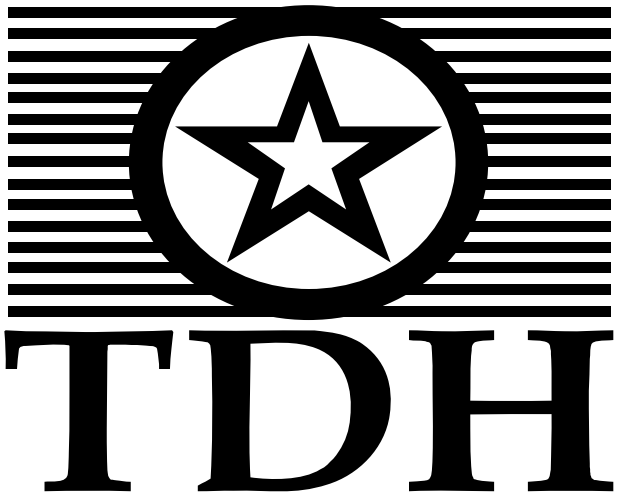

End Stage Renal Disease Facilities Licensing Rules

25 TAC §117.1 - 117.86

Effective February 1, 2006

THE TEXAS DEPARTMENT OF HEALTH
HEALTH FACILITY LICENSING
AND COMPLIANCE DIVISION

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25 Texas Administrative Code

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§117.1. Purpose.

(a) The purpose of this chapter is to implement Health and Safety Code, Chapter 251, which requires an end stage renal disease facility providing routine, repetitive, outpatient dialysis to be licensed by the Texas Department of Health.

(b) This chapter provides minimum standards for the design and space requirements; equipment used by the facility; water treatment and reuse; sanitary and hygienic conditions; quality assurance for patient care; indicators of quality care; provision and coordination of treatment and services; qualifications and supervision of the professional staff, including physicians and other personnel; clinical records; curricula and instructors used to train dialysis technicians; and the competency evaluation of dialysis technicians.

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

§117.2. Definitions.

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

(1) Action level--The point at which steps should be taken to interrupt the trend towards unacceptable levels.

(2) Advanced practice nurse--A registered nurse approved by the Board of Nurse Examiners for the State of Texas to practice as an advanced practice nurse.

(3) Administrator--A person who is delegated the responsibility for the implementation and proper application of policies, programs, and services established for the end stage renal disease facility.

(4) Affiliate--An applicant or owner which is:

(A) a corporation--includes each officer, consultant, stockholder with a direct ownership of at least 5.0%, subsidiary, and parent company;

(B) a limited liability company--includes each officer, member, and parent company;

(C) an individual--includes:

(i) the individual's spouse;

(ii) each partnership and each partner thereof of which the individual or any affiliate of the individual is a partner; and

(iii) each corporation in which the individual is an officer, consultant, or stockholder with a direct ownership of at least 5.0%;

(D) a partnership--includes each partner and any parent company; and

(E) a group of co-owners under any other business arrangement--includes each officer, consultant, or the equivalent under the specific business arrangement and each parent company.

(5) Applicant--The owner of an end stage renal disease facility which is applying for a license under the statute. This is the person in whose name the license is issued.

(6) Biofilm--A coating on surfaces consisting of microcolonies of bacteria embedded in a protective extracellular matrix. The matrix, a slimy material secreted by the cells, protects the bacteria from antibiotics and disinfectants.

(7) Board--The Texas Board of Health.

(8) Change of ownership--A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership and the tax identification number of the partnership changes; or a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons and the tax identification number of the corporation changes.

(9) Charge nurse--A registered professional nurse practicing nursing in accordance with applicable provisions of law who is responsible for making daily staff assignments based on patient needs, providing immediate supervision of patient care, monitoring patients for changes in condition, and/or communicating with the physician, dietician, and social worker regarding patient needs.

(10) Commissioner--The commissioner of health.

(11) Competency--The demonstrated ability to carry out specified tasks or activities with reasonable skill and safety that adheres to the prevailing standard of practice.

(12) Core staff members--The facility's medical director, supervising nurse, dietitian, social worker, administrator, and chief technician.

(13) Corrective action plan--A written strategy for correcting a licensing violation. The corrective action plan is developed by the facility and addresses the system(s) operation(s) of the facility as the system(s) operation(s) applies to the deficiency.

(14) Delegation--The transfer to a qualified and properly trained individual of the authority to perform a selected task or activity in a selected situation.

(15) Department--The Texas Department of Health.

(16) Dialysate--An aqueous fluid containing electrolytes and usually dextrose, which is intended to exchange solutes with blood during hemodialysis. The word "dialysate" is used throughout this document to mean the fluid made from water and concentrate which is delivered to the dialyzer by the dialysate supply system. Such phrases as "dialyzing fluid" or "dialysis solution" may be used in place of dialysate. It does not include peritoneal dialysis fluid.

(17) Dialysate supply system--Devices that prepare dialysate on line from water and concentrates or store and distribute premixed dialysate; circulate the dialysate through the dialyzer; monitor the dialysate for temperature, conductivity, pressure, flow and blood leaks; and prevent dialysis during disinfection or cleaning modes. The term includes reservoirs; conduits; proportioning devices for the dialysate; and monitors, associated alarms, and controls assembled as a system for the characteristics listed above. The dialysate supply system is often an integral part of single-patient dialysis machines.

(18) Dialysis--A process by which dissolved substances are removed from a patient's body by diffusion, osmosis and convection (ultrafiltration) from one fluid compartment to another across a semipermeable membrane.

(19) Dialysis technician--An individual who is not a registered nurse or physician and who provides dialysis care under the direct supervision of a registered nurse or physician. If unlicensed, this individual may also be known as a patient care technician.

(20) Dietitian--A person who is currently licensed under the laws of this state to use the title of licensed dietitian, is eligible to be a registered dietitian, and has one year of experience in clinical dietetics after becoming eligible to be a registered dietitian.

(21) Director--The director of the Health Facility Licensing and Compliance Division of the department or his or her designee.

(22) Empty bed contact time (EBCT)--A measure of how much contact occurs between particles, such as activated carbon, and water as the water flows through a bed of the particles.

(23) End stage renal disease--That stage of renal impairment that appears irreversible and permanent and that requires a regular course of dialysis or kidney transplantation to maintain life.

(24) End stage renal disease (ESRD) facility--A facility that provides dialysis treatment or dialysis training to individuals with end stage renal disease.

(25) Full-time--The time period established by a facility as a full working week, as defined and specified in the facility's policies and procedures.

(26) Full-time equivalent--Work time equivalent to 2,080 hours per 12 consecutive months.

(27) Health care facility--Any type of facility or home and community support services agency licensed to provide health care in any state or is certified for Medicare (Title XVIII) or Medicaid (Title XIX) participation in any state.

(28) Governing body--An identified group, which includes the medical director and a representative(s) of the owner of the facility, with full legal authority and responsibility for the governance and operation of the facility.

(29) Hospital--A facility that is licensed under the Texas Hospital Licensing Law, Health and Safety Code, Chapter 241, or if exempt from licensure, certified by the United States Department of Health and Human Services as in compliance with conditions of participation for hospitals in Title XVIII, Social Security Act (42 United States Code, §1395 et seq.).

(30) Interdisciplinary team--A group composed of the primary physician, the registered nurse, the dietitian and the social worker who are responsible for planning care for the patient.

(31) Intermediate level disinfection--A surface treatment using chemical germicides or disinfectants which are capable of inactivating various classes of microorganisms including, but not limited to, viruses (primarily medium to large viruses and lipid-containing viruses), fungi, and actively growing bacteria (including tubercle bacteria) when such chemical germicides or disinfectants are used in accordance with the manufacturer's instructions or per established guidelines. Intermediate level disinfection is generally not effective in inactivating or eliminating bacterial endospores. Examples of intermediate level disinfectants include bleach, 70-90% ethanol or isopropanol, and certain phenolic or iodophor preparations.

(32) Inspection--An investigation or survey conducted by a representative of the department to determine if an applicant or licensee is in compliance with this chapter.

(33) LAL (Limulus Amoebocyte Lysate) test--An assay used to detect endotoxin which exploits the immune response of the horse shoe crab (Limulus polyphemus).

(34) Licensed nurse--A registered nurse or licensed vocational nurse.

(35) Licensed vocational nurse (LVN)--A person who is currently licensed under Texas Civil Statutes, Article 4528c to use the title licensed vocational nurse and who may provide dialysis treatment after meeting the competency requirements specified for dialysis technicians.

(36) Manager--An individual approved or selected by the department who assumes overall management of an end stage renal disease facility to ensure adequate and safe services are provided to patients.

(37) Medical director--A physician who:

(A) is board eligible or board certified in nephrology or pediatric nephrology by a professional board; or

(B) during the five-year period prior to September 1, 1996, has served for at least 12 months as director of a dialysis program.

(38) Medical review board (MRB)--A medical review board that is appointed by a renal disease network organization which includes this state, with the network having a contract with the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services under 42 United States Code §1395rr.

(39) Monitor--An individual approved or selected by the department who observes, supervises, consults, and educates a facility to correct identified violations of the statute or this chapter.

(40) Notarized copy(ies)--A sworn affidavit stating that attached copy(ies) is a true and correct copy(ies) of the original documents.

(41) Owner--One of the following which holds or will hold a license issued under the statute in the person's name or the person's assumed name:

(A) a corporation;

(B) a limited liability company;

(C) an individual;

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

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

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

(42) Patient--An individual receiving dialysis treatment or training from an end stage renal disease facility.

(43) Patient care plan--Documentation of the interactive process whereby the interdisciplinary team and the patient and/or family member or guardian develop a plan to assist the end stage renal disease patient in managing the disease and its complications.

(44) Pediatric patient--An individual 18 years of age or younger under the care of a facility.

(45) Person--An individual, corporation, or other legal entity.

(46) Physician--An individual who is licensed to practice medicine under the Medical Practice Act, Texas Civil Statutes, Article 4495b.

(47) Physician assistant--A person who is licensed as a physician assistant under the Physician Assistant Licensing Act, Texas Civil Statutes, Article 4495b-1.

(48) Presurvey conference--A conference held with department staff and the applicant or his or her representatives to review licensure standards and survey documents and provide consultation prior to the issuance of the temporary license. The applicant's representatives shall include an individual who will be responsible for the day-to-day supervision of care by the facility.

(49) Product water--The effluent water from the last component of the facility's water treatment system.

(50) Progress note--A dated and signed written notation by a facility staff member summarizing facts about care and a patient's response during a given period of time.

(51) Quality--The degree to which health services for individuals and populations increase the likelihood of desired outcomes that are consistent with current professional knowledge.

(52) Quality assurance--An ongoing, objective, and systematic process of monitoring, evaluating, and improving the quality, appropriateness, and effectiveness of care. The term includes the quality management and quality improvement processes.

(53) Quality management--A management philosophy used to plan and achieve desired processes and outcomes based upon a quality plan, which establishes quality objectives and the means to achieve; quality control, which is a process to evaluate actual performance against expected performance; and quality improvement, which is a process to identify, plan, and implement change for improvement.

(54) Registered nurse (RN)--A person who is currently licensed under the Nursing Practice Act, Texas Civil Statutes, Article 4513 et seq. as a registered nurse.

(55) Social worker--A person who:

(A) is currently licensed as a social worker under the Human Resources Code, Chapter 50, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; or

(B) has worked for at least two years as a social worker, one year of which was in a dialysis facility or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who has a masters degree from a graduate school of social work accredited by the Council on Social Work Education.

(56) Supervising nurse (also may be known as the director of nursing)--An RN who:

(A) has at least 18 months experience as an RN, which includes at least 12 months experience in dialysis which has been obtained within the last 24 months; or

(B) has at least 18 months experience as an RN and holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis.

(57) Supervision--Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Immediate supervision means the supervisor is actually observing the task or activity as it is performed. Direct supervision means the supervisor is on the premises but not necessarily immediately physically present where the task or activity is being performed. Indirect supervision means the supervisor is not on the premises but is accessible by two-way communication and able to respond to an inquiry when made, and is readily available for consultation.

(58) Statute--The Health and Safety Code, Chapter 251.

(59) Training--The learning of tasks through on-the-job experience or instruction by an individual who has the capacity through education or experience to perform the task or activity to be delegated.

(60) Technical supervisor--The supervisor of the facility's mechanical, reuse and water treatment systems.

(61) Ultrafilter--A membrane filter with a pore size in the range 0.001 to 0.05 µm. Performance is usually rated in terms of a nominal molecular weight cut-off (MWCO), which is defined as the smallest molecular weight species for which the filter membrane has more than 90% rejection. Ultrafilters with a nominal MWCO of 20,000 or less are generally adequate for endotoxin removal.

(62) Water distribution systems--Components to include any storage tanks and piping used to distribute the product water from the purification cascade to or from its point of use, including individual hemodialysis machines, dialyzer reprocessing equipment and dialysate concentrate preparation systems.

(63) Water treatment system--A collection of water purification devices and associated piping, pumps, valves, gauges, etc., that together produce purified water for hemodialysis applications and deliver it to the point of use.

(64) Working day--Any day of the calendar week excluding Saturday or Sunday.

§117.11. General Requirements for a License.

(a) License required. A facility shall obtain a license prior to admitting patients.

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

(c) Alteration. A facility license shall not be altered.

(d) Transfer or assignment prohibited. A facility license shall not be transferred or assigned. The facility shall comply with the provisions of §117.12(h) of this title (relating to Application and Issuance of Initial License) in the event of a change in the ownership.

(e) Changes which affect the license.

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

(A) any construction, renovation, or modification of the facility buildings;

(B) cessation of operation of the facility; or

(C) change in facility name, telephone number or administrator.

(2) A facility shall obtain written approval from the department prior to the utilization of added services or an increased number of stations. The written request shall be submitted 30 calendar days prior to the planned change.

(A) For an additional service or increase in stations, the department may request that the facility provide evidence of appropriate staffing and policies and procedures which demonstrate the intent to comply with the applicable requirements, and any other documentation it determines is necessary to evaluate the request.

(B) For an increase in stations, the facility shall also be required to submit written evidence that the water treatment system is of sufficient size to accommodate the increase and maintain a safe water supply.

(C) The department may conduct on on-site inspection prior to taking action on the requested change.

(D) No later than three weeks after initiating the use of the new stations, the facility is required to complete chemical and bacteriological cultures of the product water to ensure they are in compliance with §4.2.1 (relating to Water Bacteriology) and §4.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 200, Arlington, Virginia 22201, 703-525-4890. Deviations from acceptable levels must be immediately reported to the department. The reports must be kept on file at the facility and made available to department staff during the next on-site inspection.

(3) The department shall send the facility written notice of the approval or disapproval of the requested change.

(f) Facility relocation.

(1) A facility planning to relocate shall notify the department a minimum of 60 days prior to the planned relocation. Relocations must be within the same geographical area, and services shall continue to be provided to the facility's existing patient population.

(2) The facility shall submit the following to the department:

(A) a copy of a current fire safety survey indicating approval by the local fire authority in whose jurisdiction the new location is based;

(B) results of chemical and bacteriological cultures of the product water at the new location to ensure they are in compliance with §§4.2.1 (relating to Water Bacteriology) and 4.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 200, Arlington, Virginia 22201, (703) 525-4890;

(C) documentation verifying compliance with paragraph (1) of this subsection; and

(D) a written plan for the orderly transition of all patient services to the new location.

(3) The department shall conduct the design and space inspection described in §117.16(b)(1)(A) of this title (relating to Inspections) prior to issuance of the initial license, unless the department waives the requirement.

(4) The department may conduct additional on-site inspections, or request additional information, before approving the relocation.

(5) The department will notify the facility in writing of the approval or disapproval of relocation. If approved, the license will be reissued for the new location effective on the day that patient services are transferred to the new location.

§117.12. Application and Issuance of Initial License.

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

(1) an accurate and complete application form;

(2) an approved fire safety report from the local fire authority; and

(3) the appropriate license fee as required in §117.14 of this title (relating to Fees).

(b) Design and space inspection. The department shall conduct the design and space inspection described in §117.16(b)(1)(A) of this title (relating to Inspections) prior to issuance of the initial license, unless the department waives the requirement.

(c) Presurvey conference. The applicant or the applicant's representative shall attend a presurvey conference at the office designated by the department. The purpose of the presurvey conference, which is conducted by department staff, is to review facility staff qualifications, facility policies and procedures, results of water cultures and analysis of product water, survey documents and licensure rules, and to provide consultation prior to the on-site licensure survey. The department staff conducting the presurvey conference is responsible for making a recommendation regarding the issuance of the initial license. The department may waive the presurvey conference requirement.

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

(1) Effective date. The license shall be effective on the date the facility is determined to be in compliance with subsections (a) - (c) of 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.

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

(f) Denial of a license. Denial of a license shall be governed by §117.84 of this title (relating to Enforcement).

(g) Inspections. During the initial licensing period, the department shall conduct an inspection of the facility to ascertain compliance with the provisions of the Health and Safety Code, Chapter 251, and this chapter.

(1) A facility shall request an on-site inspection to be conducted after one inpatient has been admitted and provided services.

(2) A facility shall be providing services to at least one inpatient in the facility at the time of the inspection.

(h) Change of ownership. A change of ownership occurs when there is a change in the person legally responsible for the operation of the facility, whether by lease or by ownership. If a corporate licensee amends its articles of incorporation to revise its name and the tax identification number does not change, this subsection does not apply, except that the corporation must notify the department within 10 calendar days after the effective date of the name change. The sale of stock of a corporate licensee does not cause this subsection to apply. A change of ownership requires submission of an initial license application.

(1) The new owner shall submit an application for an initial license to the department prior to the date of the change of ownership or not later than 10 calendar days following the date of a change of ownership. The application shall be in accordance with subsections (a) - (c) of this section. The applicant shall include the effective date of the change of ownership.

(2) Inspections. The design and space and health inspections required by subsections (b) and (g) of this section may be waived by the department.

(3) Issuance of license. When the new owner has complied with the provisions of subsections (a) - (c) of this section, the department shall issue a license which shall be effective the date of the change of ownership.

(4) Expiration of license. The expiration date of the license shall be in accordance with subsection (d) of this section.

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

(i) Temporary initial license. The department may issue a temporary initial license in lieu of the initial license.

§117.13. Application and Issuance of Renewal License.

(a) Renewal notice. The department may send a renewal notice to a facility up to 60 calendar days before the expiration date of a license.

(1) If the facility has not received the renewal notice from the department within 30 calendar days prior to the expiration date, it is the duty of the facility to notify the department and request a renewal application for a license.

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

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

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

(A) a complete and accurate application form;

(B) a copy of a fire safety survey indicating approval by the local fire authority in whose jurisdiction the facility is based that is dated no earlier than one year prior to the application date;

(C) the renewal license fee; and

(D) verification that the facility submitted the annual reports required by §117.42 of this title (relating to Indicators of Quality of Care).

(2) The department may conduct an inspection prior to issuing a renewal license in accordance with §117.16 of this title (relating to Inspections).

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

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

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

(c) Notice to cease operation and return license. If a facility fails to submit the application, documents, and fee by the expiration date of the license, the department shall notify the facility that it must cease operation and immediately return the license by certified mail to the department. If the facility wishes to provide services after the expiration date of the license, it shall apply for a license under §117.12 of this title (relating to Application and Issuance of Initial License).

§117.14. Fees.

(a) General.

(1) All fees paid to the department are nonrefundable.

(2) All fees shall be paid to the department.

(b) License fees.

(1) The fees for both initial and renewal licenses are as follows:

(A) $3,500 for facilities licensed for 0 to 10 dialysis stations;

(B) $4,300 for facilities licensed for 11 to 20 dialysis stations;

(C) $5,100 for facilities licensed for 21 to 30 dialysis stations;

(D) $5,900 for facilities licensed for 31 to 40 dialysis stations; and

(E) $6,700 for facilities licensed for 41 dialysis stations or more.

(2) All licenses are valid for 24 months.

(c) Other fees. For all applications and renewal applications, 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.

§117.15. 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 Texas Department of Health (department).

(2) An application for an initial license is complete when the department has received, reviewed, and found acceptable the information described in §117.12 of this title (relating to Application and Issuance of Initial License).

(3) An application for an annual renewal license is complete when the department has received, reviewed and found acceptable the information described in §117.13 of this title (relating to Application and Issuance of Renewal 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 Administrative Procedure Act, Texas Government Code, Chapter 2001, and the department's formal hearing procedures in Chapter 1 of this title (relating to the Texas Board of Health).

§117.16. Inspections.

(a) General. The Texas Department of Health (department) may conduct an inspection at any time to verify compliance with the statute or this chapter. By applying for or holding a license, the facility consents to entry and inspection of the facility by the department or representative of the department in accordance with the statute and this chapter.

(1) An authorized representative of the department (surveyor) may enter the premises of a license applicant or license holder at reasonable times during business hours to conduct an on-site inspection incidental to the issuance of a license, and at other times as the department considers necessary to ensure compliance with:

(A) the statute or this chapter;

(B) an order of the commissioner of health (commissioner);

(C) a court order granting injunctive relief;

(D) a corrective action plan; or

(E) other enforcement action(s).

(2) The surveyor is entitled to access all books, records, or other documents maintained by or on behalf of the facility to the extent necessary to ensure compliance with the statute, this chapter, an order of the commissioner, a court order granting injunctive relief, a corrective action plan, or other enforcement action. The department shall maintain the confidentiality of facility records as applicable under federal or state law. Ensuring compliance includes permitting photocopying by the department or providing photocopies to a department surveyor of any records or other information by or on behalf of the department as necessary to determine or verify compliance with the statute or this chapter.

(b) Types of inspections.

(1) Design and space inspection.

(A) The department shall conduct an inspection to determine compliance with the design and space requirements described in §117.31 of this title (relating to Design and Space Requirements), the requirements in §117.32(a), (c), (e), and (g) of this title (relating to Equipment), and §117.33(b)(1) and (3) - (10) of this title (relating to Water Treatment and Reuse) prior to issuance of the temporary initial license, unless the department waives the requirement.

(B) During any license period, the department may conduct a design and space inspection to determine whether modifications or renovations comply with §117.31 of this title.

(2) Initial inspection for the issuance of the initial license. A department surveyor may conduct an initial inspection after the date of issuance of the initial license to determine if the facility meets the requirements of the statute and this chapter. The initial inspection is an evaluation of compliance with all requirements of the statute and this chapter.

(3) Renewal inspection. At the department's discretion, a department surveyor may perform an on-site inspection prior to renewal of a facility license to verify compliance with the statute and this chapter. The renewal inspection may include an evaluation of compliance with all requirements of the statute and this chapter.

(4) Inspection to investigate a complaint. The department surveyor shall perform an inspection of a facility on-site or by mail if the facility has demonstrated noncompliance with the statute or this chapter, or to investigate a complaint received by the department.

(5) Inspection based on annual report. After review of a facility's annual report, the department may request additional information or conduct an inspection by mail or on-site to determine compliance with the statute and this chapter.

(6) Inspection related to a report(s) to the director. The department may conduct an inspection incidental to a report to the director described in §117.46 of this title (relating to Reports to the Director).

(7) Follow-up inspection. A department surveyor shall perform an inspection on-site or by mail to verify completion of a corrective action plan(s) for deficiencies cited during any of the inspections described in paragraphs (1) - (6) of this subsection.

(c) Inspection procedures.

(1) Entrance conference. The department's surveyor shall hold a conference with the person who is in charge of the facility prior to commencing the inspection for the purpose of explaining the nature and scope of the inspection.

(2) Evaluation of compliance. Except for the purposes of conducting an inspection under subsection (b)(1), (4), (6), or (7) of this section, an onsite inspection will include an evaluation to determine compliance with the statute and this chapter.

(3) Exit conference. After an inspection of a facility the surveyor shall hold an exit conference with the facility administrator or his or her designee. During the exit conference, the surveyor shall:

(A) fully inform the facility representative of the preliminary finding(s) of the inspection;

(B) give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings; and

(C) identify any records that were duplicated.

(4) Written notice of findings.

(A) The surveyor shall:

(i) prepare and provide the facility administrator or his or her designee specific and timely written notice of the findings in accordance with subparagraphs (B) and (C) of this paragraph; or

(ii) if the findings result in a referral described in §117.81(a)(1) of this title (relating to Corrective Action Plan), submit a written summary of the findings to the medical review board for its review and recommendation for appropriate action by the department.

(B) If no deficiencies are found during an inspection, the department shall provide a statement indicating this fact.

(C) If the written notice of findings includes deficiencies, the department and the facility shall comply with the procedure set out in this subparagraph.

(i) The department shall provide the facility with a statement of the deficiencies at the time of the exit conference or within 10 working days after the exit conference.

(ii) The facility administrator or administrator's designee shall sign the written statement of deficiencies and return it to the department with a corrective action plan(s) for each deficiency no later than 10 working days of its receipt of the statement of deficiencies. The signature does not indicate the administrator's or designee's agreement with deficiencies stated on the form.

(iii) The facility shall come into compliance 60 calendar days prior to the expiration date of the license or no later than the dates designated in the corrective action plan(s), whichever comes first.

(iv) The requirements in clause (i) of this subparagraph do not apply if the surveyor's written notice of findings results in a referral to the medical review board as described in subparagraph (A)(ii) of this paragraph.

(v) A corrective action plan completion date shall not exceed 45 calendar days from the date the deficiency(ies) is cited (exit date of the survey).

(vi) The facility may challenge any deficiency cited after receipt of the statement of deficiencies. A challenge to a deficiency(ies) shall be in accordance with this subparagraph.

(I) The facility shall comply with clause (ii) of this subparagraph regardless of its intent to challenge the deficiency(ies).

(II) An initial challenge to a deficiency(ies) shall be submitted in writing no later than five working days from the facility's receipt of the statement of deficiencies to the Program Director, End Stage Renal Disease Licensing Program or his or her designee, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas, 78756-3199, (512) 834-6646.

(III) If the initial challenge is favorable to the department, the facility may request a review of the initial challenge by submitting a written request to the Director or his or her designee, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199. The facility shall submit its written request for review of the initial challenge no later than five working days of its receipt of the department's response to the initial challenge. The department will not accept or review any documents that were not submitted with the initial challenge. A determination by the Director of the Health Facility Licensing and Compliance Division relating to a challenge to a deficiency(ies) is the department's final determination concerning the challenge.

(IV) The department shall respond to any written challenge submitted under subclause (II) or (III) of this clause no later than 15 working days from its receipt.

(V) The department shall determine if a written corrective action plan(s) is acceptable. If the corrective action plan(s) is not acceptable to the department, the department shall notify the facility by telephone and request that the corrective action plan(s) be modified and resubmitted no later than 10 working days from the facility's receipt of such request.

(VI) If the facility does not come into compliance by the required date of correction reflected on the corrective action plan(s), the department may:

(-a-) appoint a monitor as described in §117.81 of this title;

(-b-) appoint a temporary manager as described in §117.83 of this title (relating to Involuntary Appointment of Temporary Manager);

(-c-) propose to deny, suspend, or revoke the license in accordance with §117.84 of this title (relating to Enforcement).

(-d-) assess an administrative penalty(ies) in accordance with §117.85 of this title (relating to Administrative Penalties); or

(-e-) take all of the actions described in items (-a-) - (-d-) of this subclause.

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

(VIII) Acceptance of a corrective action plan does not preclude the department from taking enforcement action as appropriate under §§117.83, 117.84, or 117.85 of this title.

(IX) The department shall refer issues and complaints relating to the conduct of or action(s) by licensed health care professionals to the appropriate licensing board(s).

§117.17. Optional Plan Review and Inspection.

(a) Request for a plan review. Plans and specifications covering the construction of new buildings or alterations, additions, conversions, modernizations or renovations to existing buildings may be submitted to the Texas Department of Health (department) for review to determine compliance with this chapter. Submission of plans and specifications is not mandatory.

(1) If a plan review is requested by the facility, plans and specifications shall be submitted in accordance with this section.

(2) A review of minor alterations or remodeling changes which do not include alterations to load-bearing members of partitions, change functional operation, affect fire safety, or add additional stations may be requested. The request for review shall be in writing to the department with a brief description of the proposed changes.

(3) If review of preliminary plans and outline specifications is requested, the submittal shall contain sufficient information to establish the scope of the project and compliance with the design and space requirements in this chapter.

(4) If review of final drawings and specifications is requested, one complete set of drawings shall be submitted. All working drawings shall be well-prepared so that clear and distinct prints may be obtained, be accurately dimensioned, and include all necessary explanatory notes, schedules, and legends. Final drawings shall be complete and adequate for construction contract purposes. All final plans and specifications shall be appropriately sealed and signed by a registered architect and professional engineer

licensed by the State of Texas. Drawings and specifications shall comply with the design and space requirements in this chapter.

(b) Inspection. At 100% completion of construction and prior to occupancy, the department may schedule a construction inspection at the department's convenience for the purpose of verifying compliance with design and space requirements in this chapter.

§117.18. Exceptions to These Rules.

(a) While all subject ESRD facilities are required to maintain continuous compliance with these rules, these rules do not prohibit the use of alternative concepts, methods, procedures, techniques, equipment, facilities, personnel qualifications of the conducting of pilot projects or research. Requests for temporary exceptions to these rules must:

(1) be submitted to the department in writing;

(2) identify the specific rule for which an exception is requested;

(3) describe in detail the specific circumstances which are believed by facility administration to justify the exception;

(4) describe in detail what alternatives were considered, if any, and why alternatives (including compliance with the rule) were not selected;

(5) demonstrate that the proposed exception is desirable to maintain or improve the health and safety of the patients, will not jeopardize patient health and safety, and will maintain patient access to care; and

(6) describe the proposed duration of the exception.

(7) exceptions to staffing requirements:

(A) may only be granted in an emergency situation for a maximum of 120 days, with a single renewal period for an additional 120 days;

(B) the facility shall develop an action plan to resolve the staffing crisis situation;

(C) the facility shall submit the action plan to the department within 60 days of the granting of the exception; and

(D) during the period of exception to staffing requirements, the facility shall monitor outcome data related to quality of care and report these outcomes on a monthly basis to the department.

(b) Requests for exceptions to the rules shall be submitted to the applicable zone office.

(c) The department may conduct a survey and consult with the MRB prior to approving an exception.

(d) Upon finding that the facility has satisfied the conditions of this rule, the department may grant an exception, to include the duration of the exception. The department will respond to a waiver request within 90 days.

(e) The facility may implement an exception only after written approval from the department.

(f) Granting of an exception is considered public information, is subject to disclosure, and may be posted on the department web site.

§117.31. Design and Space Requirements.

(a) General.

(1) The standards in this section shall apply to all facilities that provide outpatient dialysis services. Dialysis facilities in operation on or before September 1, 2003 shall meet the design and space requirements of this section which were in effect at the time the facility was constructed.

(2) A facility must provide a physical environment that protects the health and safety of patients, personnel and the public. The physical premises of the facility and those areas of the facility's surrounding physical structure that are used by the patients (including all stairwells, corridors and passageways) must meet the local building and fire safety codes as they relate to design and space requirements for safe access and patient privacy.

(3) A facility shall comply with Chapter 38 of the National Fire Protection Association 101, Code for Safety to Life from Fire in Buildings and Structures, 2000 Edition (NFPA 101), relating to new business occupancies, published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, Batterymarch Park, Quincy, Massachusetts 02169, 1-800-344-3555.

(4) Water distribution systems shall be configured as a continuous recirculation loop and designed to minimize bacterial proliferation and biofilm. A minimum of three feet per second water flow must be achieved in the distribution loop. This rule shall apply only to new facilities.

(5) Water treatment systems shall include a minimum of two carbon tanks in a series, with the total empty bed contact time (EBCT) of at least ten minutes, and the final tank providing at least five minutes EBCT.

(6) A facility shall provide a reception and information counter or desk and a waiting room separate from the patient treatment area. The waiting room shall provide adequate seating.

(7) The patient treatment area shall be designed and equipped to provide proper and safe treatment as well as privacy and comfort for patients. At a minimum, patient treatment stations shall be 70 square feet, with the smallest dimension at seven feet. The 70 square feet may include aisles or counters.

(8) If hepatitis B positive patients are treated, a separate room with its own designated machine(s), clamp(s), blood pressure cuff(s), sink(s) and other equipment shall be used.

(9) A facility shall provide a call system in patient areas outside the treatment area (e.g., patient restrooms, training rooms, and examination rooms) which is usable by a collapsed patient lying on the floor (e.g., inclusion of a pull cord). Calls shall register at and activate a visible signal in the central nurses station. Call systems which provide two-way communication shall be equipped with an indicating light at each call station which lights and remains lighted as long as the voice circuit is operating.

(10) A facility shall have separate toilet and lavatory facilities for staff and patients.

(11) A facility shall provide a private area for meetings with patients or family members.

(12) A facility shall have a room for medical examinations which includes an examination table, a work counter, and a hand washing sink or lavatory.

(13) Telephone access shall be available in the facility to patients and family members.

(14) A facility located above the ground floor must have an elevator of sufficient size to accommodate a gurney available at all times.

(15) A facility shall provide two exits remote from each other in accordance with NFPA 101, §7-5.1.3. At least one exit door shall be accessible by an ambulance from the outside. This door may also serve as an entry for loading or receiving goods.

(16) A facility shall provide a separate room for peritoneal dialysis patients if the facility provides on-site peritoneal dialysis training. This room shall include a lavatory or sink for hand washing.

(17) Doors to an isolation room or peritoneal dialysis room shall not be lockable from inside the room.

(18) Public corridor widths and all other areas where patients may traverse shall accommodate wheel chair or gurney passage.

(19) Items such as drinking fountains, telephone booths, vending machines and portable equipment (including patient care equipment) shall be located so that they do not project into, restrict, or obstruct exit corridor traffic.

(20) A facility shall utilize a ventilation system which provides adequate comfort to patients during treatment and which minimizes the potential of insect access.

(21) Floors that are subject to traffic while wet shall have nonslip surfaces.

(b) Storage areas.

(1) All storage areas shall be kept clean and orderly at all times.

(2) A facility premises shall be kept free from accumulations of combustible materials not necessary for immediate operation of the facility. Local supplies of combustible liquids shall be stored in cabinets or shelves which are well-ventilated from top to bottom.

(3) A facility shall have a separate space for wheel chair storage.

(4) A facility shall store oxygen in compliance with §4-3 of the National Fire Protection Association 99, Standard for Health Care Facilities, 1999 Edition (NFPA 99) published by the National Fire Protection Association.

(c) Provisions for the handicapped.

(1) If Texas Civil Statutes, Article 9102 applies, a facility shall be designed in accordance with 16 Texas Administrative Code, Chapter 68 (Elimination of Architectural Barriers) administered by the Texas Department of Licensing and Regulation, effective April 1, 1994.

(2) A facility shall meet applicable requirements of 29 United States Code, §794. When federal funds are used for construction, for program requirements, or for client services, the handicapped requirements of §794 will apply.

(3) A facility shall comply with the design and space requirements of the Americans with Disabilities Act, 42 United States Code, §12182(b)(2)(A)(iv) and (v) and §12183, and the regulations and guidelines promulgated under §12186(b) and (c) and §12204, effective July 28, 1991.

(d) Fire protection.

(1) All sprinkler systems, smoke detectors, and other fire-fighting equipment shall be inspected and tested at least once each year to maintain it in serviceable condition. If a facility has a sprinkler system, the sprinkler system shall be installed and maintained in accordance with the National Fire Protection Association 13, Standard for the Installation of Sprinkler Systems, 1999 Edition, published by the National Fire Protection Association.

(2) A facility shall have an emergency lighting system capable of providing sufficient illumination to allow safe evacuation from the building. Battery pack systems shall be maintained and tested quarterly. If a facility maintains a back-up generator, the generator must be installed, tested and maintained in accordance with the National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 1999 Edition (NFPA 110), published by the National Fire Protection Association.

(3) A facility housed in or adjacent to a building classified as a "high hazard industrial occupancy," as defined in §40-1.4.1 of the NFPA 101, must have a special feature such as a two-hour fire wall between the facility and the other occupancy and written approval by the fire authority having jurisdiction.

(e) Construction. If construction takes place in or near occupied areas, adequate provision shall be made for the safety and comfort of patients during the construction.

(f) Other standards. A facility may impose more stringent design and space standards than the minimum standards in this section.

§117.32. Equipment.

(a) All equipment used by a facility, including backup equipment, shall be operated within manufacturer's specifications, and maintained free of defects which could be a potential hazard to patients,

staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.

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

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

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

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

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

(b) A facility shall develop, implement and enforce a written preventive maintenance program to ensure patient care related equipment used in a facility or provided by a facility for use by the patient in the patient's home receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. The preventive maintenance may be provided by facility staff or by contract.

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

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

(e) All equipment and appliances shall be properly grounded in accordance with the National Fire Protection Association 99, Standard for Health Care Facilities, §§3-3.2.1.2(a)(2) and 7-5.1, 1999 Edition (NFPA 99), published by the National Fire Protection Association. All documents published by the NFPA as referenced in this section may be obtained by writing or calling the NFPA at the following address and telephone number: Post Office Box 9101, Batterymarch Park, Quincy, Massachusetts 02169, 1-800-344-3555.

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

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

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

(A) oxygen;

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

(C) suction equipment;

(D) supplies specified by the medical director;

(E) electrocardiograph; and

(F) automated external defibrillator.

(2) If pediatric patients are treated, the facility shall have the appropriate type and size emergency equipment and supplies listed in paragraph (1) of this subsection for this special population.

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

§117.33. Water Treatment, Dialysate Concentrates and Reuse.

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

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

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

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

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

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

(2) When a public water system supply is not used by a facility, the source water shall be tested by the facility at monthly intervals in the same manner as a public water system as described in 30 Texas Administrative Code, §290.104 (Control Tests), §290.105 (Maximum Contaminant Levels (MCLs) for

Microbiological Contaminants), and §290.106 (Bacteriological Monitoring) as adopted by the Texas Commission on Environmental Quality.

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

(4) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality described in §4.2.1 (concerning Water Bacteriology) and §4.2.2 (concerning Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI). All documents published by the AAMI as referenced in this section may be obtained by writing the following address: 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201.

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

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

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

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

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

(B) Deionization systems.

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

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

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

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

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

(C) Carbon tanks.

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

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

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

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

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

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

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

(viii) If means other than granulated carbon are used to remove chlorine/chloramine, the facility's governing body must approve such use in writing after review of the safety

of the intended method for use in hemodialysis applications. If such methods include the use of additives, there must be evidence the product water does not contain unsafe levels of these additives.

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

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

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

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

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

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

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

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

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

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

(19) Microbiological testing of product water.

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

(B) Sample sites. At a minimum, sample sites chosen for the testing shall include the beginning of the distribution piping, the product water in the reuse room, at any site of dialysate mixing, and the end of the distribution piping.

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

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

(E) Required action for unacceptable results. If the action levels described at paragraph (D) are observed in the product water, corrective measures shall be taken promptly to reduce the levels into an acceptable range.

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

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

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

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

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

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

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

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

(25) Only persons qualified by the education or experience described in §117.44(f) of this title (relating to Qualifications of Staff) may operate, repair, or replace components of the water treatment system.

(c) Dialysate.

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

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

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

(4) Bacteriological testing.

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

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

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

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

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

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

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

(9) Concentrate mixing systems.

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

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

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

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

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

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

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

(10) Acid concentrate mixing systems.

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

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

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

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

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

(11) Bicarbonate concentrate mixing systems.

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

(B) Bicarbonate concentrate mixing tanks shall not be pre-filled the night before use.

(C) If disinfectant remains in the mixing tank overnight, this solution must be completely drained, the tank rinsed and tested for residual disinfectant prior to preparing the first batch of that day of bicarbonate concentrate.

(D) Unused portions of bicarbonate concentrate shall not be mixed with fresh concentrate.

(E) At a minimum, bicarbonate distribution systems shall be disinfected weekly. More frequent disinfection shall be done if required by the manufacturer, or if dialysate culture results are above the action level.

(F) If jugs are reused to deliver bicarbonate concentrate to individual hemodialysis machines:

(i) jugs shall be emptied of concentrate, rinsed and inverted to drain at the end of each treatment day;

(ii) at a minimum, jugs shall be disinfected weekly, more frequent disinfection shall be considered by the facility quality management committee if dialysate culture results are above the action level; and

(iii) following disinfection, jugs shall be drained, rinsed free of residual disinfectant, and inverted to dry. Testing for residual disinfectant should be done and documented.

(12) Labeling of concentrate containers. All mixing tanks, bulk storage tanks, dispensing tanks and containers for single hemodialysis treatments shall be labeled as to the contents.

(A) Mixing tanks. Prior to batch preparation, a label shall be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling shall remain on the mixing tank until the tank has been emptied.

(B) Bulk storage/dispensing tanks. These tanks shall be permanently labeled to identify the chemical composition or formulation of their contents.

(C) Single-machine containers. At a minimum, single-machine containers shall be labeled with sufficient information to differentiate the contents from other concentrate formulations used in the facility and permit positive identification by users of container contents.

(13) Records of concentrate mixing. Permanent records of batches produced shall be maintained to include the concentrate formula produced, the volume of the batch, lot number(s) of powdered concentrate packages, the manufacturer of the powdered concentrate, date and time of mixing, test results, person performing mixing, test results, and expiration date (if applicable).

(14) Maintenance of dialysate mixing systems. If dialysate concentrates are prepared in the facility, the manufacturers' recommendations shall be followed regarding any preventive maintenance. Records shall be maintained indicating the date, time, person performing the procedure, and the results (if applicable).

(d) Reuse of hemodialyzers and related devices.

(1) Reuse practice in a facility must comply with the American National Standard, Reuse of Hemodialyzers, 1993 Edition published by the AAMI.

(2) Dialyzer manufacturer's labeling shall be reviewed to determine if a specific dialyzer requires special considerations.

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

(4) Arterial lines may be reused only when the arterial lines are labeled to allow for reuse by the manufacturer and the manufacturer-established protocols for the specific line have been approved by the United States Food and Drug Administration.

(5) The water supply in the reuse room shall incorporate a check valve to prevent chemical agents used from inadvertently back flowing into the water distribution system.

(6) Ventilation systems in the reuse room shall be connected to an exhaust system to the outside which is separate from the building exhaust system, have an exhaust fan located at the discharge end of the system, and have an exhaust duct system of noncombustible corrosion-resistant material as needed to meet the planned usage of the system. Exhaust outlets shall be above the roof level and arranged to minimize recirculation of exhaust air into the building.

(7) A facility shall establish, implement, and enforce a policy for dialyzer reuse criteria (including any facility-set number of reuses allowed) which is included in patient education materials and posted in the waiting room and patient treatment areas. A dialyzer may be reused only if that dialyzer's original volume is measured and recorded prior to its first use and the volume of that dialyzer is used as the basis for discard for that dialyzer.

(8) A facility shall consider and address the health and safety of patients sensitive to disinfectant solution residuals.

(9) A facility shall provide each patient with information regarding the reuse practices at the facility, the opportunity to tour the reuse area, and the opportunity to have questions answered.

(10) A facility shall restrict the reprocessing room to authorized personnel.

(11) A facility shall obtain written informed consent of the patient or legal representative.

(e) Centralized dialyzer reprocessing. If a facility participates in centralized reprocessing in which dialyzers from multiple facilities are reprocessed at one site, the facility shall:

(1) appoint a medical director for the centralized reprocessing facility;

(2) require the use of automated reprocessing facility;

(3) maintain responsibility and accountability for the entire reuse process;

(4) adopt, implement, and enforce policies to ensure that the transfer and transport of used and reprocessed dialyzers to and from the off-site location does not increase contamination of the dialyzers, staff, or the environment;

(5) assure that each dialyzer is returned to the appropriate facility or patient home and in the case of home patients who participate in a dialyzer reprocessing program, a system shall be established to verify that the correct dialyzers are being returned to each patient's home; and

(6) provide department staff access to the off-site reprocessing site as part of a facility inspection.

§117.34. Sanitary Conditions and Hygienic Practices.

(a) General infection control measures.

(1) Universal precautions.

(A) Universal precautions shall be followed in the facility for all patient care activities in accordance with 29 Code of Federal Regulations, §1910.1030(d)(1)-(3) (concerning Bloodborne Pathogens) and the Health and Safety Code, Chapter 85, Subchapter I (concerning Prevention of HIV and Hepatitis B Virus by Health Care Workers).

(B) Facility staff shall wash their hands before and after each patient contact in which there is a potential exposure to blood or body fluids. Location and arrangement of hand washing facilities shall permit ease of access and proper use.

(i) Hand washing sinks shall be readily accessible in each patient care area.

(ii) All fixtures and lavatories shall be trimmed with valves which can be operated without the use of hands. There shall be sufficient clearance for the operation of blade-type handles, if they are used.

(iii) Provisions for hand drying shall be included at all hand washing facilities.

(C) Facility staff shall explain the potential risks associated with blood and blood products to patients and family members and provide the indicated personal protective equipment to a patient or family member if the patient or family member assists in procedures which could result in contact with blood or body fluids.

(2) Documentation and coordination of infection control activities.

(A) The facility must designate a person to monitor and coordinate infection control activities.

(B) A facility shall develop and maintain a system to identify and track infections to allow identification of trends or patterns. This activity shall be reviewed as a part of the facility's quality assurance program described in §117.41 of this title (relating to Quality Assurance for Patient Care). The record shall include trends, corrective actions, and improvement actions taken.

(3) Smoking policy. The facility shall establish, implement, and enforce a smoking policy.

(b) Environmental infection control.

(1) General procedures.

(A) A facility shall provide and actively monitor a sanitary environment which minimizes or prevents transmission of infectious diseases.

(i) The facility shall provide a janitor's closet with space for cleaning supplies and equipment.

(ii) Wall bases in patient treatment and other areas which are frequently subject to wet cleaning methods shall be tightly sealed to the floor and the wall, impervious to water and constructed without voids that can harbor insects.

(iii) Floor materials shall be easily cleanable and have wear resistance appropriate for the location involved. In all areas subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions.

(iv) Wall finishes shall be washable and, in the immediate areas of plumbing fixtures, smooth and moisture resistant.

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

(vi) All exposed ceilings and ceiling structures in areas normally occupied by patients, staff, and visitors shall be finished so as to be cleanable with equipment used in daily housekeeping activities. Ceiling tiles stained with blood shall be cleaned or replaced.

(vii) Ceiling fans shall not be utilized in patient treatment areas.

(B) Blood spills shall be cleaned immediately or as soon as is practical with a disposable cloth and an appropriate chemical disinfectant.

(i) The surface should be subjected to intermediate level disinfection in accordance with the manufacturer's instructions, if a commercial liquid chemical disinfectant is used.

(ii) If a solution of chlorine bleach (sodium hypochlorite) is used, the solution shall be at least 1:100 sodium hypochlorite and the surface to be treated must be compatible with this type of chemical treatment.

(2) Specific procedures for equipment and dialysis machines.

(A) Routine disinfection of active and backup dialysis machines shall be performed according to facility defined protocol, accomplishing at least intermediate level disinfection and the disinfectant removed.

(B) Between patient shifts, facility staff shall clean machine exteriors, treatment chairs, tourniquets, and hemostats. Blood pressure cuffs which become contaminated with blood shall be removed from service, disinfected, and allowed to dry prior to being returned to use.

(c) Medical waste and liquid/sewage waste management.

(1) The facility shall comply with the requirements set forth by the department in §§1.131-1.137 of this title (relating to Definition, Treatment and Disposition of Special Waste from Health Care Related Facilities) and the Texas Commission on Environmental Quality's requirements in Title 30, Texas Administrative Code, §330.1004 (Generators of Medical Waste).

(2) All sewage and liquid wastes shall be disposed of in a municipal sewerage system or a septic tank system permitted by the Texas Commission on Environmental Quality in accordance with Title 30, Texas Administrative Code, Chapter 285 (On-site Sewage Facilities).

(d) Hepatitis B prevention.

(1) Prevention requirements concerning staff. The facility shall offer hepatitis B vaccination to previously unvaccinated, susceptible new staff members in accordance with 29 Code of Federal Regulations,

§1910.1030(f)(1)-(2) (concerning Bloodborne Pathogens). Staff vaccination records shall be maintained in each staff member's health record.

(2) Prevention requirements concerning patients.

(A) Hepatitis B vaccination.

(i) With the advice and consent of a patient's attending nephrologist, facility staff shall make the hepatitis B vaccine available to a patient who is susceptible to hepatitis B, provided that the patient has coverage or is willing to pay for vaccination.

(ii) The facility shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.

(B) Serologic screening of patients.

(i) A patient new to dialysis or returning to a facility after extended hospitalization or absence of 30 calendar days or longer shall have been screened for HBsAg within one month before or at the time of admission to the facility or have a known anti-HBs status of at least 10 milli-international units per milliliter no more than 12 months prior to admission. The facility shall document how this screening requirement is met.

(ii) Repeated serologic screening shall be based on the antigen or antibody status of the patient.

(I) Monthly screening for HBsAg is required for patients whose previous test results are negative for HBsAg.

(II) Screening of HBsAg-positive or anti-HBs-positive patients may be performed on a less frequent basis, provided that the facility's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 1993, published by the United States Department of Health and Human Services.

(C) Isolation procedures for the HBsAg-positive patient.

(i) The facility shall treat patients positive for HBsAg in a segregated treatment area which includes a handwashing sink, a work area, patient care supplies and equipment, and sufficient space to prevent cross-contamination to other patients.

(ii) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for the HBsAg-positive patient's use only.

(iii) When a caregiver is assigned to both HBsAg-negative and HBsAg-positive patients, the HBsAg-negative patients assigned to this grouping must be Hepatitis B antibody positive. Hepatitis B antibody positive patients are to be seated at the treatment stations nearest the isolation station and be assigned to the same staff member who is caring for the HBsAg+ patient.

(iv) If an HBsAg-positive patient is discharged, the equipment which had been reserved for that patient shall be given intermediate level disinfection prior to use for a patient testing negative for HBsAg.

(v) In the case of patients new to dialysis or a patient returning to a facility after extended hospitalization or absence of 30 calendar days or longer, if these patients are admitted for treatment before results of HBsAg or anti-HBs testing are known, these patients shall undergo treatment as if the HBsAg test results were potentially positive, except that they shall not be treated in the HBsAg isolation room, area, or machine.

(I) The facility shall treat potentially HBsAg-positive patients in a location in the treatment area which is outside of traffic patterns and may not reuse the dialyzer until the HBsAg test results are known.

(II) The dialysis machine used by this patient shall be given intermediate level disinfection prior to its use by another patient.

(III) The facility shall obtain HBsAg status results of the patient no later than three days from admission.

(e) Tuberculosis prevention.

(1) Prevention requirements concerning staff.

(A) Facility staff shall be screened for tuberculosis upon employment or receiving privileges as a member of the medical staff and prior to patient contact.

(B) Subsequent screening of facility staff shall be performed after any potential exposure to laryngeal or pulmonary tuberculosis.

(C) Respiratory isolation procedures and precautions developed by the facility shall be employed by facility staff providing treatment to patients with pulmonary tuberculosis.

(2) Prevention requirements concerning patients.

(A) If the facility treats active pulmonary tuberculosis patients, a separate room with an isolated air handling system shall be utilized for these patients.

(B) The facility shall screen patients for tuberculosis when indicated by the presence of risk factors for, or the signs and symptoms of tuberculosis. Screening shall be performed after potential exposure to active laryngeal or pulmonary tuberculosis.

§117.41. Quality Assurance for Patient Care.

(a) A facility shall perform a systematic, ongoing, concurrent and comprehensive review of the care provided. The review shall be specific to the facility. A facility shall adopt, implement, and enforce a quality assurance system which meets the criteria and standards described in this section.

(b) The quality assurance system shall include a quality management program which is planned with the participation of the facility's governing body; a quality control mechanism for data management and analysis; and a quality improvement mechanism to identify opportunities for improvement, develop improvement plan(s), and evaluate the implementation of the improvement plan(s).

(c) The governing body is responsible for:

(1) establishing the facility's quality mission;

(2) conducting quality planning;

(3) providing guidance and revising goals to achieve the quality mission;

(4) assuring allocation of sufficient time and resources to support the quality management program; and

(5) reviewing and monitoring the quality management activities at least quarterly.

(d) Quality management activities shall demonstrate that facility staff evaluate the provision of dialysis care and patient services, set treatment goals, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until resolution is achieved. Evidence shall support that aggregate patient data including identification and tracking of patient infections, is continuously reviewed for trends.

(e) Core staff members shall actively participate in the quality management activities.

(f) A facility shall conduct quality management meetings monthly or more often as necessary to identify or correct problems. At a minimum, the facility's medical director, supervising nurse, and the technical supervisor described in §117.44(f)(2) of this title (relating to Qualifications of Staff) shall participate in the quality management meetings. The quality management meetings shall be conducted separately from a patient care conference and the meetings shall be documented.

(g) The facility's quality control and quality improvement mechanisms shall include:

(1) an ongoing review of key elements of care using comparative and trend data to include aggregate patient data;

(2) identification of areas where performance measures or outcomes indicate an opportunity for improvement;

(3) appointment of interdisciplinary improvement team(s) to:

(A) identify variation from desired outcomes;

(B) create and implement improvement plan(s);

(C) evaluate the implementation of the improvement plan(s); and

(D) continue monitoring and improvement activities until goals are achieved and data demonstrates that improvement(s) have been made and maintained; and

(4) establishment and monitoring of quality assurance indicators for key aspects of care. For each quality assurance indicator, the facility shall establish and monitor a level of performance consistent with current professional knowledge. At a minimum, the following indicators shall be monitored on an ongoing basis:

(A) water quality (chemical, bacteriological analysis, and other indicators specific to the facility's water treatment system);

(B) equipment preventive maintenance and repair;

(C) reprocessing of hemodialyzers (dialyzer performance measures, labeling, and disinfection);

(D) infection control (staff and patient screening; standard precautions; bacteriological monitoring of dialyzer(s), water, machine(s), and dialysate; pyrogen reactions; sepsis episodes; and peritonitis rate);

(E) incidents and rate of occurrence (accidents, medication errors, adverse drug reactions, and other occurrences affecting patient(s), patient(s) family member(s), visitor(s), or staff). These occurrences shall include incidents required to be reported to the director under §117.46 of this title (relating to Reports to the Director). Review of these occurrences shall include analysis of the patient history and specific circumstances to identify potential ways to prevent recurrence;

(F) mortality (review of each death and monitoring modality specific mortality rate(s));

(G) complaints and suggestions (from patients, family, or staff);

(H) staffing (orientation, training, licensing and certification, and workload);

(I) safety (fire and disaster preparedness and disposal of special waste);

(J) medical records;

(K) clinical outcomes (laboratory indicators, hospitalizations, vascular access complications, and transplantation; and

(L) patient's quality of life to include rehabilitation.

(h) The department may review a facility's quality assurance activities to determine compliance with this section.

(1) A department surveyor shall verify that the facility has a quality management program which addresses concerns relating to quality of care provided to its patients and that facility staff know how to access the program's process.

(2) The department may not require disclosure of quality management program records except when disclosure is necessary to determine compliance with this section.

(3) The department will not use good faith efforts by the quality management program to identify and correct deficiencies relating to quality as a basis for a deficiency(ies) cited under this chapter.

§117.42. Indicators of Quality of Care.

(a) Each facility shall submit an annual report to the Texas Department of Health (department) or the department's designee to include aggregrate data on specified indicators of the quality of care provided to patients. Examples of indicators include:

(1) anemia management;

(2) albumin level;

(3) measures of the adequacy of dialysis;

(4) vascular access management;

(5) bone disease management ;

(6) peritonitis rate; and

(7) hospitalization rate.

(b) The form and data to be submitted will be specified annually by the department. The department shall provide notice to a facility of the required content for the report in sufficient time to enable facility staff to collect the data. The form required by the department will be constructed in consideration of the reports required by the Centers for Medicare and Medicaid Services and Centers for Disease Control to reduce or eliminate redundancy. The department may request data to validate the aggregate information contained in the annual report. All information gathered will be available to the department for review.

(c) Data from each facility will be reviewed and compared with statewide and national aggregrate data to identify opportunities to improve care. Assistance in improving care from the department or department's designee may include feedback of comparative data, a corrective action plan, or an onsite inspection.

(d) A renewal license will not be issued to a facility until the facility's current annual report is received complete.

§117.43. Provision and Coordination of Treatment and Services.

(a) Patient rights. Each facility shall adopt, implement, and enforce policies and procedures appropriate to the patient population served which ensure each patient is:

(1) treated with respect, dignity, and full recognition of the patient's individuality and personal needs;

(2) provided privacy and confidentiality, for the patient and the clinical record;

(3) provided a safe and comfortable treatment environment;

(4) provided information in a manner to facilitate understanding by the patient and the patient's legal representative, family or significant other. Written patient information materials shall be available, with materials in languages other than English if the census of the facility includes more than four patients who read that primary language. In lieu of written materials in the patient's primary language, an interpreter may be provided if documentation and patient interview support that information sufficient to allow the patient to participate in the treatment has been communicated;

(5) informed by a physician of the patient's medical status;

(6) informed of all treatment modalities and settings for the treatment of end stage renal disease;

(7) informed about and participates in, if desired, all aspects of care, including the right to refuse treatment, and informed of the medical consequences of such refusal;

(8) aware of all services available in the facility and the charges for services provided;

(9) informed about the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are used to describe a facility and its services, the brochures shall contain a statement with respect to reuse;

(10) assured of a reasonable response by the facility to the patient's requests and needs for treatment or service, within the facility's capacity, the facility's stated mission, and applicable law and regulation;

(11) provided hours of dialysis that are scheduled for patient convenience whenever feasible or possible. Consideration shall be given to a patient's work or school schedule;

(12) transferred or discharged only for medical reasons, for the patient's welfare or that of other patients or staff members, or for nonpayment of fees. A patient shall be given 30 calendar days advance notice to ensure orderly transfer or discharge, except in cases where the patient presents an immediate risk to others;

(13) a facility shall establish, implement and enforce a policy whereby a disruptive patient or family member or non-compliant patient is given an opportunity and assistance to improve the problematic behavior prior to dismissal from the facility. The policy will include requirements at §117.43(b)(7);

(14) provided protection from abuse, neglect, or exploitation as those terms are defined in §1.204 of this title (relating to Abuse, Neglect, and Exploitation Defined);

(15) provided information regarding advance directives and allowed to formulate such directives to the extent permitted by law. This includes documents executed under the Natural Death Act, Health and Safety Code, Chapter 672; Civil Practice and Remedies Code, Chapter 135 concerning durable power of attorney for health care; and Health and Safety Code, Chapter 674 concerning out-of-hospital do-not-resuscitate;

(16) aware of the mechanisms and agencies to express a complaint against the facility without fear of reprisal or denial of services. A facility shall provide to each individual who is admitted to the facility a written statement that informs the individual that a complaint against the facility may be directed to the department. The statement shall be provided at the time of admission and shall advise the patient that registration of complaints may be filed with the director, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199, 1-888-973-0022. Correctional institutions shall not be required to include the 1-888 number in information provided to patients in these facilities; and

(17) fully informed of the rights listed in this subsection, the responsibilities established by the facility, and all rules and regulations governing patient conduct and responsibilities. A written copy of the patient's rights and responsibilities shall be provided to each patient or the patient's legal representative upon admission and a copy shall be posted with the facility license certificate.

(b) Patient care plan.

(1) A facility shall establish, implement, and enforce a policy whereby patient services are coordinated using an interdisciplinary team approach. The interdisciplinary team shall consist of the patient's primary dialysis physician, registered nurse, social worker, and dietitian.

(2) The interdisciplinary team shall engage in an interactive conference in order to develop a written, individualized, comprehensive patient care plan that specifies the services necessary to address the patient's medical, psychological, social, and functional needs, and includes treatment goals.

(3) The patient care plan shall include evidence of coordination with other service providers (e.g. hospitals, long term care facilities, home and community support services agencies, or transportation providers) as needed to assure the provision of safe care.

(4) The patient care plan shall include evidence of the patient's (or patient's legal representative's) input and participation, unless they refuse to participate. At a minimum, the patient care plan shall demonstrate that the content was discussed with the patient or the patient's legal representative by a member of the interdisciplinary team.

(5) The patient care plan shall be developed within 30 days from the patient's admission to the facility and updated as indicated by any change in the patient's medical, nutritional, or psychosocial condition, or at least every six months. Evidence of the review of the patient care plan with the patient and the interdisciplinary team to evaluate the patient's progress or lack of progress toward the goals of the care plan, and interventions taken when the goals are not achieved, shall be documented and included in the patient's clinical record.

(6) A team conference may be conducted via phone conferencing. A phone care plan conference conducted with the interdisciplinary team and the patient (or their legal representative) must be documented as a phone conference.

(7) In the case of disruptive patients or family members or patients who do not conform to the treatment plan, the facility will establish, implement and enforce a process for more intensive team

intervention with this patient to include assessment of needs and planned interventions to assist the patient in adjusting to the requirements for safe care.

(c) Emergency preparedness.

(1) A facility shall implement written procedures which describe staff and patient actions to manage potential medical and non-medical emergencies, including but not limited to, fire, equipment failure, power outages, medical emergencies, and natural or other disasters which are likely to threaten the health or safety of facility patients, the staff, or the public.

(2) A facility shall have a functional plan to access the community emergency medical services.

(3) A facility shall have personnel qualified to operate emergency equipment and to provide emergency care to patients on-site and available during all treatment times. A charge nurse qualified to provide basic cardiopulmonary life support (BCLS) shall be on site and available to the treatment area whenever patients are present. All clinical staff members shall maintain current certification and competency in BCLS.

(4) A facility shall have a transfer agreement with one or more hospitals which provide acute dialysis service for the provision of inpatient care and other hospital services to the facility's patients. The facility shall have documentation from the hospital to the effect that patients from the facility will be accepted and treated in emergencies. There shall be reasonable assurances that:

(A) the transfer or referral of patients will be effected between the hospital and the facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(B) the interchange of medical and other information necessary or useful in the care and treatment of the patient transferred will occur within one working day; and

(C) security and accountability will be assured for the transferred patient's personal effects.

(5) A facility shall establish, implement and enforce a written plan for the protection of patients in the event of a fire.

(A) An evacuation plan shall be developed and diagrams posted in conspicuous places.

(B) The facility shall provide approved fire extinguishing equipment adequate for the conditions involved. Every portable fire extinguisher maintained in the facility shall be installed and maintained in accordance with National Fire Protection Association 10, Standard for Portable Fire Extinguishers, 1994 Edition, and the National Fire Protection Association 101, Code for Safety to Life from Fire in Buildings and Structures, 1994 Edition, §26-3.5, published by the National Fire Protection Association, Post Office Box 9101, Batterymarch Park, Quincy, Massachussetts 02169, 1-800-344-3555. Fire extinguishers shall be refilled when necessary, kept in condition for instant use, and tagged or labeled to indicate the name, address, and telephone number of the person recharging the unit and the date of the last inspection. The hose, nozzle, gaskets, and all other parts shall be maintained in good repair at all times.

(C) The facility shall conduct fire drills at least every six months for each patient shift to include the use of alarms and equipment, and discussion with patients, visitors, employees and staff about the evacuation plan. Written reports shall be maintained to include evidence of staff and patient participation.

(D) All staff shall be familiar with the locations of fire-fighting equipment. Fire-fighting equipment shall be located so that a person shall not have to travel more than 75 feet from any point to reach the equipment.

(6) A written disaster preparedness plan for natural and other disasters specific to each facility shall be developed and in place. The plan shall be based on an assessment of the probability and type of disaster in each region and the local resources available to the facility. The plan shall be reviewed by the governing body at least annually. Contact shall be made annually with a local disaster management representative to assess the need to revise the plan and to ensure that local agencies are aware of the dialysis facility, its provision of life-saving treatment, and the patient population served. The plan shall include procedures designed to minimize harm to patients and staff along with ensuring safe facility operations. The plan and in-service programs for patients and staff shall include provisions or procedures for responsibility of direction and control, communications, alerting and warning systems, evacuation, and closure. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility's disaster preparedness plan.

(7) A facility shall have an emergency lighting system capable of providing sufficient illumination to allow safe discontinuation of treatments and safe evacuation from the building. Battery pack systems shall be maintained and tested quarterly. If a facility maintains a back-up generator, the generator must be installed, tested and maintained in accordance with the National Fire Protection Association 110, Standard for Emergency and Standby Power Systems, 1993 Edition (NFPA 110), published by the National Fire Protection Association.

(8) A facility shall develop and post a telephone number listing specific to the facility equipment and locale to assist staff in contacting mechanical and technical support in the event of an emergency.

(d) Medication storage and administration.

(1) Pharmaceutical services shall be provided in accordance with accepted professional principles and federal and state laws and regulations.

(2) Medications shall be administered only if such medication is ordered by the patient's physician.

(3) All verbal or telephone orders shall be received by a licensed nurse or physician assistant. Orders relating to a specific service (e.g. dietary services), may be received by the licensed professional responsible for providing the service (e.g. dietitian) and countersigned by the physician within 15 calendar days.

(4) Medications maintained in the facility shall be properly stored and safeguarded in enclosures of sufficient size which are not accessible to unauthorized persons. Refrigerators used for storage of medications shall maintain appropriate temperatures for such storage.

(5) A facility shall maintain an emergency stock of medications, as specified by the medical director, to treat the emergency needs of patients.

(6) Medications shall not be prepared for administration in the patient's immediate treatment area. The medication preparation area shall be located in such a manner as to prevent contamination of medicines being prepared for administration and shall include a work counter and a sink.

(7) Multi-dose vials shall not be taken to a patient station. Protocols approved by the Centers for Disease Control must be used in those cases where single-use vials are entered more than once.

(8) Medications not given immediately shall be labeled with the patient's name, the name of the medication, the dosage prepared, and the initials of the person preparing the medication. All medications shall be administered by the individual who prepares them.

(9) All medications shall be administered by licensed nurses, physician assistants, or physicians except that intravenous normal saline, intravenous heparin, subcutaneous lidocaine, and oxygen may be administered as part of a routine hemodialysis treatment by dialysis technicians qualified according to §117.62(b) and (f) of this title (relating to Training Curricula and Instructors) and §117.63(b), (c) and (e) of this title (relating to Competency Evaluation). Such administration by dialysis technicians shall be in compliance with Chapter 157 of the Texas Occupations Code concerning the delegation of medical acts by a licensed physician in the State of Texas.

(e) Nursing services.

(1) Nursing services to prevent or reduce complications and to maximize the patient's functional status shall be provided to a patient and the patient's family or significant other.

(2) A full-time supervising nurse shall be employed to manage the provision of patient care.

(3) A registered nurse shall be responsible for:

(A) conducting admission nursing assessments;

(B) conducting assessments of a patient when indicated by a question relating to a change in the patient's status or at the patient's request;

(C) participating in team review of a patient's progress;

(D) recommending changes in treatment based on the patient's current needs;

(E) facilitating communication between the patient, patient's family or significant other, and other team members to ensure needed care is delivered;

(F) providing oversight and direction to dialysis technicians and licensed vocational nurses; and

(G) participating in continuous quality improvement activities.

(4) A nurse or nurses functioning in the charge role shall be on site and available to the treatment area to provide patient care during all dialysis treatments.

(5) At least one licensed nurse shall be available on-site to provide patient care for every twelve patients or portion thereof. This may include the nurse(s) functioning in the charge role required by paragraph (4) of this subsection.

(6) If pediatric dialysis is provided, a registered nurse with experience or training in pediatric dialysis shall be available to provide care for pediatric dialysis patients smaller than 35 kilograms in weight.

(7) Sufficient direct care staff shall be on-site to meet the needs of the patients.

(A) The staffing level for a facility shall not exceed four patients per licensed nurse or patient care technician per patient shift. During treatment of eight or more patients, one of the licensed nurses qualified to function in the charge role shall not be included in this ratio.

(B) For pediatric dialysis patients, one licensed nurse shall be provided on-site for each patient weighing less than ten kilograms and one licensed nurse provided on-site for every two patients weighing from ten to 20 kilograms.

(8) A facility shall provide a nursing station(s) to allow adequate visual monitoring of patients by nursing staff during treatment.

(9) A licensed nurse or dialysis technician shall collect and document objective and subjective data for each patient before and after treatment according to facility policy and the staff member's level of training. Written protocols may identify parameters which would require a patient be referred to a nurse for evaluation. A registered nurse shall conduct a patient assessment when indicated by a question relating to a change in the patient's status or at the patient's request.

(10) The initial patient evaluation shall be initiated by a licensed nurse qualified to function in the charge role or a registered nurse at the time of the first treatment in the facility and completed by a registered nurse within the first three treatments.

(f) Licensed vocational nurses. This chapter does not preclude a licensed vocational nurse (LVN) from practicing in accordance with the rules adopted by the Texas Board of Vocational Nurse Examiners. If the LVN is acting in the capacity of a dialysis technician, the facility shall determine that the LVN has passed a training and competency evaluation curriculum which meets the requirements in §117.62 of this title (relating to Training Curricula) and §117.63 of this title (relating to Competency Evaluation).

(g) Dialysis technicians. A dialysis technician providing direct patient care shall demonstrate knowledge and competency for the responsibilities specified in §117.62 of this title and §117.63 of this title.

(h) Nutrition services.

(1) Nutrition services shall be provided to a patient and the patient's caregiver(s) in order to maximize the patient's nutritional status.

(2) The dietitian shall be responsible for:

(A) conducting a nutrition assessment of a patient;

(B) participating in a team review of a patient's progress;

(C) recommending therapeutic diets in consideration of cultural preferences and changes in treatment based on the patient's nutritional needs in consultation with the patient's physician;

(D) counseling a patient, a patient's family, and a patient's significant other on prescribed diets and monitoring adherence and response to diet therapy. Correctional institutions shall not be required to provide counseling to family members or significant others;

(E) referring a patient for assistance with nutrition resources such as financial assistance, community resources or in-home assistance;

(F) participating in continuous quality improvement activities; and

(G) providing ongoing monitoring of subjective and objective data to determine the need for timely intervention and follow-up. Measurement criteria include but are not limited to weight changes, blood chemistries, adequacy of dialysis, and medication changes which affect nutrition status and potentially cause adverse nutrient interactions.

(3) The collection of objective and subjective data to assess nutrition status shall occur within two weeks or seven treatments from admission to the facility, whichever occurs later. A comprehensive nutrition assessment with an educational component shall be completed within 30 days or 13 treatments from admission to the facility, whichever occurs later.

(4) A nutrition reassessment shall be conducted annually or more often if indicated.

(5) Each facility shall employ or contract with a dietitian(s) to provide clinical nutrition services for each patient. One full-time equivalent of dietitian time shall be available for up to 100 patients with the maximum patient load per full-time equivalent of dietitian time being 125 patients.

(6) Nutrition services shall be available at the facility during scheduled treatment times. Access to services may require an appointment.

(i) Social services.

(1) Social services shall be provided to patients and their families and shall be directed at supporting and maximizing the adjustment, social functioning, and rehabilitation of the patient.

(2) The social worker shall be responsible for:

(A) conducting psychosocial evaluations;

(B) participating in team review of patient progress;

(C) recommending changes in treatment based on the patient's current psychosocial needs;

(D) providing case work and group work services to patients and their families in dealing with the special problems associated with end stage renal disease;

(E) except in the case of social workers providing service in correctional institutions, identifying community social agencies and other resources and assisting patients and families to utilize them; and

(F) participating in continuous quality improvement activities.

(3) Initial contact between the social worker and the patient shall occur and be documented within two weeks or seven treatments from the patient's admission, whichever occurs later. A comprehensive psychosocial assessment shall be completed within 30 days or 13 treatments from the patient's admission, whichever occurs later.

(4) A psychosocial reassessment shall be conducted annually or more often if indicated.

(5) Each facility shall employ or contract with a social worker(s) to meet the psychosocial needs of the patients. One full-time equivalent of qualified social worker time shall be available for each 100 patients. If the facility provides additional staff who perform supportive services (e.g. assistance with financial services/ transportation), the maximum patient load per full-time equivalent of qualified social worker time may be 125 patients.

(6) Social services shall be available at the facility during the times of patient treatment. Access to social services may require an appointment.

(j) Medical services.

(1) Medical director. The medical director is responsible for:

(A) developing facility treatment goals which are based on review of aggregate data assessed through quality management activities;

(B) assuring adequate training of licensed nurses and dialysis technicians;

(C) adequate monitoring of patients and the dialysis process; and

(D) developing and implementing all policies required by this chapter.

(2) Medical staff.

(A) Each patient shall be under the care of a physician on the medical staff.

(B) The care of a pediatric dialysis patient shall be in accordance with this subparagraph. If a pediatric nephrologist is not available as the primary physician, an adult nephrologist may

serve as the primary physician with direct patient evaluation by a pediatric nephrologist according to the following schedule:

(i) for patients two years of age or younger--monthly (two of three evaluations may be by phone);

(ii) for patients three to 12 years of age--quarterly; and

(iii) for patients 13 to 18 years of age--semiannually.

(C) At a minimum, each patient receiving dialysis in the facility shall be seen by a physician on the medical staff once every two weeks during the patient's treatment time. Home patients shall be seen by a physician at least every three months. The record of these contacts shall include evidence of assessment for new and recurrent problems and review of dialysis adequacy, monthly for in-facility patients and quarterly for home patients.

(D) A physician on the medical staff shall be on call and available 24 hours a day (in person or by telecommunication) to patients and staff.

(E) Orders for treatment shall be in writing and signed by the prescribing physician. Routine orders for treatment shall be updated at least annually.

(i) Orders for hemodialysis treatment shall include length of treatment, dialyzer, blood flow rate, dialysate composition, target weight, medications including heparin, and, as needed, specific infection control measures.

(ii) Orders for peritoneal dialysis treatment shall include fill volume(s), number of exchanges, dialysate concentrations, catheter care, medications, and, as needed, specific infection control measures.

(F) If advanced practice nurses or physician assistants are utilized:

(i) there shall be evidence of communication with the treating physician whenever the advanced practice nurse or physician assistant changes treatment orders;

(ii) the advanced practice nurse or physician assistant may not replace the physician in participating in patient care planning or in quality management activities; and

(iii) the treating physician shall be notified and direct the care of patient medical emergencies.

(k) Home dialysis (self dialysis).

(1) If a facility provides self dialysis training, a registered nurse with at least 12 months clinical experience and six months experience in home dialysis shall be responsible for training the patient or family. When other personnel assist in the training, supervision by the registered nurse shall be demonstrated.

(2) For a patient who performs self dialysis at home, the following services shall be provided:

(A) a yearly physical examination;

(B) monthly contact from facility staff by telephone calls or clinic visits;

(C) a clinic visit at least every three months;

(D) communication with the appropriate interdisciplinary team member(s);

(E) routine laboratory work according to facility policy;

(F) a mechanism to contact staff at any time in the event of an emergent need; and

(G) surveillance of the patient's home adaptation, including provisions for visits to the home.

(3) The facility shall provide directly or under arrangement the following services.

(A) For hemodialysis, the required services are:

(i) consultation for the patient with a registered nurse, social worker and a dietitian;

(ii) a record keeping system which assures continuity of care;

(iii) installation and maintenance of equipment;

(iv) testing and appropriate treating of the water used for dialysis; and

(v) ordering of supplies on an ongoing basis.

(B) For continuous ambulatory peritoneal dialysis, the required services are:

(i) consultation for the patient with a registered nurse, a social worker and a dietitian;

(ii) a record keeping system which assures continuity of care; and

(iii) ordering of supplies on an ongoing basis.

(C) For continuous cycling peritoneal dialysis, the required services are:

(i) consultation for the patient with a registered nurse, a social worker and a dietitian;

(ii) a record keeping system which assures continuity of care;

(iii) installation and maintenance of equipment; and

(iv) ordering of supplies on an ongoing basis.

(l) Temporary and transient admissions.

(1) Temporary admissions. If a facility dialyzes a patient who is normally dialyzed in another local facility, the referring and receiving facilities shall meet the requirements in this paragraph.

(A) The individual to be treated by the receiving facility must be a patient of a physician who is a member of the medical staffs of the referring and receiving facilities.

(B) The referring and receiving facilities shall establish, implement, and enforce written policies and procedures for communication of medical information and transfer of clinical records between facilities.

(C) The receiving facility shall continuously evaluate staffing levels and utilize this information in determining whether to accept a temporary admission for treatment.

(D) The receiving facility shall obtain the information described in §117.45(e) of this title (relating to Clinical Records) prior to providing dialysis. However, if the referring facility is closed when the patient's need for dialysis treatment is identified, the receiving facility may provide dialysis with, at a minimum, the following information:

(i) orders for treatment;

(ii) hepatitis B status;

(iii) medical justification by the physician ordering treatment that the patient's need for dialysis outweighs the need for the additional clinical information set out in §117.45(e) of this title.

(E) In the event a temporary patient's hepatitis status is unknown, the patient may undergo treatment as if the HBsAg test results were potentially positive, except that such a patient shall not be treated in the HBsAg isolation room, area, or machine.

(2) Transient admissions. If a facility dialyzes a patient who is normally dialyzed in a distant facility, the facility shall meet the requirements in this paragraph.

(A) The facility shall continuously evaluate staffing levels and utilize this information in determining whether to accept a transient patient for treatment.

(B) The facility shall obtain the information described in §117.45(e) of this title (relating to Clinical Records) prior to providing dialysis. However, if the transient patient arrives unannounced, the facility may provide dialysis with, at a minimum, the following information:

(i) evidence of evaluation of the patient by a physician on the staff of the facility;

(ii) orders for treatment;

(iii) hepatitis B status;

(iv) medical justification by the physician ordering treatment that the patient's need for dialysis outweighs the need for the additional clinical information set out in §117.45(e) of this title.

(C) In the event a transient patient's hepatitis status is unknown, the patient may undergo treatment as if the HBsAg test results were potentially positive, except that such a patient shall not be treated in the HBsAg isolation room, area, or machine.

(m) Laboratory services. A facility that provides laboratory services shall comply with the requirements of Federal Public Law 100-578, Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988). CLIA 1988 applies to all facilities that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(n) Illegal remuneration prohibited. A facility shall not violate the Health and Safety Code, §161.191, et seq. concerning the prohibition on illegal remuneration for the purpose of securing or soliciting patients or patronage.

(o) Do-not-resuscitate orders. The facility shall comply with the Health and Safety Code, Chapter 674 concerning out-of-hospital do-not-resuscitate orders.

(p) Audits of billing. A facility shall develop, implement, and enforce a compliance policy for monitoring its receipt and expenditure of state or federal funds.

(q) Student health care professionals. If the facility has a contract or agreement with an accredited school of health care to use their facility for a portion of the students' clinical experience, those students may provide care under the following conditions.

(1) Students may be used in facilities, provided the instructor gives class supervision and assumes responsibility for all student activities occurring within the facility. If the student is licensed (e.g., a licensed vocational nurse attending a registered nurse program for licensure as a registered nurse) the facility shall ensure that the administration of any medication(s) is within the student's licensed scope of practice.

(2) A student may administer medications only if:

(A) on assignment as a student of his or her school of health care; and

(B) the instructor is on the premises and immediately supervises the administration of medication by an unlicensed student and the administration of such medication is within the instructor's licensed scope of practice.

(3) Students shall not be used to fulfill the requirement for administration of medications by licensed personnel.

(4) Students shall not be considered when determining staffing levels required by the facility.

(r) Complaint resolution. A facility shall adopt, implement, and enforce procedures for the resolution of complaints relevant to quality of care or services rendered by licensed health care professionals and other members of the facility staff, including contract services or staff. The facility shall document the receipt and the disposition of the complaint. The investigation and documentation must be completed within 30 calendar days after the facility receives the complaint, unless the facility has and documents reasonable cause for a delay.

§117.44. Qualifications of Staff.

(a) General.

(1) A written orientation program to familiarize all new employees (including office staff) with the facility, its policies, and job responsibilities shall be developed and implemented.

(2) In order to assure that each new direct patient care staff member is provided sufficient time to become familiar with the facility, the orientation program provided by the facility shall be a minimum time of two weeks for individuals with previous dialysis experience. For new direct patient care staff members with no previous dialysis experience, the orientation program shall be two weeks plus additional orientation time as determined by the facility.

(3) In facilities with similar policies and equipment, experienced staff oriented to one facility may be shared with another facility after a shorter orientation period. Documentation of current competency of any shared staff and delegation by that facility's medical director to unlicensed technicians must be on file in each facility where the shared employee works.

(4) A facility shall provide registered nurses with no previous dialysis experience an orientation program of a minimum of six weeks. For these registered nurses, the six-week orientation program shall contain at least the following subject content specific to the management of the end stage renal disease patient and appropriate to the population served by the facility:

(A) fluid, electrolyte and acid-base balance;

(B) kidney disease and treatment;

(C) dietary management of kidney disease;

(D) principles of dialysis;

(E) dialysis technology;

(F) venipuncture technique;

(G) care of the dialysis patient;

(H) psychological, social, financial, and physical complications of long-term dialysis;

(I) prevention of hepatitis and other infectious diseases; and

(J) risks and benefits of reuse (if reuse is practiced).

(5) Each licensed nurse and dialysis technician shall demonstrate competency through written and skills testing annually. Evidence of competency shall be documented in writing and maintained in personnel files. Current certification by a nationally recognized board may substitute for the annual written test.

(6) A facility shall maintain documentation to demonstrate that each staff member providing patient care completes at least five hours of continuing education related to end stage renal disease annually. Continuing education may be provided by facility staff.

(b) Medical staff.

(1) Each physician on the medical staff shall have a current license to practice medicine in the State of Texas.

(2) The governing body of a facility shall designate a medical director.

(3) The members of the medical staff may include nephrologists and other physicians with training or demonstrated experience in the care of end stage renal disease patients.

(4) If an advanced practice nurse or physician assistant is utilized, such individuals shall meet the requirements established by the Board of Nurse Examiners (for an advanced practice nurse) or the Board of Medical Examiners (for a physician assistant).

(c) Nursing staff.

(1) Each licensed nurse shall have a current Texas license to practice nursing.

(2) Each nurse assigned charge responsibilities shall be a registered nurse and have six months experience in hemodialysis obtained within the last 24 months. An RN who holds a current certification from a nationally recognized board in nephrology nursing or hemodialysis may substitute the certification for the six months experience in dialysis obtained within the last 24 months. The responsibilities of an RN functioning as a charge nurse shall include:

(A) making daily assignments based on patient needs;

(B) providing immediate supervision of direct patient care;

(C) making patient assessments when indicated; and

(D) communicating with the physician(s), social worker(s) and dietitian(s).

(3) The following provisions create an exception to the requirement that the licensed nurse functioning in the charge role be a registered nurse.

(A) A licensed vocational nurse (LVN) who meets one of the following requirements may function in the charge role:

(i) the LVN was employed in a facility as of September 1, 1996, and had two years full time experience functioning in the charge role in a facility prior to September 1, 1996; or

(ii) the LVN has two years full time experience in hemodialysis, is certified as a hemodialysis nurse by a nationally recognized board (e.g. Board of Nephrology Nurse and Technician Examination), has completed a facility based training program for the charge role, and has demonstrated competence in the charge role.

(B) The responsibilities of an LVN functioning in the charge role, as delegated by the medical director, shall include:

(i) making daily assignments based on protocols to allow change of assignments based on patient needs;

(ii) providing immediate supervision of the direct patient care provided by dialysis technicians;

(iii) monitoring patients for changes in condition and notifying a RN or physician of such changes;

(iv) communicating with the physician(s), social worker(s) and dietitian(s).

(C) A LVN with two years full time experience in dialysis may function in the charge role in the temporary absence of the nurse functioning in the charge role at the facility.

(D) If a LVN is functioning in the charge role, in order to provide the direct supervision of dialysis technicians required by the statute, the facility's full time supervising nurse shall establish written protocols addressing the supervision of the technicians. The implementation of the protocol shall be considered to constitute direct supervision of the technicians by the RN. In the alternative, an RN who is the instructor of the facility's dialysis technician course, another RN, or a physician may provide onsite, direct supervision of the dialysis technicians.

(E) If a facility uses LVNs in the charge role, there must be written protocols specific to the facility to guide actions to be taken by the LVN functioning in the charge role in the event a patient's condition changes during treatment. These protocols must be approved by the medical director and be congruent with the state practice acts for registered nurses and licensed vocational nurses.

(F) In accordance with Title 22, Texas Administrative Code (TAC), §217.12 relating to designations for registered nurse/titles deemed misleading, an LVN functioning in the charge role may not be titled a "charge nurse."

(4) If patient self-care training is provided, a registered nurse who has at least 12 months clinical experience and six months experience in home dialysis shall be responsible for training the patient or family. When other personnel assist in the training, supervision by the registered nurse shall be demonstrated.

(d) Nutritional staff. Each dietitian shall be licensed in Texas, be eligible for registration by the Commission on Dietetic Registration of the American Dietetic Association, and have one year of experience in clinical dietetics after becoming eligible for registration.

(e) Social services staff. Each social worker shall:

(1) be licensed as a social worker under the Human Resources Code, Chapter 50, and hold a masters degree in social work from a graduate school of social work accredited by the Council on Social Work Education; or

(2) have worked for at least two years as a social worker, one year of which was in a dialysis facility or transplantation program prior to September 1, 1976, and have established a consultative relationship with a social worker who has a masters degree in social work from a graduate school of social work accredited by the Council on Social Work Education.

(f) Technical staff. A facility shall have the technical staff as described in this subsection. The facility's technical staff may be one or more individuals (including nursing staff) employed by or under contract with the facility as long as the individual(s) meets the minimum qualifications for each required level of responsibility as described in this subsection.

(1) All staff assigned technical responsibilities. Only individuals qualified by training, education, or experience may operate, repair, or replace components of the systems utilized in providing dialysis treatment or reprocessing dialyzers.

(A) Technical staff shall have the following minimum education, training and experience and documentation of such education, training, and experience shall be maintained on file in the facility:

(i) high school diploma or equivalent. For technical staff employed by the facility for two or more years prior to the effective date of these rules, this requirement is waived; and

(ii) training or experience in one or more of the following:

(I) completion of a college based technical dialysis program;

(II) completion of the didactic training and education requirement for patient care technicians set out in §117.62(a) and (b) of this title (relating to Training Curricula and Instructors);

(III) current certification in technical aspects of dialysis by a nationally recognized testing organization; or

(IV) 12 months experience in dialysis within the last two years.

(B) Any staff member assigned responsibilities in the technical area shall pass a written competency examination, demonstrate skills related to the required level of responsibility and be certified by the facility's medical director as competent to perform their assigned duties. Current certification by a national board in dialysis technology may substitute for written testing.

(C) The technical staff shall demonstrate competency for the required level of responsibility through written and skills testing annually. Current certification by a national board in dialysis technology may substitute for written testing. Evidence of competency shall be documented in writing and maintained in the personnel file.

(D) The technical staff shall complete a minimum of five hours of continuing education with a technical or end stage renal disease focus annually. The continuing education may be obtained through informal or formal education programs and shall be documented in facility files.

(2) Technical supervisory staff. The technical supervisor is responsible for the supervision of technical services. The technical supervisor shall meet the education, training, and experience requirements described in this paragraph.

(A) The technical supervisor shall meet the requirements in paragraph (1) of this subsection.

(B) At a minimum, the technical supervisor shall demonstrate competency in equipment maintenance and repair; mechanical service; water treatment systems; and reprocessing of hemodialyzers (if applicable).

(i) Prior to initially assuming technical supervisory responsibility, a technical supervisor trainee shall successfully complete the facility's orientation and training course(s) as established for each technical area.

(ii) The training course(s) shall be approved by the medical director and follow a written curriculum with stated objectives. The curriculum shall include all items noted in paragraphs (3)(B)(ii), (4)(B), and (5)(A) of this subsection.

(3) Staff responsible for water treatment and dialysate systems.

(A) Facility staff responsible for the water treatment and dialysate systems shall demonstrate understanding of the risks to patients of exposure to water which has not been treated so as to remove contaminants and impurities. Documentation of training to assure safe operation of the water treatment and dialysate systems shall be maintained for each individual who operates (regularly or intermittently) these systems.

(B) The staff responsible for the water treatment and dialysate systems shall meet the education, training, and experience requirements described in paragraph (1) of this subsection and shall demonstrate competency by:

(i) successful completion of the facility training course specific to water treatment, dialysate preparation and related tasks. The training course shall be approved by the medical director and follow a written curriculum with stated objectives;

(ii) completion of a training curriculum which includes the following minimum components:

(I) introduction to end stage renal disease;

(II) principles of hemodialysis;

(III) principles of infection control and basic microbiology for water treatment systems, machines, and sampling techniques;

(IV) rationale for water treatment for dialysis;

(V) risks and hazards of the use of unsafe water for dialysis;

(VI) current water standards;

(VII) source water characteristics;

(VIII) communication with source water agencies and water treatment vendors;

(IX) selection of water treatment equipment;

(X) water purification equipment to include filtration, carbon adsorption and reverse osmosis;

(XI) ion exchange to include softeners and deionizers;

(XII) water distribution system and other equipment specific to the facility;

(XIII) monitoring system performance to include on-line and off-line monitoring, aseptic sample collection, incubation of samples and interpretation of results;

(XIV) evaluation of water treatment component performance to include filters, activated carbon adsorption beds, reverse osmosis, and ion exchange; and

(XV) evaluation of system performance to include monitoring schedules and review of system failures;

(XVI) purpose of each component of dialysate to include electrolytes, glucose, acid, and buffer;

(XVII) hazards of exposure of patients to a dialysate containing a different concentration of electrolytes than prescribed;

(XVIII) testing methods in use to verify expected concentrations in any reconstituted components of the dialysate are achieved;

(XIX) action to take in the event testing of a mixed batch of dialysate concentrate does not meet the expected parameters;

(XX) labeling employed to positively identify each concentrate; and

(XXI) procedures to ensure the proper transfer of concentrates from the manufacturer's drums to the holding tanks.

(iii) confirmation of the ability to distinguish all primary colors; and

(iv) successful completion of the facility's orientation and training course as established for the water treatment and dialysate preparation systems technician trainee prior to the trainee's initial assumption of responsibility.

(4) Equipment maintenance and repair staff. The staff responsible for equipment maintenance and repair shall meet the education, training, and experience requirements described in paragraph (1) of this subsection and shall demonstrate competency by:

(A) successful completion of the facility training course outlined in paragraph (3) of this subsection, relating to water treatment systems;

(B) successful completion of a training curriculum which includes the following minimum components:

(i) prevention of transmission of hepatitis through dialysis equipment;

(ii) safety requirements of dialysate delivery systems;

(iii) repair and maintenance of dialysis and other equipment specific to the facility;

(iv) electrical safety, including lockout or tagout;

(v) emergency equipment maintenance;

(vi) building maintenance;

(vii) fire safety and prevention requirements; and

(viii) emergency response procedures; and

(C) successful completion of a written competency exam and demonstration of skills specific to the facility's mechanical and equipment service and water treatment and distribution systems.

(5) Reprocessing staff. The staff responsible for reprocessing hemodialyzers and other supplies shall meet the education, training, and experience requirements described in paragraph (1) of this subsection and shall demonstrate competency by:

(A) successful completion of a training curriculum which includes the components in the American National Standard, Reuse of Hemodialyzers, 1993 Edition, §5.2.1 published by the Association

for the Advancement of Medical Instrumentation, 3330 Washington Boulevard, Suite 400, Arlington, Virginia 22201; and

(B) successful completion of a written competency exam which includes return demonstration of skills specific to reprocessing of hemodialyzers and other dialysis supplies.

§117.45. Clinical Records.

(a) A facility shall establish and maintain a clinical record system to assure that the care provided to each patient is completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(1) All information shall be centralized in the patient's clinical record and be protected against loss or damage in accordance with state and Federal regulations.

(2) The facility shall provide an area for clinical records storage which is separate from all patient treatment areas. The clinical records area shall have adequate space for reviewing, dictating, sorting, or recording records. If electronic imaging devices are employed (i.e., microfilm or optical disc), the clinical records area shall have adequate space for transcribing records in the electronic format. The facility shall store the active clinical record of each patient currently treated by the facility on site.

(3) The facility shall ensure that each patient's personal and medical records are treated with confidentiality.

(4) Signature stamps may not be used to authenticate medical record entries.

(5) Clinical records may be preserved electronically. Computerized records shall meet all requirements of paper records including protection from casual access and retention for the specified period. Systems shall assure that entries regarding the delivery of care may not be altered without evidence and explanation of such alteration.

(6) Inactive clinical records may be preserved on microfilm, optical disc or other electronic means and may be stored off-site as long as security is maintained and the record is readily retrievable for review by the department or the department's designee.

(7) Each clinical record shall include:

(A) identifying information;

(B) consents and notifications;

(C) physician orders;

(D) progress notes;

(E) problem list;

(F) medical history and physical;

(G) professional assessments by the registered nurse, social worker, and dietitian;

(H) medication record to include medications given during treatment (which may be listed on the treatment record) and a listing of medications the patient takes at home;

(I) transfusion record;

(J) laboratory reports;

(K) diagnostic studies;

(L) hospitalization records;

(M) consultations;

(N) record of creation and revision of access for dialysis;

(O) patient care plans, including evidence of team review and adjustment;

(P) evidence of patient education;

(Q) daily treatment records; and

(R) discharge summary, if applicable.

(b) A comprehensive medical history and physical shall be completed 30 days before or within two weeks after any patient's admission to the facility. For a patient new to dialysis, the physician(s) responsible for the dialysis care shall complete the history and physical. For an established dialysis patient, the history and physical may be completed by a nurse practitioner or physician assistant. Prior to the first treatment in the facility, the physician shall inform the nurse functioning in the charge role of at least the patient's diagnoses, medications, hepatitis status, allergies, and dialysis prescription. The clinical record shall include this data.

(c) Progress notes shall provide an accurate picture of the progress of the patient, reflecting changes in patient status, plans for and results of changes in treatment, diagnostic testing, consultations, and unusual events. Each of the interdisciplinary team members shall record the progress of the patient as indicated by any change in the patient's medical, nutritional, or psychosocial condition or at least every six months.

(d) The patient's condition and response to treatment shall be noted on the daily treatment record.

(e) Prior to providing dialysis treatment of a transient patient, a facility shall obtain and include, at a minimum:

(1) orders for treatment in this facility;

(2) list of medications and allergies;

(3) laboratory reports. Such reports shall indicate laboratory work was performed no later than one month prior to treatment at the facility and include screening for hepatitis B status;

(4) the most current patient care plan;

(5) the most current treatment records from the home facility; and

(6) records of care and treatment at this facility.

(f) Clinical records shall be completed within 30 days after discharge. The discharge summary shall clearly identify the disposition of the patient and include the diagnosis or cause of death, date of discharge or death, location of death, transplant or relocation information when appropriate, and reason for discharge if not for transplantation or death.

(g) Clinical records are the property of the facility and shall be safeguarded against loss, destruction, or unauthorized use.

(h) Copies of pertinent portions of a patient's record shall be provided when the patient is transferred. The records provided shall include, at a minimum, the most current orders for dialysis treatment, the last three treatment records, the current hepatitis status, and the most current patient care plan. If the patient is transferred to another outpatient facility, copies of the most recent history and physical and assessment of each member of the interdisciplinary team shall also be provided.

(i) Records shall be retained by a facility for a minimum of five years after the discharge of the patient and in accordance with state and Federal regulations. The facility may not destroy clinical records that relate to any matter that is involved in litigation if the facility knows the litigation has not been finally resolved.

(j) If a facility ceases operation, there shall be an arrangement for the preservation of records to insure compliance with this section. The facility shall send the department written notification of the location of the clinical records and the name and address of the clinical records custodian.

§117.46. Reports to the Director.

(a) A facility shall report the following occurrence(s) to the department within ten working days of the occurrence(s):

(1) an accident or incident resulting in the death of a patient; or

(2) conversion of staff or a patient to HbsAg positive.

(b) An occurrence listed in subsection (a) of this section shall be reported to the Director, Health Facility Licensing and Compliance Division, 1100 West 49th Street, Austin, Texas, 78756-3199, telephone number 512-834-6646, fax number 512-834-4514. The report to the director shall be on a form provided by the department and include the information requested on the form. The facility may reproduce the form as needed to maintain an adequate supply.

§117.61. General Requirements.

(a) An individual may not act as a dialysis technician unless that individual is trained and competent under this subchapter.

(b) Trainees shall be identified as such during any time spent in the patient treatment area.

(c) Until the successful completion of the competency evaluation, the trainee may provide patient care only as part of a training program and under the immediate supervision of a registered nurse or an assigned preceptor. A preceptor shall be a licensed nurse or dialysis technician who has one year of experience in hemodialysis obtained within the last 24 months, a recommendation by the supervising nurse to be a preceptor and a current competency skills checklist on file in the facility.

§117.62. Training Curricula and Instructors.

(a) Specific objectives for training curricula. Each training program for dialysis technicians shall develop a written curriculum with objectives specified for each section.

(b) Components of training curricula. The training curricula for dialysis technicians shall include the following minimum components:

(1) introduction to dialytic therapies to include history and major issues as follows:

(A) history of dialysis;

(B) definitions and terminology;

(C) communication skills;

(D) ethics and confidentiality;

(E) multidisciplinary process;

(F) roles of other team members; and

(G) information about renal organizations and resources;

(2) principles of hemodialysis to include:

(A) principles of dialysis;

(B) access to the circulatory system; and

(C) anticoagulation, local anesthetics, and normal saline;

(3) understanding the individual with kidney failure to include:

(A) basic renal anatomy, physiology, and pathophysiology;

(B) the effect of renal failure on other body systems;

(C) symptoms and findings related to the uremic state;

(D) modes of renal replacement therapy, including transplantation;

(E) basic renal nutrition;

(F) basic psychosocial aspects of end stage renal disease (ESRD);

(G) medications commonly administered to patients with ESRD;

(H) confidentiality of patient personal and clinical records;

(I) professional conduct;

(J) patient rights and responsibilities; and

(K) rehabilitation;

(4) dialysis procedures to include:

(A) using aseptic technique;

(B) technical aspects of dialysis, operation and monitoring of equipment, initiation and termination of dialysis;

(C) delivering an adequate dialysis treatment and factors which may result in inadequate treatment;

(D) observing and reporting patient reactions to treatment;

(E) glucose monitoring and hemoglobin/hematocrit monitoring;

(F) emergency procedures and responses such as cardiopulmonary resuscitation, air embolism management, and response to line separation and hemolysis;

(G) external and internal disasters, fire, natural disasters, and emergency preparedness; and

(H) safety, quality control, and continuous quality improvement;

(5) hemodialysis devices to include:

(A) theory and practice of conventional, high efficiency, and high flux dialysis;

(B) dialysate composition, options, indications, complications, and safety;

(C) monitoring and safety; and

(D) disinfection of equipment;

(6) water treatment to include:

(A) standards for water treatment used for dialysis as described in the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the American Association for the Advancement of Medical Instrumentation (AAMI), 1110 North Glebe Road, Suite 220, Arlington, Virginia 22201;

(B) systems and devices;

(C) monitoring; and

(D) risks to patients of unsafe water;

(7) reprocessing, if the facility practices reuse, to include:

(A) principles of reuse;

(B) safety, quality control, universal precautions, and water treatment; and

(C) standards for reuse as described in the American National Standard, Reuse of Hemodialyzers, 1993 Edition, published by the AAMI;

(8) patient teaching to include:

(A) the role of the technician in supporting patient education goals; and

(B) adult education principles;

(9) infection control and safety to include:

(A) risks to patients of nosocomial infections, accidents, and errors in treatment;

(B) universal precautions, aseptic technique, sterile technique, and specimen handling;

(C) basic bacteriology and epidemiology;

(D) risks to employees of blood and chemical exposure; and

(E) electrical, fire, disaster, environmental safety, and hazardous substances; and

(10) quality assurance and continuous quality improvement (QA/CQI) to include:

(A) role of the technician in quality assurance activities;

(B) principles of QA/CQI; and

(C) the importance of ongoing quality control activities in assuring safe dialysis treatments are provided to patients.

(c) Additional responsibilities.

(1) If a dialysis technician is to assist with training or treatment of peritoneal dialysis patients, the following content must also be included:

(A) principles of peritoneal dialysis;

(B) sterile technique;

(C) peritoneal dialysis delivery systems;

(D) symptoms of peritonitis; and

(E) other complications of peritoneal dialysis.

(2) If a dialysis technician, other than a licensed vocational nurse (LVN), is to cannulate access or administer normal saline, heparin, or lidocaine, the following content must be included:

(A) access to the circulation to include:

(i) fistula: creation, development, needle placement, and prevention of complications;

(ii) grafts: materials used, creation, needle placement, and prevention of complications; and

(iii) symptoms to report;

(B) safe administration of medications to include:

(i) identifying the right patient;

(ii) assuring the right medication;

(iii) measuring the right dose;

(iv) ascertaining the right route; and

(v) checking the right time for administration;

(C) administration of normal saline to include:

(i) reasons for administration;

(ii) potential complications;

(iii) administration limits; and

(iv) information to report and record;

(D) administration of heparin to include:

(i) reasons for administration;

(ii) methods of administration;

(iii) preparation of ordered dose;

(iv) potential complications; and

(v) information to report and record; and

(E) administration of lidocaine to include:

(i) reasons for administration;

(ii) method of administration;

(iii) preparation of ordered dose;

(iv) potential complications and risks; and

(v) information to report and record.

(F) administration of oxygen to include:

(i) reasons for administration;

(ii) method of administration;

(iii) delivery of the ordered flow rate;

(iv) potential complications and risks; and

(v) information to report and record.

(d) Roster. A roster of attendance for each training class shall be maintained by the instructor.

(e) Trainee evaluation. Each trainee shall be evaluated on a weekly basis during the training program to ascertain the trainee's progress.

(f) Written examination. The dialysis technician trainee shall complete a written examination. The examination shall encompass the content required in subsection (b) of this section. If the dialysis technician trainee will cannulate access and administer medications, the examination shall encompass the content described in subsection (c) of this section. A score of 80% is required on the written examination(s) covering the required content prior to the dialysis technician trainee's release from orientation. Other than the first examination for a specific responsibility in a facility, current certification as a dialysis technician by a nationally recognized testing organization may be substituted for the written examination.

(g) Instructors. An instructor for the course to train an individual as a dialysis technician shall be:

(1) a physician who qualifies as a medical director;

(2) a registered nurse with at least 12 months of experience in hemodialysis obtained within the last 24 months and a current competency skills checklist on file in the facility or a registered nurse instructor of a dialysis technician training course of an accredited college or university;

(3) a qualified dietitian or social worker providing training only within the person's area of expertise; or

(4) a technician with at least 12 months experience, qualified by training and experience in water treatment, dialysate preparation, reprocessing or other technical aspects of dialysis providing training within their area of expertise.

(h) Preceptors. Licensed nurses and patient care technicians who have at least one year of experience in hemodialysis and a current competency skills checklist on file in the facility may assist in didactic sessions and serve as preceptors.

(i) Length of training. For persons with no previous experience in direct patient care, a minimum of 80 clock hours of classroom education and 200 clock hours of directly supervised clinical training shall be required. Training programs for dialysis technician trainees who have previous direct patient care experience may be shortened if competency with the required knowledge and skills is demonstrated, but may not be less than a total of 80 clock hours of combined classroom education and clinical training.

§117.63. Competency Evaluation.

(a) Each facility shall appoint a training review committee to consist of at least the medical director, supervising nurse, technical supervisor, and administrator. This committee shall review the training records of each trainee, including tests and skills checklists, hear comments from the training instructor(s) and preceptor(s), and validate that the trainee has successfully completed the training program.

(b) An individual who completed the facility's orientation program and was determined by the facility to be qualified to deliver dialysis patient care before September 1, 1996, may qualify as a dialysis technician by passing the written examination described in §117.62(f) of this title (relating to Training Curricula and Instructors) and demonstrating competency by completion of the skills checklist described in subsection (c) of this section. Current certification as a dialysis technician by a nationally recognized testing organization may be substituted for the written examination.

(c) The supervising nurse or a registered nurse who qualifies as an instructor under §117.62(e)(2) of this title shall complete a competency skills checklist to document each dialysis technician trainee's knowledge and skills for the following allowed acts:

(1) assembling necessary supplies;

(2) preparing dialysate according to procedure and dialysis prescription;

(3) assembling and preparing the dialysis extracorporeal circuit correctly;

(4) securing the correct dialyzer for the specific patient;

(5) installing and rinsing dialyzer and all necessary tubing;

(6) testing monitors and alarms, conductivity, and (if applicable) presence and absence of residual sterilants;

(7) setting monitors and alarms according to facility and manufacturer protocols;

(8) obtaining predialysis vital signs, weight, and temperature according to facility protocol and informing the registered nurse of unusual findings;

(9) inspecting access for patency and, after cannulation is performed and heparin administered, initiating dialysis according to the patient's prescription, observing universal precautions, and reporting unusual findings to the registered nurse;

(10) adjusting blood flow rates according to established protocols and the patient's prescription;

(11) calculating and setting the dialysis machine to allow fluid removal rates according to established protocols and the patient's prescription;

(12) monitoring the patient and equipment during treatment, responding appropriately to patient needs and machine alarms, and reporting unusual occurrences to the registered nurse;

(13) changing fluid removal rate, placing patient in Trendelenburg position, and administering replacement normal saline as directed by the registered nurse, physician order, or facility protocol;

(14) documenting findings and actions per facility protocol;

(15) describing appropriate response to dialysis-related emergencies such as cardiac or respiratory arrest, needle displacement or infiltration, clotting, blood leaks, or air emboli and to nonmedical emergencies such as power outages or equipment failure;

(16) discontinuing dialysis and establishing hemostasis:

(A) inspecting, cleaning, and dressing access according to facility protocol; and

(B) reporting unusual findings and occurrences to the registered nurse;

(17) obtaining and recording post dialysis vital signs, temperature, and weight and reporting unusual findings to the registered nurse;

(18) discarding supplies and sanitizing equipment and treatment chair according to facility protocol;

(19) communicating the patient's emotional, medical, psychological, and nutritional concerns to the registered nurse;

(20) obtaining current certification in cardiopulmonary resuscitation; and

(21) maintaining professional conduct, good communication skills, and confidentiality in the care of patients.

(d) For dialysis technician trainees who will be assisting with training or treatment of peritoneal dialysis patients, the following checklist shall be completed satisfactorily:

(1) assisting patients in ordering supplies;

(2) making a dialysate exchange (draining and refilling the peritoneal space with dialysate) to include continuous ambulatory peritoneal dialysis exchange procedures and initiation or discontinuation of continuous cycling peritoneal dialysis;

(3) observing peritoneal effluent;

(4) knowing what observations to report;

(5) collecting dialysate specimen;

(6) performing a transfer tubing change; and

(7) setting up and operating continuous cycling peritoneal dialysis equipment.

(e) For dialysis technician trainees who will be cannulating dialysis access and administering heparin and normal saline, the following checklist shall also be completed satisfactorily:

(1) cannulation to include:

(A) inspecting the access for patency;

(B) preparing the skin;

(C) using aseptic technique;

(D) placing needles correctly;

(E) establishing blood access;

(F) replacing needles;

(G) knowing when to call for assistance; and

(H) securing needles;

(2) administration of heparin to include:

(A) checking the patient's individual prescription;

(B) preparing the dose;

(C) labeling the prepared syringe;

(D) administering the dose; and

(E) observing for complications;

(3) administration of normal saline to include:

(A) understanding unit protocol;

(B) checking the patient's prescription;

(C) recognizing signs of hypotension;

(D) notifying the registered nurse;

(E) administering normal saline; and

(F) rechecking vital signs; and

(4) administration of lidocaine to include:

(A) checking the patient's prescription;

(B) identifying the correct vial of medication;

(C) preparing the dose;

(D) administering the dose; and

(E) observing for complications.

(5) administration of oxygen to include:

(A) verifying the ordered flow rate from the nurse functioning in the charge role;

(B) setting up the equipment; and

(C) connecting the tubing for the patient.

(f) If a dialysis technician other than an LVN is to cannulate a dialysis access, administer normal saline, heparin, lidocaine or oxygen, the medical director shall verify and document competency of the dialysis technician to perform these tasks and delegate authority to the technician in accordance with the Medical Practice Act, Article 4495b, §3.06(d).

§117.64. Documentation of Competency.

(a) A training program is required to provide a document to the trainee on the successful completion of the training program and competency evaluation. This document shall indicate that the program completed met the requirements of this subchapter.

(b) The document described in subsection (a) of this section may be accepted by another facility that may later employ the dialysis technician. Each employing facility shall have newly hired experienced dialysis technicians complete a written test and a competency checklist in accordance with §117.63(c), (d), and (e) of this title (relating to Competency Evaluation) within two weeks of hire.

§117.65. Prohibited Acts.

(a) Performance of the following acts by any dialysis technician who is not a licensed vocational nurse qualified to function in the charge role is prohibited:

(1) initiation of patient education; or

(2) alteration of ordered treatment, including shortening of the treatment time.

(b) Performance of the following acts by a dialysis technician who is not a licensed vocational nurse is prohibited:

(1) initiation or discontinuation of dialysis via a central catheter, manipulation of a central catheter, or dressing changes for a central catheter;

(2) administration of medications other than normal saline, heparin, lidocaine, or oxygen, which may only be administered in the course of a routine dialysis treatment;

(3) administration of blood or blood products;

(4) performance of non-access site arterial puncture;

(5) acceptance of physician orders;

(6) provision of hemodialysis treatment to pediatric patients under 35 kilograms;

(7) alteration of the level of electrolytes in dialysate through the use of additive(s) ("spiking"); or

(8) initiation or discontinuation of dialysis via an implantable port.

§117.81. Corrective Action Plan.

(a) Medical review board. The medical review board (MRB) may assist the Texas Department of Health (department) in determining the corrective action required when the results of an inspection or an annual report indicate that significant problems potentially impacting patient outcomes exist.

(1) At the conclusion of an on-site inspection, the department may refer a facility to the MRB if the results of the inspection present concerns related to patient outcomes.

(2) The MRB will review data from facilities' annual reports and identify to the department facilities with potential quality issues. These facilities may be requested to provide additional information or may be subject to an on-site inspection, corrective action plan or enforcement action.

(b) Corrective action plan. A corrective action plan may be used in accordance with §251.061 of the statute. This subsection is consistent with §251.061 of the statute.

(1) The department may use a corrective action plan as an alternative to enforcement action under the statute.

(2) Before taking enforcement action, the department shall consider whether the use of a corrective action plan is appropriate. In determining whether to use a corrective action plan, the department shall consider whether:

(A) the facility has violated the statute or this chapter and the violation has resulted in a adverse patient result;

(B) the facility has a previous history of lack of compliance with the statute, this chapter or a previously executed corrective action plan; or

(C) the facility fails to agree to a corrective action plan.

(3) The department may use a level one, level two, or level three corrective action plan, as determined by the department in accordance with this subsection, after inspection of the facility.

(A) If deficiencies are identified after an inspection, the surveyor may request a corrective action plan. The surveyor shall identify the level of corrective action plan required.

(B) The facility shall develop and implement a corrective action plan approved by the department. The facility shall provide the corrective action plan within the time frames specified by the department. A corrective action plan shall identify dates by which compliance will be accomplished. The dates by which compliance will be accomplished on a corrective action plan shall not exceed 45 days from the date the deficiency is cited.

(C) The department shall review and approve the corrective action plan. If the corrective action plan is not acceptable, the department shall notify the facility of changes needed in order for the department to approve the plan.

(D) The facility shall come into compliance within the time frames set out in the corrective action plan.

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

(F) Acceptance of a corrective action plan does not preclude the department from taking other enforcement action as appropriate under this subchapter.

(4) A level one corrective action plan is appropriate if the department finds that the facility is not in compliance with the statute or this chapter, but the circumstances are not serious or life-threatening. The department or a monitor may supervise the implementation of the plan.

(5) A level two corrective action plan is appropriate if the department finds that the facility is not in compliance with the statute or this chapter and the circumstances are potentially serious or life-threatening or if the department finds that the facility failed to implement or comply with a level one corrective action plan. The department or a monitor shall supervise the implementation of the plan. Supervision of the implementation of the plan may include on-site supervision, observation, and direction.

(6) A level three corrective action plan is appropriate if the department finds that the facility is not in compliance with the statute or this chapter and the circumstances are serious or life-threatening or if the department finds that the facility failed to comply with a level two corrective action plan or to cooperate with the department in connection with that plan. The department may require the appointment of a monitor to supervise the implementation of the plan, the appointment of a temporary manager, or the appointment of a monitor and temporary manager. Appointment of a temporary manager by agreement shall be in accordance with §117.82 of this title (relating to Voluntary Appointment of a Temporary Manager). Involuntary appointment of a temporary manager shall be in accordance with §117.83 of this title (relating to Involuntary Appointment of a Temporary Manager).

(7) A corrective action plan is not confidential. Information contained in the plan may be excepted from required disclosure under the Government Code, Chapter 552 or other applicable law.

(8) The department shall approve the monitor for a corrective action plan. The monitor shall be an individual or team of individuals and may include a professional with end stage renal disease experience or a member of the MRB.

(A) The monitor may not be or include individuals who are current or former employees of the facility that is the subject of the corrective action plan or of an affiliated facility.

(B) The purpose of the monitor is to observe, supervise, consult, and educate the facility and the employees of the facility under a corrective action plan.

(C) The facility shall pay the cost of the monitor.

§117.82. Voluntary Appointment of a Temporary Manager.

(a) A person holding a controlling interest in a facility may, at any time, request the department to assume the management of the facility through the appointment of a temporary manager in accordance with §251.091 of the statute.

(b) After receiving the request, the department may enter into an agreement providing for the appointment of a temporary manager to manage the facility under conditions considered appropriate by both parties if the department considers the appointment desirable.

(c) An agreement under this section shall:

(1) specify all terms and conditions of the temporary manager's appointment and authority; and

(2) preserve all rights of individuals served by the facility granted by law.

(d) The primary duty of the temporary manager is to ensure that adequate and safe services are provided to patients until temporary management ceases.

(e) The appointment terminates at the time specified by the agreement.

§117.83. Involuntary Appointment of a Temporary Manager.

(a) Under §251.092 of the statute, the department may request the attorney general to bring an action in the name and on behalf of the state for the appointment of a temporary manager to manage a facility if:

(1) the facility is operating without a license;

(2) the department has denied, suspended or revoked the facility's license but the facility continues to operate;

(3) the license denial, suspension or revocation proceedings against the facility are pending and the department determines that an imminent or reasonably foreseeable threat to the health and safety of a patient of the facility exists;

(4) the department determines that an emergency exists that presents an immediate threat to the health and safety of a patient of the facility;

(5) the facility is closing and arrangements for the care of patients by other licensed facilities have not been made before closure; or

(6) the department determines a level three corrective action plan under §117.81(b)(6) of this title (relating to Corrective Action Plan) that includes appointment of an involuntary temporary manager is necessary to address serious or life-threatening conditions at the facility.

(b) After a hearing, a court shall appoint a temporary manager to manage a facility if the court finds that the appointment of the manager is necessary.

(1) The court order shall address the duties and authority of the temporary manager, which may include management of the facility and the provision of dialysis services to facility patients until specified circumstances occur, such as new ownership of the facility, compliance with the statute or this chapter, or closure of the facility.

(2) If possible the court shall appoint as temporary manager an individual whose background includes administration of end stage renal disease facilities or similar facilities.

(3) Venue for an action under this section is in Travis County.

(c) A temporary manager appointed under this section is entitled to a reasonable fee as determined by the court in accordance with §251.093 of the statute.

(1) The fee shall be paid by the facility.

(2) The temporary manager may petition the court to order the release to the manager of any payment owed the manager for care and services provided to patients of the facility if the payment has been withheld.

(3) Withheld payments that may be released may include payments withheld by a governmental agency or other entity before or during the appointment of the temporary manager, including:

(A) Medicaid, Medicare, or insurance payment; or

(B) payments from another third party.

§117.84. Disciplinary Action.

(a) The department may deny, suspend, or revoke a license if the applicant or facility:

(1) fails to comply with any provision of the statute;

(2) fails to comply with any provision of this chapter;

(3) commits fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to the department or required to be maintained by the facility pursuant to this chapter;

(4) aids, abets, or permits the commission of an illegal act;

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

(6) fails to comply with applicable requirements within a designated probation period.

(b) The department may deny a license if the applicant or licensee fails to provide the required license fee, application or renewal information.

(c) 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 a licensed facility.

(1) In determining whether a criminal conviction directly relates, the department shall consider the provisions of Texas Occupations Code, §§53.022 and 53.023.

(2) The following felonies and misdemeanors directly relate because these criminal offenses indicate an inability or a tendency for the person to be unable to own or operate a facility:

(A) a misdemeanor violation of the statute;

(B) a conviction relating to deceptive business practices;

(C) a misdemeanor or felony involving moral turpitude;

(D) a misdemeanor of practicing any health-related profession without a required license;

(E) a conviction under any federal or state law relating to drugs, dangerous drugs, or controlled substances;

(F) an offense under the Texas Penal Code, Title 5, involving a patient or a patient of any health care facility, a home and community support services agency, or a health care professional; or

(G) other misdemeanors and felonies which indicate an inability or tendency for the person to be unable to own or operate a facility if action by the department will promote the intent of the statute, this chapter, or Texas Occupations Code, §§53.022 and 53.023.

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

(d) If the department proposes to deny, suspend, or revoke a license, the department shall notify the facility by certified mail, return receipt requested, or personal delivery of the reasons for the proposed action and offer the facility an opportunity for a hearing.

(1) The facility shall request a hearing within 30 calendar days of receipt of the notice. Receipt of the notice is presumed to occur on the tenth calendar day after the notice is mailed to the last address known to the department unless another date is reflected on a United States Postal Service return receipt.

(2) The request for a hearing shall be in writing and submitted to the Director, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199.

(3) A hearing shall be conducted pursuant to the Administrative Procedure Act, Texas Government Code, Chapter 2001, and the department's formal hearing procedures in Chapter 1 of this title (relating to Texas Board of Health).

(4) If the facility does not request a hearing in writing within 30 calendar days of receipt of the notice, the facility is deemed to have waived the opportunity for hearing and the proposed action shall be taken.

(5) If the facility fails to appear or be represented at the scheduled hearing, the facility has waived the right to a hearing and the proposed action shall be taken.

(e) If the department suspends a license, the suspension shall remain in effect until the department determines that the reason for suspension no longer exists. An authorized representative of the department shall investigate prior to making a determination.

(1) During the time of suspension, the suspended license holder shall return the license to the department.

(2) If a suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in this chapter; however, the department may not renew the license until the department determines that the reason for suspension no longer exists.

(f) If the department revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in this chapter at the time of reapplication. The department may refuse to issue a license if the reason for revocation or nonrenewal continues to exist.

(g) Upon revocation or nonrenewal, a license holder shall return the license to the department.

(h) 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 or 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 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.

(i) The department may schedule the facility for a probation period of not less than 30 days if the facility is found in repeated non-compliance, and the facility's non-compliance does not endanger the health and safety of the public.

§117.85. Administrative Penalties.

(a) Under §§251.066-251.070 of the statute, the department may assess an administrative penalty against a person who violates the statute or this chapter.

(b) The penalty may not exceed $1,000 for each violation. Each day of a continuing violation constitutes a separate violation.

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

(1) the seriousness of the violation;

(2) the history of previous violations;

(3) the amount necessary to deter future violations;

(4) efforts made to correct the violation; and

(5) any other matters that justice may require.

(d) All proceedings for the assessment of an administrative penalty are subject to the Administrative Procedure Act, Government Code, Chapter 2001.

(e) If after investigation of a possible violation and the facts surrounding that possible violation the department determines that a violation has occurred, the department shall give written notice of the violation to the person alleged to have committed the violation. The notice shall include:

(1) a brief summary of the alleged violation;

(2) a statement of the amount of the proposed penalty, based on the factors listed in subsection (c)(2) of this section. This statement shall be mailed to the facility no later than 90 working days after the investigation is completed (exit date); and

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

(f) Not later than the 20th calendar day after the date the notice is received, the person notified may accept the determination of the department made under this section, including the recommended penalty, or make a written request for a hearing on that determination.

(g) If the person notified of the violation accepts the determination of the department, the commissioner shall issue an order approving the determination and ordering that the person pay the recommended penalty.

(h) If the person notified fails to respond in a timely manner to the notice or if the person requests a hearing, the commissioner's designee shall:

(1) set a hearing;

(2) give written notice of the hearing to the person; and

(3) designate a hearings examiner to conduct the hearing. The hearings examiner shall make findings of fact and conclusions of law and shall promptly issue to the commissioner a proposal for decision as to the occurrence of the violation and a recommendation as to the amount of the proposed penalty if a penalty is determined to be warranted.

(i) Based upon the findings of fact and conclusions of law and the recommendation of the hearings examiner, the commissioner by order may find that a violation has occurred and may assess a penalty, or may find that no violation has occurred. The commissioner or the commissioner's designee shall give notice of the commissioner's order to the person notified. The notice shall include:

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

(2) the amount of any penalty assessed; and

(3) a statement of the right of the person to judicial review of the commissioner's order.

(j) Not later than the 30th calendar day after the date the decision is final, the person shall:

(1) pay the penalty in full;

(2) pay the amount of the penalty and file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty; or

(3) without paying the amount of the penalty, file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty. Within the 30-day period, a person who acts under this paragraph may:

(A) stay enforcement of the penalty by:

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

(ii) giving to 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 board'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 amount of the penalty and is financially unable to give the supersedeas bond; and

(ii) giving a copy of the affidavit to the department by certified mail.

(k) If the department receives a copy of an affidavit under subsection (j)(3)(B) of this section, the department may file with the court, within five calendar days after the date the copy is received, a contest to the affidavit.

§117.86. Recovery of Costs.

(a) The department may assess reasonable expenses and costs against a person in a administrative hearing if, as a result of the hearing, the person's license is denied, suspended, or revoked or if administrative penalties are assessed against the person.

(b) The person shall pay expenses and costs assessed under this section not later than the 30th calendar day after the date of a board order requiring the payment of expenses and costs is final.

(c) The department may refer the matter to the attorney general for collection of the expenses and costs.

(d) If the attorney general brings an action against a person under §251.063 or §251.065 of the statute or to enforce an administrative penalty assessed, and an injunction is granted against the person or the person is found liable for a civil or administrative penalty, the attorney general may recover, on behalf of the attorney general and the department, reasonable expenses and costs.

(e) For purposes of this section, "reasonable expenses and costs" include expenses incurred by the department and the attorney general in the investigation, initiation, or prosecution of an action, including reasonable investigative costs, court costs, attorney's fees, witness fees, and deposition expenses.