piping systems and plumbing fixture requirements. All piping systems and plumbing fixtures shall be designed and installed in accordance with the requirements of the Uniform Plumbing Code, 1997 Edition, published by the International Conference of Building Officials, 5360 Workman Mill Road, Whittier, California 90601, telephone (562) 699-0541; or the Standard Plumbing Code, 1997 edition, published by the Southern Building Code Congress International, Inc., 900 Montclair Road, Birmingham, Alabama 35213-1206, telephone (205) 591-1853.

(A) Water supply piping systems. Water supply 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 valved. Stop valves shall be provided at each fixture.

(ii) Backflow preventers. Backflow preventers (vacuum breakers) shall be installed on hose bibs, laboratory sinks, janitor sinks, bedpan flushing attachments, and on all other fixtures to which hoses or tubing can be attached. Connections to high hazard sources, e.g., x-ray film processors, shall be from a cold water hose bibb through a reduced pressure principle type backflow preventer (RPBFP).

(iii) Flushing valves. Flush valves installed on plumbing fixtures shall be of a quiet operating type, equipped with silencers.

(iv) Water storage tanks. Water storage tanks shall be fabricated of corrosion-resistant metal or lined with noncorrosive material.

(B) Fire sprinkler systems. When provided, fire sprinkler systems shall comply with the requirements of NFPA 101, §9.7 "Automatic Sprinklers and Other Extinguishing Equipment" and the requirements of this clause. All fire sprinkler systems shall be designed, installed, and maintained in accordance with the requirements of NFPA 13, "Standard for the Installation of Sprinkler Systems," 1999 edition, and shall be certified as required by §135.53(e)(4) of this title (relating to Preparation, Submittal, Review, and Approval of Plans).

(C) Piped nonflammable medical gas and clinical vacuum systems. When provided, piped nonflammable medical gas and clinical vacuum system installations shall be designed, installed and certified in accordance with the requirements of NFPA 99, §4-3 for "Level 1 Piped Systems" and the requirements of this subparagraph.

(i) Outlets. Nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 3 of §135.54(c) 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 tests and inspections by a party, other than the installer, shall be conducted by individuals who are technically competent and experienced in the field of piped medical gas systems.

(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 a system shall be repaired with all new 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 at 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) Written certification. Written certification for piped medical gas and 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. The certification shall document compliance with NFPA 99 and the integrity of the completed system. The written certification shall be submitted directly to the ASC and the installer. A copy shall be available at final department construction inspection.

(x) Facility responsibility. Before new piped medical gas systems, additions, renovations, or repaired portions of an existing system are put into use, ASC medical personnel shall verify that the gas delivered at the outlet corresponds with labeling required at each outlet.

(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 (e.g., oxygen, vacuum, medical air, nitrogen, nitrous oxide) shall be documented and arranged tabularly by room numbers and room types.

(D) 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, §4-3.3.

(7) Steam and hot water systems.

(A) Boilers. When provided, boilers shall have the capacity, based upon the net ratings published by the Hydronics Institute or another acceptable national standard, to supply the normal heating, hot water, and steam requirements of all systems and equipment.

(i) 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.

(ii) Boiler certification. When required, the ASC shall ensure compliance with Texas Department of Licensing and Regulation, Boiler Section, Texas Boiler Law, 1995 (Health and Safety Code, Chapter 755, Boilers), which requires certification documentation for boilers to be posted on site at each boiler installation.

(B) Domestic hot water system. Hot water distribution system serving all patient care areas shall be under constant recirculation to provide continuous hot water at each hot water outlet.

(i) Capacity of water heating equipment. Water heating equipment shall have sufficient capacity to supply water for all clinical needs based on accepted engineering practices using actual number and type of fixtures and for heating, when applicable.

(ii) Water temperature measurements. Water temperatures shall be measured at hot water point of use or at the inlet to processing equipment. Hot water temperature at point of use for patients, staff and visitors shall not exceed 110 degrees Fahrenheit.

(8) Drainage systems. Building sewers shall discharge into a community sewage system. Where such a system is not available, a facility providing sewage treatment must conform to applicable local and state regulations.

(A) Above ground piping. Soil stacks and roof drains 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 Schedule 40 polyvinyl chloride (PVC) pipe. Buildings or portions of buildings remodeled to an ASC need not comply with this requirement.

(B) Underground piping. All underground building drains shall be cast iron soil pipe, hard temper copper tube (DWV or heavier), acrylonitrile-butadiene-styrene (ABS) plastic pipe (DWV Schedule 40 or heavier), or PVC pipe (DWV Schedule 40 or heavier). Underground piping shall have at least 12 inches of earth cover or comply with local codes. Existing building or portions of buildings that are being remodeled need not comply with this subparagraph.

(C) 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 borosilicate glass pipe, high silicone content cast iron pipe, polypropylene plastic pipe, or plastic lined pipe.

(9) Thermal insulation for piping systems and equipment. Asbestos containing insulation materials shall not be used.

(A) Insulation. 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; and

(v) other piping, ducts, and equipment as necessary to maintain the efficiency of the system.

(B) Flame spread. Flame spread shall not exceed 25 and smoke development rating shall not exceed 50 for pipe insulation as determined by an independent testing laboratory in accordance with NFPA 255, "Standard Method of Test of Surface Burning Characteristics of Building Materials," 2000 edition.

(10) Plumbing fixtures. Plumbing fixtures shall be made of nonabsorptive, acid resistant materials and shall comply with the requirements of the Uniform Plumbing Code, 1997 edition, and this paragraph.

(A) Sink and lavatory controls. All lavatories used by medical and nursing staff and by patients shall be trimmed with valves or electronic controls 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 also be used.

(B) Clinical sink traps. Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

(C) Sinks for disposal of plaster of paris. Sinks that are used for the disposal of plaster of paris shall have a plaster trap.

(D) 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.

(E) 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 and in compliance with the American Disabilities Act.

(F) 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.

(G) 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.

(H) Bedpan washers and sterilizers. When provided, 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.

(I) Flood level rim clearance. The water supply spouts 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.

(J) Scrub sink controls. Freestanding scrub sinks and lavatories used for scrubbing in procedure rooms shall be trimmed with foot, knee, or electronic hands-free controls. Single lever wrist blades are not acceptable at scrub sinks.

(K) 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 a grilled drain cover to prevent entry of large particles of waste which might cause stoppages.

(L) Under counter piping. Under counter piping and above floor drains shall be arranged (raised) so as not to interfere with cleaning of the floor below the equipment.

(11) Moisture sensor. A moisture sensor with remote indicator light or drainage system shall be provided for the drain pans located beneath the plumbing lines above operating rooms.

(i) Electrical requirements. All electrical material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of the NFPA 70, "National Electrical Code," 1999 edition, §517-50; NFPA 99, Chapter 13; the requirements of this subsection; 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 manufacturer's instructions.

(1) All fixtures, switches, sockets, and other pieces of apparatus shall be maintained in a safe and working condition.

(2) Extension cords and cables shall not be used for permanent wiring.

(3) 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.

(4) All equipment, fixtures, and appliances shall be properly grounded in accordance with NFPA 70.

(5) Under-counter electrical installations shall be arranged (raised) to not interfere with cleaning of the floor below the equipment.

(6) Installation testing and certification.

(A) Installation testing. The electrical installations, including grounding continuity, fire alarm, nurses calling system and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional. A written record of performance tests on special electrical systems and equipment must show compliance with applicable codes and standards and shall be available to the department upon request.

(B) Installation certification. Certifications, in affidavit form, signed by a registered electrical engineer attesting that the electrical service, electrical equipment, and electrical appliances have been installed in compliance with the approved plans and applicable standards, shall be submitted to the department upon request.

(7) 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.

(8) Services and switchboards. Main switchboards shall be located in an area separate from plumbing and mechanical equipment and shall be accessible to authorized persons only. Switchboards shall be convenient for use, readily accessible for maintenance, away from traffic lanes, and located in dry, ventilated spaces free of corrosive or explosive fumes, gases, or any flammable material. Overload protective devices must operate properly in ambient temperatures.

(9) Panelboard. Distribution panels containing circuit breakers which control lighting and power to essential and normal electrical circuits shall be located within the ASC.

(10) Wiring. All conductors for controls, equipment, lighting and power operating at 100 volts or higher shall be installed in metal or metallic raceways 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.

(11) Lighting.

(A) 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 (IES) Handbook published by the Illuminating Engineering Society of North America, 120 Wall Street, New York, NY 10005.

(i) Consideration should be given to controlling light intensity and wavelength to prevent harm to the patient's eyes.

(ii) Approaches to buildings and parking lots, and all spaces within buildings shall have fixtures that can be illuminated as necessary. All rooms including storerooms, electrical and mechanical equipment rooms, and all attics shall have sufficient artificial lighting so that all 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.

(B) Means of egress and exit sign lighting intensity shall comply with NFPA 101, §§7.8, 7.9, and 7.10.

(C) 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.

(D) Ceiling mounted surgical and examination light fixtures shall be suspended from rigid support structures mounted above the ceiling.

(E) Operating rooms shall have general lighting in addition to local lighting provided by special lighting units at the surgical tables. Each fixed special lighting unit at the tables, except for portable units, shall be connected to an independent circuit.

(F) X-ray film illuminators for handling at least two films simultaneously shall be provided in each operating room and special procedure room.

(12) Receptacles. Only listed hospital grade grounding receptacles shall be used in the operating rooms and post-operative recovery suite. This does not apply to special purpose receptacles.

(A) Installations of multiple ganged receptacles shall not be permitted in patient care areas.

(B) All receptacles powered from the critical branch shall be colored red.

(C) 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.

(D) 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.

(E) Each receptacle shall be grounded to the reference grounding point by means of a green insulated copper equipment grounding conductor in accordance with NFPA 70, §517-13.

(F) Each operating room and special procedure room shall have at least four duplex receptacles located convenient to the head of the procedure table and one receptacle on the other walls.

(G) Appliances shall be grounded in accordance with NFPA 99, Chapter 9.

(H) A minimum of one duplex receptacle in each wall shall be installed in each work area or room other than storage or lockers. Each examination and work table shall have access to a minimum of two duplex receptacles.

(13) Equipment.

(A) The following shall be powered from the Type I essential electrical system in accordance with the requirements of NFPA 99, §3-4.2.2.3 when such a system is required for safe operation of the ASC referenced in paragraph (17) of this subsection.

(i) Boiler accessories including feed pumps, heat-circulating pumps, condensate return pumps, fuel oil pumps, and waste heat boilers shall be connected to the equipment system.

(ii) Ventilating system serving preoperative areas, operating rooms, and the post-operative recovery suite shall be connected to the equipment system in accordance with the requirements of NFPA 99, Chapter 3.

(B) Laser equipment shall be installed according to manufacturer recommendations and shall be registered with Radiation Control, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.

(C) A "kill switch" shall be provided for disconnection of each HVAC serving the building.

(14) Wet patient care location. Wet patient care locations shall be protected against shock in accordance with the requirements of NFPA 99, §3-3.2.1.2(f).

(15) Grounding requirements. Fixed electrical equipment shall be grounded in accordance with the requirements of NFPA 99, §3.3.2.1.2 and NFPA 70, Article 517-13.

(16) Nurses calling systems.

(A) A nurse 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 an audible signal which repeats every five seconds at a staffed location and shall activate a distinct visible signal outside of toilet room where the call originated. The visible and audible signals shall be cancelable only at the patient calling station. Activation of the system shall also activate

distinct visible signals in the clean workroom, in the soiled workroom, and if provided, in the nourishment station.

(B) A staff emergency assistance calling system station shall be located in each operating room, treatment room, examination room, post-operative recovery and preoperative holding area to be used by staff to summon additional help in an emergency. Activation of the system shall sound an audible signal at a staffed location, indicate type and location of call on the system monitor and activate a distinct visible signal in the corridor at the door. Additional visible signals shall be installed at corridor intersections in multi-corridor facilities. Distinct visible and audible signals shall be activated in the clean workroom, in soiled workroom, and if provided, in the nourishment station.

(17) Essential electrical system. The essential electrical system shall comply with the requirements of NFPA 99, §13-3.3.2.

(A) A Type 1 essential electrical system shall be installed, maintained and tested in each ASC in accordance with requirements of NFPA 99, §3-4; NFPA 101, §20.2.9; and National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 1999 edition.

(i) All autoclaving/sterilizing equipment shall be connected to the emergency power system.

(ii) One electrical outlet connected to the life safety branch of the electrical system shall be provided adjacent to (or on) the emergency generator.

(iii) The battery charger for emergency lighting at the emergency generator shall be connected to the life safety branch of the electrical system.

(B) Fuel storage capacity for an on-site generator for a Type 1 essential electrical system shall allow continuous operation, under full load for eight hours and six months of testing as required by NFPA 99, §3-4.4.1.1(b).

(18) Fire alarm system. A fire alarm system which complies with the requirements of NFPA 101, §20.3.4; NFPA 70, Article 760; and NFPA 72, Chapter 3 requirements, shall be provided in each ASC.

(A) Fire alarm system shall be installed by or under direct supervision of a fire alarm installer licensed by the State Fire Marshal.

(B) The ASC shall submit a copy of the Fire Alarm Installation Certificate (State Fire Marshal's form FML 009 040392) to the department for all new installations and for any material changes to the existing systems.

§135.53. Preparation, Submittal, Review, and Approval of Plans.

(a) General.

(1) ASC owners or operators may not begin construction of a new building or additions to or renovations or conversions of existing buildings until final construction documents are reviewed and approved by the department.

(2) Before the department will perform a plan review for a new ASC, the ASC owner or operator shall submit a license application and license fee in accordance with §135.20 of this title (relating to Application and Issuance of License for Initial Applicants).

(3) Plans and specifications describing the construction of new buildings and additions to or renovations and conversions of existing buildings shall be prepared by design professionals.

(4) Preliminary documents shall be prepared and submitted in accordance with subsection (b) of this section.

(5) Construction documents shall be prepared and submitted in accordance with subsection (c) of this section.

(6) When construction is delayed for longer than one year from the plan 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.

(7) Department files will be closed after one year from the date of receipt of plans for projects which have been placed on hold.

(8) The licensee or the owner shall notify the department in writing when a project has been canceled or abandoned.

(b) Preliminary documents. Preliminary documents shall consist of a functional program narrative, preliminary plans, and outline specifications. These 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, services, and the usage of all spaces, areas, and rooms on every floor level.

(1) Functional program narrative. The narrative shall be prepared by medical professionals and presented on ASC letterhead. The narrative shall describe the medical procedure(s) to be performed, staffing, patient types, hours of operation, function and space relationships, transfer provisions and availability of offsite services, and the scope of the project, type of construction (existing or proposed) as stated in National Fire Protection Association 101, Life Safety Code, 2000 edition (NFPA 101), §20.1.6, published by the National Fire Protection Association (NFPA), functional description of each space (may be shown on plans), energy conservation measures included in building, mechanical and electrical designs. 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) Preparation of preliminary plans. Preliminary plans shall be of a sufficiently large scale to clearly illustrate the proposed design but not less than one-eighth inch equals one foot. Preliminary plans shall provide the following information.

(A) Area map. A map of the area within a 500 foot radius of the ASC site shall be provided and any hazardous and undesirable location noted in §135.52(a)(3) and (4) of this title (relating to Construction Requirements for New Ambulatory Surgical Centers) shall be identified.

(B) Site plan. A site plan shall be submitted and shall indicate the location of the proposed building(s) in relation to property lines, existing buildings or structures, access and approach roads, and parking areas and drives. Any overhead or underground utilities or service lines shall also be indicated. Any extreme variations in grade shall be indicated.

(C) Floor plans.

(i) New facilities. Each floor plan shall indicate and identify all individual spaces, doors, windows and means of egress. The total floor area on each level involved in construction shall be shown on the drawings. Each smoke compartment area shall be calculated and shown.

(ii) Existing facilities. An overall floor plan showing existing spaces, smoke partitions, smoke compartments, and exits and their relationship to the new construction shall be submitted on all renovations or additions to an existing facility. Plans for remodeling of spaces above or below the level of discharge shall include the level of discharge floor plan which shows all exits at that level. When there are two different levels of discharge, plans for both levels shall be submitted.

(D) Construction type and fire rating. Building sections shall be provided to illustrate construction type and fire protection rating. Section(s) shall be drawn at a scale sufficiently large to clearly present the proposed construction system.

(E) Outline specifications. Outline specifications shall contain a general description of the construction; materials; and finishes not shown on the drawings; type of heating, ventilation and air conditioning system; and type of essential electrical system.

(3) Submission of preliminary plans. One set of preliminary plans and outline specifications covering the construction of new buildings, additions, or renovations to existing buildings, a functional program narrative, and an Application for Plan Review shall be submitted to the Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 for review and approval. For convenience, preliminary plans may be of a reduced size or scale.

(4) Preliminary plan review. All deficiencies noted in the preliminary plan review shall be satisfactorily resolved. Written department approval of preliminary plans must be obtained prior to proceeding with final plans and specifications. This requirement also applies to fast-track projects.

(c) Construction documents. Construction documents or final plans and specifications shall be submitted to the department for review and approval prior to the start of construction. All final plans and specifications shall be appropriately sealed and signed by a registered architect and professional engineers licensed by the State of Texas.

(1) Preparation of 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 NFPA 20, "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 rooms shall be identified by usage 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 site plan showing all new topography, newly established levels and grades, existing structures on the site (if any), new buildings and structures, roadways, walks, 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;

(ii) a plan of each floor and roof with identification of all spaces;

(I) when a new ASC is to be located above the ground floor (above level of exit discharge) of a multi-story building, whether new or existing, a floor plan of the entire floor containing the ASC and every floor below shall be submitted. These floor plans shall clearly show exits, such as stairs, to grade discharge. A roof plan shall also be submitted for the building; and

(II) when an existing ASC which is located above the ground floor (level of exit discharge) is to be remodeled and/or expanded, then only the plan of that floor and a plan of the floor of exit discharge need be submitted;

(iii) schedules of doors, windows, and finishes;

(iv) elevations of each facade;

(v) sections through building; and

(vi) scaled details as necessary.

(B) Fire safety plans. Fire safety plans shall be provided in addition to the architectural floor plan(s) for all newly constructed or renovated ASCs. 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 indicating the designated smoke compartments required by NFPA 101, §20.3.7, location of fire rated walls, location and fire resistance rating of each fire and smoke damper, and the required means of egress (corridors, stairs, exits, exit passageways);

(ii) 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

(iii) 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 that is necessary for the operation of the ASC as planned. The design shall indicate provisions for the installation of large and special items of equipment and for service accessibility;

(ii) fixed 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 sterilizers, 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, expansion joints;

and

(vi) special openings and pipe sleeves dimensioned or otherwise noted for easy reference.

(E) Mechanical drawings. Documentation for selection of the type of heating and cooling system based on requirements contained in §135.52(h)(1) of this title (relating to Construction Requirements for New Ambulatory Surgical Centers) shall be included with the mechanical plans. 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 name identification of all spaces;

(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), and special piping systems such as for deionized water;

(iv) nonflammable medical gas piping (oxygen, compressed medical air, vacuum systems, nitrous oxide), emergency shut-off 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 if used);

(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;

(iii) light fixtures marked distinctly to indicate connection to critical or life safety branch circuits or to normal lighting circuits;

(iv) outlets marked distinctly to indicate connection to critical, life safety or normal power circuits;

(v) telephone and communication, fixed computers, terminals, connections, outlets, and equipment;

(vi) nurses calling system showing all stations, signals, and annunciators on the plans;

(vii) 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 ASCs, and remodeled portions of existing ASCs. Feeder and conduit sizes shall be shown with a schedule of feeder breakers or switches; and

(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); and

(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

(viii) schedules of all panels indicating connection to life safety branch, critical branch, equipment system or normal system, and connected load at each panel.

(2) Correction of final plan deficiencies. All deficiencies noted in the final plan review shall be satisfactorily resolved before approval of project for construction will be granted.

(3) Construction approval. Construction shall not begin until written approval by the department is received by the owner of the ASC.

(4) Construction document changes. Any changes to 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.

(d) Special submittals.

(1) Designer certification. In an effort to shorten the plan review and approval process, design professionals may submit, at the discretion of the department, a set of final construction documents, the department's completed checklist of licensing requirements and a certification letter which states that the plans and specifications, based on the department's checklist comply with the requirements of this chapter. Project certification letter and checklist shall be signed by the architect and engineer(s) of record.

(2) Fast-track projects. Submittal of fast-track projects shall be at the discretion of the department and shall be submitted in not more than three separate packages. Each package shall be approved by the department before construction is begun on that package.

(A) First package. The first package shall include:

(i) a map showing the location of the proposed site and the adjacent surrounding area, at least two miles in radius, which identifies any hazardous and undesirable location noted in §135.52(a)(3) of this title;

(ii) 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

(iii) 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 (c)(1)(A) and (c)(1)(B) 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 (c)(1)(E)-(F) of this section.

(3) Fire sprinkler systems. Fire sprinkler systems, when provided, shall comply with the requirements of NFPA 13, "Standard for the Installation of Sprinkler Systems," 1999 edition. Fire sprinkler systems shall be designed or reviewed by an engineer who is registered by

the Texas State Board of Registration for 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.

(A) Fire sprinkler working plans, complete hydraulic calculations and water supply information shall be prepared in accordance with NFPA 13, §§8.1, 8.2, and 8.3, for new fire sprinkler systems, alterations of and additions to existing systems.

(B) Installation certification of changes to an existing system is not required when such change involves only the relocation of fewer than 20 heads.

(C) One set of fire sprinkler working plans (sealed by the engineer), calculations and water supply information shall be forwarded to the department together with the engineer's certification letter stating that the sprinkler system design complies with the requirements of NFPA 13. Certification of the fire sprinkler system design shall be submitted prior to system installation.

(e) Construction and inspections.

(1) Major construction. Construction, of other than minor alterations, shall not commence until the final plan review deficiencies have been satisfactorily resolved, the appropriate licensing fee 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 of an existing ASC, adequate provision shall be made for the safety and comfort of occupants during construction.

(2) Construction commencement notification. The architect of record shall provide written notification to the department when construction will commence.

(3) Completion. Construction shall be completed in compliance with the construction documents including all addenda or modifications approved for the project.

(4) Certification of sprinkler system installations. 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.

(5) Construction inspections. The department shall determine the number of required inspections necessary to complete all proposed construction projects. Normally, a minimum of two construction inspections of the project shall be scheduled for the purpose of verifying compliance with requirements contained in §135.51 of this title (relating to Construction Requirements for an Existing Ambulatory Surgical Centers) and §135.52 of this title and the approved plans and specifications.

(A) Intermediate and final inspections shall be requested only by the architect of record or the licensee by the submission of an "Application for Construction Inspection" form supplied by the department. The department must receive such request for inspections at least three weeks prior to the requested inspection date. To save time, these inspection request forms may be faxed to the department. Inspection requests by contractors will not be honored.

(i) The intermediate construction inspection shall be requested at approximately 80% completion. All major work above the ceiling shall be essentially completed at the time of the intermediate inspection but ceilings should not yet be installed.

(ii) The final construction inspection shall be requested by the architect of record or the licensee 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. Requests for final inspections shall follow the same procedure as noted above for the 80% intermediate inspection.

(B) During the final construction inspection by the department, the inspector will determine if the project can be approved for patient occupancy. If the inspector finds that it cannot be approved for occupancy, the facility will have to schedule another final inspection after corrections are made. If the inspector finds only a few minor deficiencies which do not jeopardize patient health, safety and welfare, the inspector may approve the project for occupancy based on an acceptable written "Plan of Correction" signed by the licensee. Depending on the number and nature of the deficiencies cited in a "Plan of Correction," the inspector may require that a "follow-up" reinspection be conducted to confirm correction of all deficiencies cited.

(6) Approval for occupancy. Patients shall not occupy a new structure or a remodeled or renovated space until the appropriate approval has been received from the local building and fire authorities and until all required documentation has been received by the department.

(7) Resubmittal of construction documents. When construction is delayed for longer than one year from the plan 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.

(8) Project cancellation. The licensee or the owner shall notify the department in writing when a project has been canceled or abandoned.

§135.54. Construction Tables.

(a) Table 1. Ventilation and Pressure Relationship Requirements.

VENTILATION AND PRESSURE RELATIONSHIP REQUIREMENTS ¹					
Area designation	Pressure relationship to adjacent areas ²	Minimum 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
Operating room	P	3	15	---	No
Examination, treatment and pre-op rooms	V	---	6	---	---
Post-anesthesia recovery	P	2	6	---	No
Medication room	P	---	4	---	---
Pharmacy	P	---	4	---	---
Radiology	E	---	6	---	---
Darkroom	N	---	10	Yes	---
Soiled workroom or soiled holding	N	---	10	Yes	No
Clean workroom or clean holding	P	---	4	---	---
Toilet room	N	---	10	Yes	No
Bathroom	N	---	10	Yes	No
Janitor's closet	N	---	10	Yes	No
Sterilizer equipment room	N	---	10	Yes	No
Linen and trash chute room	N	---	10	Yes	No
Laboratory	N	---	6	---	---
Soiled linen sorting and storage	N	---	10	Yes	No
Clean linen storage	V	---	2	---	---
Anesthesia storage	V	---	8	Yes	No
Decontamination room	N	---	6	Yes	No
Equipment storage	V	---	2	---	---

Notes applicable to Table 1:
"Ventilation and Pressure Relationship Requirements"

¹ The ventilation rates in this table cover ventilation for comfort, as well as for asepsis and odor control in areas of acute care that directly affect patient care and are determined based on healthcare 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 Standard 62-1989, Ventilation for Acceptable Indoor Air Quality, and American Society of Heating Refrigeration and Air-conditioning Engineers, Handbook of Applications, 1991 edition. Specialty procedure rooms 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. Required pressure relationship of the different space with respect to adjacent areas is indicated by the following:

P = positive pressure relationship with respect to adjacent areas
N = negative pressure relationship with respect to adjacent areas
E = equal pressure relationship with respect to adjacent areas
V = pressure relationship with respect to adjacent areas may vary

If any form of variable air volume or load shedding system is used for energy conservation, it must not compromise the minimum air changes required by the table.

³ To satisfy exhaust needs, replacement air from the outside is necessary. Table 1 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.

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 pressure relationship shall remain the same when the number of air changes is reduced. Areas not indicated as requiring either a positive or negative pressure relationship with adjacent areas 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 pressure balancing relationships are not compromised.

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.

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." Gravity-type heating or cooling units such as radiators or convectors shall not be used in operating rooms and other special care areas.

(b) Table 2. Filter Efficiencies for Ventilation and Air Conditioning Systems.

FILTER EFFICIENCIES FOR VENTILATING AND AIR CONDITIONING SYSTEMS			
Area Designation	Minimum number of filter beds	Filter efficiencies (%)*	
		Filter bed No. 1	Filter bed No. 2
Operating, recovery, and treatment rooms	2	30	90
Laboratories	1	80	---
All other areas	1	30	---

* The filter efficiency ratings are based on American Society of Heating Refrigeration and Air Conditioning Engineers, Standard 52-92.

(c) Table 3. Station outlets for Oxygen, Vacuum (Suction), and Medical Air Systems.

STATION OUTLETS FOR OXYGEN, VACUUM (SUCTION), AND MEDICAL AIR SYSTEMS			
Location	Number of outlets*		
	Oxygen	Vacuum	Medical Air
Operating room	2	3	1
Treatment room	1	1	---
Recovery room	1	3	---
Decontamination room	---	1	1

* Number of outlets required for each recovery bed location or treatment unit.

(d) Table 4. Flame Spread and Smoke Production Limitations for Interior Finishes

FLAME SPREAD AND SMOKE PRODUCTION LIMITATIONS FOR INTERIOR FINISHES		
	Flame Spread Rating	Smoke Production Rating
Walls and Ceilings – Exitways, storage rooms, and areas of unusual hazard	25 or less ASTM STD E84	450 or less ¹ NFPA 255
All other areas	75 or less ASTM STD E84	450 or less NFPA 255
Floors ²	Minimum of 0.45 watts/cm ² (NFPA 253, Floor Radiant Panel Test)	

¹ Average of flaming and non flaming values.

² See §135.52(c)(4) of this title (relating to Construction Requirements for New Ambulatory Surgical Centers 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.