

TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 289 RADIATION CONTROL
SUBCHAPTER E REGISTRATION REGULATIONS

§289.226. Registration of Radiation Machine Use and Services.

(a) Purpose.

(1) This section provides for the registration of persons using radiation machines and persons who are in the business of providing radiation machine services.

(2) Requirements for the registration of persons using radiation machines.

(A) No person shall use radiation machines except as authorized in a certificate of registration issued by the Department of State Health Services (department) per the requirements of this section.

(B) A person who receives, possesses, uses, owns, or acquires radiation machines before receiving a certificate of registration is subject to the requirements of this chapter.

~~[(2) A person who receives, possesses, uses, owns, or acquires radiation machines prior to receiving a certificate of registration is subject to the requirements of this chapter.]~~

(b) Scope.

(1) In addition to the requirements of this section, all registrants are subject to the requirements of:

(A) §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections); [7]

(B) §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services); [7]

(C) §289.205 of this title (relating to Hearing and Enforcement Procedures); [7] and

(D) §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation).

(2) Registrants using radiation machines in the healing arts are also subject to the requirements of §289.227 of this title (relating to Use of Radiation Machines in the Healing Arts). Morgues, educational facilities, and forensic medicine or

investigations utilizing radiation machines for non-human use are subject to the specific requirements of §289.227 of this title.

(3) Registrants using analytical and other industrial radiation machines, such as x-ray equipment used for cathodoluminescence, ion implantation, gauging, or electron beam welding, are subject to the requirements of §289.228 of this title (relating to Radiation Safety Requirements for Industrial Radiation Machines).

(4) Registrants using accelerators, therapeutic radiation machines, simulators, and electronic brachytherapy devices are also subject to the requirements of §289.229 of this title (relating to Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices).

(5) Registrants using mammography radiation machines are also subject to the requirements of §289.230 of this title (relating to Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography) and §289.234 of this title (relating to Mammography Accreditation).

(6) Registrants using radiation machines in industrial radiographic operations are also subject to the requirements of §289.255 of this title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).

(7) Registrants using radiation machines in dental medicine [~~dental radiation machines~~] are subject to the requirements of §289.232 of this title (relating to Radiation Control Regulations for Dental Radiation Machines).

(8) Registrants using radiation machines in veterinary medicine are subject to the requirements of §289.233 of this title (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine).

(9) Registrants using laser radiation machines [~~or performing laser services~~] are subject to the requirements of §289.301 of this title (relating to Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices) [~~or the requirements of §289.302 of this title (relating to Registration and Radiation Safety Requirements for Use of Laser Hair Removal Devices)~~].

(10) To determine compliance with the requirements in this chapter for radiation machines [~~used on humans~~], all radiation air kerma rate [~~exposure rate (air kerma rate)~~] or dose measurements for fluoroscopy or computed tomography radiation machines shall be performed by a licensed medical physicist with a specialty in diagnostic medical physics.

(11) For purposes of this section, radiation services include [~~but are not limited to~~]:

(A) measurement of air kerma rate or dose measurements on radiation machines that are not for human use;

(B) measurement of air kerma for human-use, general radiographic and special purpose radiation machines, as defined in §289.227 and §289.229 of this title, by or under the supervision of a licensed medical physicist;

~~[(A) radiation machines that are not for human use, performance of exposure rate (air kerma rate) or dose measurements;]~~

~~[(B) radiation machines for human use, collecting entrance exposure (air kerma) data for general radiographic and special purpose radiation machines, as defined in §289.227(e) of this title, by or under the supervision of a licensed medical physicist;]~~

(C) ~~[radiation machines for human use,]~~ performance of services specified in paragraph (10) of this subsection or services requiring a licensed medical physicist as specified in §289.227(e) and §289.229 of this title on radiation machines for human use;

(D) presentation of department-accepted ~~[agency-accepted]~~ training courses that are specifically required by this chapter;

(E) demonstration and sale of radiation machines or imaging acquisition systems that require the individual to operate a radiation machine or cause a radiation machine to be energized ~~[that require the individual to operate or cause a radiation machine to be operated in order to demonstrate or sell];~~

(F) assembly, installation or repair of a radiation machine to ensure it ~~[a radiation machine]~~ is operating according to manufacturer's specifications;

(G) completion of equipment performance evaluations (EPE) on dental radiation machines and ~~[æ]~~ machines used in veterinary medicine; and

(H) provision of ~~[providing]~~ radiation machines to a facility for limited ~~[time]~~ periods.

(12) For purposes of this section, a person providing the services described in paragraph (11)(H) of this subsection is a provider of equipment.

(13) For purposes of this section, a practitioner of the healing arts is a person licensed to practice healing arts by either the Texas Medical Board as a physician, the Texas Board of Chiropractic Examiners, or the Texas State Board of Podiatric Medical Examiners.

(14) For purposes of this section, a physician is an individual licensed by the Texas Medical Board.

(15) For purposes of this section, a certified physician is a physician licensed by the Texas Medical Board and certified in radiation oncology or therapeutic radiology.

(16) For purposes of this section, veterinary-use is the use of a radiation machine for the practice of veterinary medicine as defined by Texas Occupations Code Chapter 801. Animal research is not considered veterinary-use.

~~(17) [(16)]~~ This section does not apply to an entity under the jurisdiction of the federal government.

(c) Prohibitions.

(1) No person shall cause the operation of a radiation machine that results in exposure of an individual to the useful beam [~~expose an individual to radiation~~] for training, demonstration, or other non-healing arts purposes.

(2) No person shall use radiation machines or perform radiation machine services except as authorized in a certificate of registration issued by the department per [~~agency in accordance with~~] the requirements of this section.

(3) Radiation machines shall be designated for human-use or veterinary-use but shall not be designated for both unless one of the following conditions are met:

(A) the machine use is for human research conducted per subsection (u) of this section; or

(B) the facility has applied for and received written authorization from the department.

(d) Exemptions.

(1) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this section, provided that the dose equivalent rate averaged over an area of 10 square centimeters (cm^2) does not exceed 0.5 millirem per hour (mrem/hr)(0.005 mSv per hour (mSv/hr)) at 5 centimeters (cm) from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(2) Radiation machines in transit or [~~in~~] storage incident to transit are exempt from the requirements of this section. This exemption does not apply to the providers of radiation machines for mobile services.

(3) Facilities that have placed all radiation machines in storage, including on-site storage secured from unauthorized use or removal, and have notified the department [~~agency~~] in writing, are exempt from the requirements of this section. This exemption is void if any radiation machine is energized resulting in the

production of radiation. ~~Before~~ ~~[Prior to]~~ resuming use of the machine(s) for human use, the machine shall meet all requirements of this section.

(4) Inoperable radiation machines are exempt from the requirements of this section. For ~~[the purposes of]~~ this section, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

(5) Domestic television receivers, video display terminals, transmission microscopes, and electron microscopes, including the servicing of such devices, are exempt from the requirements of this section.

(6) A person that takes possession of a radiation machine as the result of foreclosure, bankruptcy, or other default of payment may possess the machine without registering it. If the machine is energized, it shall be under the supervision of a person registered per ~~[in accordance with]~~ this section and shall be energized only to demonstrate that the machine is operable for sale, lease, or transfer purposes.

(7) Facilities, including academic institutions and research or development facilities, registered for the use of radiation machines are exempt from the registration requirements of subsection (j) of this section, regarding radiation services, to the extent that their personnel perform radiation services only for the registrant by whom they are employed.

(8) Bone densitometry machines used by, or under the supervision of, a licensed physician, are exempt from equipment performance evaluations.

(e) General requirements for application for registration.

(1) Application for registration shall be completed on forms prescribed by the department ~~[agency]~~ and shall contain all the information required by the form and accompanying instructions. For initial registrations with multiple use locations, a separate application RC Form 226-2 shall be completed for each use location under the registration.

(2) A radiation safety officer (RSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the department ~~[agency]~~ with the application. The RSO shall meet the applicable qualifications specified in paragraph (3) of this subsection and carry out the responsibilities of subsection (n) of this section.

(3) Qualifications for RSOs for registrants ~~[(except for industrial radiography)]~~.

(A) All RSOs ~~[and laser safety officers]~~ shall meet the following general qualifications in addition to qualifications in specific categories:

and (i) knowledge of potential radiation hazards and emergency precautions;

(ii) completed educational courses related to ionizing radiation safety or a radiation safety officer course; or

(iii) experience in the use and familiarity of the type of equipment used.

(B) Specific qualifications for RSOs by the facility type are as follows.

(i) RSOs for healing arts facilities shall meet the following qualifications:

(I) practitioner RSOs shall submit documentation of their licensing board number;

(II) qualifications for a non-practitioner RSO with radiation machine-related credentials, and the following credentials will be accepted for an RSO who is not a practitioner:

(-a-) evidence of a valid general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least two years of supervised radiation safety experience or supervised use of radiation machines;

(-b-) evidence of a valid limited certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least four years of supervised radiation safety experience or supervised use of radiation machines;

(-c-) evidence of registry by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists (ARCRT) and at least two years of supervised radiation safety experience or supervised use of radiation machines;

(-d-) evidence of associate degree in radiologic technology, health physics, or nuclear technology, and at least two years of supervised radiation safety experience or supervised use of radiation machines;

(-e-) for radiation therapy facilities, evidence of registry by the ARRT or ARCRT and at least four years of supervised radiation-related experience or supervised use of radiation therapy machines; or

(-f-) evidence of a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in one or more of the following appropriate specialties:

(-1-) medical health physics, diagnostic medical physics, or nuclear medical physics for diagnostic x-ray facilities; or

(-2-) medical health physics or therapeutic medical physics for radiation therapy facilities; or

(III) qualification for a non-practitioner RSO without radiation machine-related credentials, and an RSO who is not a practitioner and who does not have radiation machine-related credentials must meet the following criteria:

(-a-) credentials:

(-1-) evidence of registration with the Texas Board of Nursing as a registered nurse and at least two years of supervised experience in the use of radiation machines in their respective specialty;

(-2-) evidence of registration with the Texas Physician Assistant Board and at least two years of supervised experience in the use of radiation machines in their respective specialty; or

(-3-) evidence of bachelor's or higher degree in radiologic technology, health physics, or nuclear technology and at least two years of supervised experience in the use of radiation machines; and

(-b-) additional documentation for a non-practitioner RSO without radiation machine-related credentials, and the following documentation must be provided to be qualified:

(-1-) an attestation by a physician or qualified department director describing the radiation safety experience and performance of the RSO responsibilities listed in subsection (n) of this section, as applicable, and attestation must include that the RSO has achieved a level of radiation safety knowledge sufficient to function independently as RSO for the medical use for which they are applying; and

(-2-) documentation of an accredited radiation safety or radiation machine course completion, and the course must be at least 24 credit hours and include the principles of image processing, radiation protections, dose optimization and reduction; biological effects of ionizing radiation; radiology quality control and improvement; and review of Texas Regulations related to radiation as applicable.

(ii) Academic institutions or research and development facilities shall have RSOs who are faculty or staff members with a bachelor's degree or higher in a radiation-related field and at least two years of supervised experience in the use of radiation machines and the following documentation is also required:

(I) an attestation by a physician or qualified department director describing the radiation safety experience and performance of the RSO responsibilities listed in subsection (n) of this section, as applicable, and attestation must include that the RSO has achieved a level of radiation safety knowledge sufficient to function independently as RSO for the medical use for which they are applying.

(II) documentation that the individual has satisfactorily completed 40 hours of education related to safe use of radiation machines from an accredited institution.

~~[(B) Specific qualifications for RSOs by facility are as follows:]~~

~~[(i) Healing arts facilities shall have:]~~

~~[(I) a practitioner RSO with documentation of licensing board number;~~
or]

~~[(II) a non-practitioner RSO with at least one of the following:]~~

~~[(a) evidence of a valid general certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least 2 years of supervised experience and/or supervised use of radiation machines;]~~

~~[(b) evidence of a valid limited certificate issued under the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601, and at least 4 years of supervised experience and/or supervised use of radiation machines;]~~

~~[(c) evidence of registry by the American Registry of Radiologic Technologists (ARRT) or the American Registry of Clinical Radiologic Technologists (ARCRT) and at least 2 years of supervised experience and/or supervised use of radiation machines;]~~

~~[(d) evidence of associate degree in radiologic technology, health physics, or nuclear technology, and at least 2 years of supervised experience and/or supervised use of radiation machines;]~~

~~[(e) evidence of registration with the Texas Board of Nursing as a Registered Nurse and at least 2 years of supervised experience and/or supervised use of radiation machines in the respective specialty;]~~

~~[(f) evidence of registration with the Texas Physician Assistant Board, and at least 2 years of supervised use of radiation machines in the respective specialty;]~~

~~[(g) for radiation therapy facilities, evidence of registry by the ARRT or ARCRT and at least 4 years of supervised experience and/or supervised use of radiation therapy machines;]~~

~~[(h) evidence of bachelor's (or higher) degree in radiologic technology, health physics, or nuclear technology and at least 2 years of supervised experience and/or supervised use of radiation machines; or]~~

~~[(i) evidence of a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in one or more of the following appropriate specialties:]~~

~~[(1) medical health physics, diagnostic medical physics, or nuclear medical physics for diagnostic x-ray facilities; or]~~

~~[(2) medical health physics or therapeutic medical physics for radiation therapy facilities.]~~

~~[(ii) Academic institutions and/or research and development facilities shall have RSOs who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. This individual may also serve as the RSO over the healing arts section of the facility.]~~

(iii) Industrial radiography operations shall have an RSO who meets the requirements of §289.255(e)(4)(B) of this title.

(C) The RSO identified on a certificate of registration issued before September 1, 1993, need not comply with the training requirements in this subsection.

(D) The RSO for an application for registration of an electronic brachytherapy device shall meet the qualifications of this subsection and shall carry out the responsibilities of subsection (n) of this section.

(E) The department may determine that a person who otherwise meets the RSO qualifications specified in this section is unqualified to be named as the RSO, based on the person's history with ensuring a facility's compliance with the Act and rules of this chapter.

(4) Any time after the filing of the original application, the department ~~[agency]~~ may require additional information to determine if the certificate of registration should be issued or denied.

(5) An application for a certificate of registration may include a request for a certificate of registration authorizing one or more activities or use locations. Applications for certification of mammography systems~~[, lasers, laser services, laser~~

hair removal facilities, laser hair removal training programs, and laser hair removal individuals] shall be made separately.

(6) Applications and documents submitted to the department [agency] may be made available for public inspection except that the department [agency] may withhold any document or part thereof from public inspection per [in accordance with] §289.231(aa) of this title.

(7) Each application for a certificate of registration shall be accompanied by the fee prescribed in §289.204 of this title. [~~An application for a certificate of registration for an electronic brachytherapy device shall be accompanied by the fee prescribed in Figure: 25 TAC §289.204(j), category (3) for other therapeutic radiation machines.~~]

(8) Each application shall be accompanied by a completed RC Form 226-1 (Business Information Form) that shall contain the legal name of the entity or business. Unless exempt per [in accordance with] the Business and Commerce Code, Chapter 71, the applicant shall:

(A) be authorized to conduct business in the State of Texas as listed on the Texas Secretary of State (SOS) web site; and

(B) file an assumed name certificate with the Texas SOS if using an assumed name in their application[, and/or the office of the county clerk in the county where the business is located].

(f) Application for registration for human use of radiation machines.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person having a radiation machine used in the healing arts shall apply for registration with the department [agency] within 30 days after beginning use of the radiation machine, except for mobile services that shall be registered per [in accordance with] subsection (g) of this section, and healing arts screening that shall be approved per [in accordance with] subsection (h) of this section.

(B) Each person having an accelerator, ~~[or]~~ therapeutic radiation machine, or electronic brachytherapy device [~~capable of operating at or above 1 million electron volts (MeV)~~] shall apply for and receive a certificate of registration from the department [agency] before using the accelerator [~~for human use~~]. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registration from the department [agency].

~~[(C) Each person having a simulator and/or therapeutic radiation machine capable of operating below 1 MeV for human use shall apply for registration with the agency within 30 days of energizing the equipment.]~~

(2) The applicant shall ensure that radiation machines are operated by individuals qualified by ~~[reason of]~~ training and experience to use the radiation ~~machines~~ ~~[machine]~~ for the purpose requested ~~per~~ ~~[in accordance with]~~ this section in such a manner as to minimize danger to occupational and public health and safety.

(3) An application for healing arts shall be signed by a licensed practitioner. The signature of the administrator, president, or chief executive officer will be accepted instead ~~[in lieu]~~ of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. The application shall also be signed by the RSO.

(4) An application for accelerators or therapeutic radiation machines, including electronic brachytherapy devices, for human use, shall be signed by a physician licensed by the Texas Medical Board. The signature of the administrator, president, or chief executive officer will be accepted instead ~~[in lieu]~~ of a physician's signature if the facility has more than one physician who may direct the operation of radiation machines. The application shall also be signed by the RSO.

(5) Each applicant for accelerators, therapeutic radiation machines, and electronic brachytherapy devices, shall submit:

(A) operating and safety procedures as described in §289.229(h)(1)(G) of this title;

(B) credentials:

(i) units operating above 1 MeV and electronic brachytherapy devices shall submit credentials for a Board-Certified Radiation Oncologist; or

(ii) units under 1 MeV shall submit credentials for a Board-Certified Dermatologist or Board-Certified Radiation Oncologist;

(C) a copy of the most current record of surveys, calculations, and quality assurance checks on each device; and

(D) a floor plan of the physical facility.

~~[(5) Each applicant for accelerators or therapeutic radiation machines, other than electronic brachytherapy devices, shall submit:]~~

~~[(A) operating and safety procedures as described in §289.229(h)(1)(G) of this title; and]~~

~~[(B) a description of the proposed facilities.]~~

~~[(6) Each person having an electronic brachytherapy device shall apply for and receive a certificate of registration from the agency before using the device for human use. An application for an electronic brachytherapy device shall include:]~~

~~[(A) a list identifying the radiation safety officer, all certified physicians (except visiting certified physicians), licensed medical physicists, and qualified operators, with documentation of training and education in accordance with §289.229(h)(1)(D) and (E) of this title;]~~

~~[(B) a current copy of the quality assurance program in accordance with §289.229(h)(1)(F) of this title;]~~

~~[(C) a copy of the most current record of surveys, calculations, and quality assurance checks on each device;]~~

~~[(D) a copy of the device manufacturer's United States Food and Drug Administration certification;]~~

~~[(E) a copy of the operating and safety procedures as described in §289.229(h)(1)(G) of this title; and]~~

~~[(F) a description of the proposed facilities showing how the requirements of §289.229(k) of this title are to be met. The description of the proposed facilities shall also include:]~~

~~[(i) a diagram of the physical facility showing the location of the electronic brachytherapy treatment rooms;]~~

~~[(ii) an indication whether the facility is a new structure or a modification to an existing structure; and]~~

~~[(iii) the type and thickness of the portable shielding if used and a procedure demonstrating the use of the shielding prior to treatment.]~~

(g) Application for registration of mobile service operations.

(1) In addition to the requirements of subsections (e) and (f) of this section or §289.230 of this title, as applicable, each applicant shall apply for and receive authorization from the department [agency] before beginning mobile service operations.

(2) The following shall be submitted:

(A) an established main location where the machine(s), records, etc. will be maintained for inspection. This shall be a street address, not a post office box number;

(B) a sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed machine inside, furnish the floor plan indicating protective shielding and the operator's position; and

(C) a current copy of the applicant's operating and safety procedures regarding radiological practices for the protection of patients, operators, employees, and the general public.

(h) Application for registration of healing arts screening.

(1) In addition to the requirements of subsections (e) and (f) of this section, each applicant shall apply for and receive authorization for healing arts screening before initiating a screening program.

(2) Persons requesting approval from the department [agency] for healing arts screening programs shall submit:

(A) name and address of the applicant;

(B) diseases or conditions for which the x-ray examinations are to be used in diagnoses;

(C) a detailed description of the x-ray examinations proposed in the screening program;

(D) a description of the population to be examined in the screening program, for example, age, sex, physical condition, and other appropriate information;

(E) for mobile screening operations, location(s) where radiation machines are maintained;

(F) operating and safety procedures as follows:

(i) for all radiation machines (except bone densitometers) to include:

(I) an evaluation of the radiation machines to be used in the screening program;

(II) documentation that the evaluation was performed by a licensed medical physicist with a specialty in diagnostic medical physics;

(III) the evaluation shall show that the machines satisfy all requirements of this chapter;

(ii) for bone densitometers, the manufacturer's evaluation of the radiation machine(s) to be used in the screening program;

~~[(G) training data to include:]~~

~~[(i) the qualifications of each individual who will be operating the radiation machine(s);]~~

~~[(ii) the name and address of the physician licensed in Texas who will interpret the radiographs; and]~~

(G) ~~[(H)]~~ documentation for verification of the following procedures:

(i) a method of recommending a means of selecting a physician for patients who do not have a physician;

(ii) a description of the procedures to be used in advising the individuals screened and their physicians of the results of the screening procedure and any further medical needs indicated; and

(iii) a description of the procedures for the retention or disposition of the radiographs and other records about ~~[pertaining to]~~ the x-ray examinations.

(3) Screening standards/procedures shall meet national standards such as the American College of Radiology or other national standards.

(i) Application for registration of radiation machines for non-human use, including use in morgues, forensic medicine or investigations, and educational facilities.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person having an accelerator for non-human use shall apply for and receive a certificate of registration from the department ~~[agency]~~ before beginning the use of the accelerator. A person may energize the accelerator for purposes of installation and testing before receiving a certificate of registration from the department ~~[agency]~~.

(B) Each person having an accelerator for non-human use shall submit:

(i) operating and safety procedures as described in §289.229(f)(3)(B) of this title; and

(ii) a description of the applicant's proposed facilities per ~~[in accordance with]~~ §289.229(f)(2) and (f)(3)(A), (D) and (E) of this title.

(2) Each person having a radiation machine for non-human use, other than those specified in paragraph (1)(A) of this subsection and those used for industrial radiographic operations as defined in §289.255 of this title, shall apply for

registration with the department [~~agency~~] within 30 days after beginning use of the machine.

(3) Each applicant for use of radiation machines in industrial radiographic operations shall submit the information required in §289.255(t)(1) of this title and receive a certificate of registration from the department before beginning use of the machine(s).

(4) An application for the uses specified in this subsection shall be signed by the applicant, registrant, or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO.

(j) Application for registration of radiation machine services.

(1) In addition to the requirements of subsection (e) of this section, each applicant shall comply with the following.

(A) Each person who intends to provide radiation services described in subsection (b)(11) of this section shall apply for and receive a certificate of registration from the department [~~agency~~] before providing the service.

(B) An application for radiation services shall be signed by the applicant or registrant or a person duly authorized to act for and on the applicant's or registrant's behalf. The application shall also be signed by the RSO.

(2) The applicant shall document the qualifications of the specific training and experience that qualifies each individual to perform the service as follows:

(A) for individuals performing assembly, installation, or repair of radiation machines in subsection (b)(11)(F) of this section, document the qualifications listed in paragraph (5) of this subsection;

(B) for individuals performing the services specified in subsection (b)(10) and (11)(C) of this section, obtain a copy of the individual's license from the Texas Board of Licensure for Professional Medical Physicists; and

(C) for all other services, document the qualifications listed in paragraph (5) of this subsection.

(3) No person shall provide services specified in subsection (b)(10) and (11) of this section that are not specifically authorized by the department [~~agency~~].

(4) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the department [~~agency~~] except for:

(A) services specified in subsection (b)(11)(B), (C) and (E) of this section; or

(B) the initial installation of the first machine(s) for a new certificate of registration.

(5) The minimum [Minimum] education and training for persons performing radiation machine assembly, installation, or repair are as follows.

(A) All persons performing radiation machine assembly, installation, or repair shall meet one of the following requirements:

(i) one [±] year of formal training (may be satisfied by factory school, military technical training school, or other courses in radiation machine assembly, installation or repair techniques) or an associate [associate's] degree in biomedical equipment repair;

(ii) a bachelor's degree in electrical engineering with specialized training in radiation producing devices; or

(iii) a combination of training and experience totaling one [±] year to include:

(I) experience or education providing familiarity with the type(s) of equipment to be serviced, to include radiation safety;

(II) knowledge of protective measures to reduce potentially hazardous conditions; and

(III) six [6] months of supervised assembly and repair of the type(s) of equipment to be serviced.

(B) A registrant holding a valid certificate of registration who has hired individuals to perform services before September 1, 1993, need not comply with the education and training requirements in this paragraph. Individuals hired on or after September 1, 1993, shall comply with the education and training requirements in this paragraph.

(6) Each applicant for providers of equipment shall also submit:

(A) the address of an established main location where the radiation machines, records, etc., will be maintained for inspection. This shall be a street address, not a post office box number; and

(B) a current copy of the applicant's operating and safety procedures [~~which is required when personnel are provided in addition to equipment~~]. This is required when the applicant's personnel are provided to operate the equipment for their client.

(7) Each applicant for department-accepted [~~agency-accepted~~] training courses specifically required by §289.253 of this title (relating to Radiation Safety Requirements for Well Logging Service Operations and Tracer Studies), and §289.255 of this title shall also submit:

- (A) a course syllabus;
- (B) the number of instructional hours for each subject;
- (C) a list of training resources, for example, reference books, texts, workbooks, physical facilities, etc.;
- (D) all test questions and corresponding answers; and
- (E) the radiation safety training, education, and experience of each instructor.

(8) A record documenting the qualifications of each individual that performs the service shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(k) Issuance of certificates of registration.

(1) A certificate of registration application will be approved if the department [~~agency~~] determines that an application meets the requirements of the Act [~~Texas Radiation Control Act (Act)~~] and the requirements of this chapter. The certificate of registration authorizes the proposed activity in the form and contains the conditions and limitations as the department [~~agency~~] deems appropriate or necessary.

(2) The department [~~agency~~] may incorporate in the certificate of registration at the time of issuance, or thereafter by amendment, additional requirements and conditions concerning the registrant's possession, use, and transfer of radiation machines subject to this chapter as it deems appropriate or necessary [~~in order~~] to:

- (A) minimize danger to occupational and public health and safety;
- (B) require additional reports and the keeping of additional records as may be appropriate or necessary; and
- (C) prevent loss or theft of radiation machines subject to this section.

(3) The department [~~agency~~] may request, and the registrant shall provide, additional information after the certificate of registration has been issued to enable the department [~~agency~~] to determine whether the certificate of registration should be modified per [~~in accordance with~~] subsection (s) of this section.

(l) Terms and conditions of certificates of registration.

(1) Each certificate of registration issued per [~~in accordance with~~] this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules and orders of the department [~~agency~~].

(2) No certificate of registration issued or granted under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the department [~~agency~~] authorizes the transfer in writing.

(3) Each person registered by the department [~~agency~~] for radiation machine use per [~~in accordance with~~] this section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the certificate of registration.

(4) In deciding [~~making a determination~~] whether to grant, deny, amend, renew, revoke, suspend, or restrict a certificate of registration, the department [~~agency~~] may consider the technical competence and compliance history of an applicant or holder of a certificate of registration. After an opportunity for a hearing, the department [~~agency~~] shall deny an application for a certificate of registration, an amendment to a certificate of registration, or renewal of a certificate of registration if the applicant's compliance history reveals that at least three department [~~agency~~] actions have been issued against the applicant, within the previous 6 years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the certificate of registration.

(m) Responsibilities of the registrant.

(1) The registrant is responsible for complying with this chapter and the conditions of the certificate of registration.

(2) The registrant shall designate an individual qualified per [~~in accordance with~~] subsection (e)(3) of this section as the radiation safety officer and shall ensure the individual continually performs the responsibilities of the radiation safety officer as identified in subsection (n) of this section.

(3) Persons using radiation machines per [~~in accordance with~~] subsection (f)(1)(B) of this section (concerning radiation accelerator or therapeutic radiation machines or electronic brachytherapy devices for human use), subsection (g) of this section (concerning an application for mobile service operations), subsection (i)(1)(A) of this section (concerning persons having an accelerator for non-human use), and subsection (i)(3) of this section (concerning radiation machines in industrial radiographic operations) shall have a valid certificate of registration issued by the department before [~~agency prior to~~] use.

(4) Other than the initial installation of the first machines(s) for a new certificate of registration, no person shall use radiation machines unless they have applied for registration within 30 days of beginning use of the machines per [~~in accordance with~~] subsection (f)(1)(A) of this section.

(5) No registrant shall engage any person for services described in subsection (b)(11) of this section until the person provides to the registrant evidence of registration with the department [~~agency~~].

(6) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the department [~~agency~~] except for:

(A) the initial installation of the first machines(s) for a new certificate of registration; and

(B) the registrant authorized for demonstration and sale may demonstrate a radiation machine per [~~in accordance with~~] paragraph (13) of this subsection.

(7) The registrant shall notify the department [~~agency~~] of any changes that would render the information contained in the application for registration or [~~and/or~~] the certificate of registration inaccurate. The notification shall be in writing and signed by an authorized representative.

(A) Notification is required within 30 days after the following changes:

(i) name or mailing address;

(ii) street address where machine will be used;

(iii) additional use location;

(iv) RSO; or

(v) name and registration number of the contracted provider of equipment, registered per [~~in accordance with~~] this section.

(B) The registrant shall notify the department [~~agency~~] within 30 days after [~~of~~] changes in the radiation machines that include:

(i) any change in the category(ies) of machine type or type of use as specified in §289.231(II) of this title and as authorized in the certificate of registration; or

(ii) any increase in the number of machines authorized by the certificate of registration in any machine type or type of use category.

(8) The registrant, or the parent company, shall notify the department [~~agency~~] in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy. This notification shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed; and

(B) the case name and number, and date of filing the petition.

(9) The registrant shall inventory all radiation machines in the registrant's possession at an interval not to exceed one [±] year.

(A) The inventory shall include:

- (i) manufacturer's name;
- (ii) model and serial number of the control panel; and
- (iii) location of radiation machine(s) (for example, room number).

(B) Records of the inventory shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(10) The registrant shall maintain records of receipt, transfer, and disposal of radiation machines.

(A) The records shall include:

- (i) manufacturer's name;
- (ii) model and serial number from the control panel;
- (iii) date of the receipt, transfer, and disposal;
- (iv) name and address of person machine(s) received from, transferred to, or disposed of; and
- (v) name of the individual recording the information.

(B) Records of the receipt, transfer, or disposal of the machine(s) shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(11) The persons using loaner radiation machines shall comply with the following.

(A) For persons having a valid certificate of registration, loaner radiation machines may be used for up to 30 days. Within the following 30 days, the registrant shall:

- (i) notify the department [~~agency~~] of a change in the category(ies) of machine type or type of use as specified in §289.231(II) of this title and as authorized in the certificate of registration; or

(ii) notify the department [~~agency~~] of any increase in the number of machines authorized by the certificate of registration in any machine type or type of use category; and

(iii) perform an equipment performance evaluation on the radiation machine(s) per [~~in accordance with~~] §289.227(o) of this title.

(B) For persons who do not hold a valid certificate of registration, loaner radiation machines may be used for human use up to 30 days, by or under the direction of a practitioner, before applying for a certificate of registration per [~~in accordance with~~] subsection (e) of this section. This does not include:

(i) accelerators for human use as described in subsection (f)(1)(B) of this section;

(ii) mobile services as described in subsection (g) of this section;

(iii) healing arts screening as described in subsection (h) of this section;

(iv) accelerators for non-human use as described in subsection (i)(1)(A) of this section; and

(v) industrial radiography as described in subsection (i)(3) of this section.

(12) Persons authorized to provide radiation machines shall comply with the following.

(A) Providers of equipment shall:

(i) ensure that all radiation machines used on humans for healing arts purposes meet the requirements of §289.227(o) of this title; and

(ii) provide radiation machines only to facilities holding a valid certificate of registration.

(B) Providers of equipment shall keep a log of radiation machines provided in Texas. The record shall list the following current information:

(i) date machine is provided;

(ii) name of customer; and

(iii) customer's certificate of registration number.

(C) Records of machines provided shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(13) Persons authorized to perform demonstration and sale of radiation machines in Texas shall comply with the following.

(A) A daily log shall be maintained and shall include:

(i) date of all demonstrations and sales of radiation machines performed in Texas;

(ii) name and address of the customer; and

(iii) customer's certificate of registration number unless the service provided is an initial installation as described in paragraph (6) of this subsection.

(B) Records of all demonstrations and sales shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(C) Individuals must not be exposed to the useful beam except for healing arts purposes and unless such exposure has been specifically and individually ordered by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(i) exposure of an individual for training or demonstration;

(ii) QA/QC testing; or

(iii) other non-healing arts purposes.

~~[(C) Demonstration of radiation machines on humans shall be performed by or under the direction of a practitioner in accordance with paragraph (11) of this subsection.]~~

(D) Demonstration of radiation machines performed by the service provider shall be on phantoms only.

(E) The registrant authorized for demonstration and sale of radiation machines is responsible for performing and documenting all tests required by [~~in accordance with~~] §289.227 of this title when demonstration of a radiation machine involves exposure specifically and individually ordered by a licensed practitioner of the healing arts [~~for radiation machines used on humans for demonstration purposes~~].

(n) Responsibilities of RSOs.

(1) Duties of the RSO include[~~, but are not limited to~~]:

(A) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA)[~~, and to~~

~~review them at intervals not to exceed 12 months to ensure that the procedures are current and conform with this chapter];~~

(i) review them at intervals not to exceed 12 months to ensure that the procedures are current and conform with this chapter; and

(ii) review and ensure that all actions required in this chapter are performed at the respective intervals to maintain compliance;

(B) ensuring that individual monitoring devices are properly used by occupationally-exposed personnel, ~~[that]~~ records are kept of the monitoring results, and ~~[that]~~ timely notifications are made as required by §289.203 of this title;

(C) investigating and reporting to the department ~~[agency]~~ each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter;

(D) assuming control and having the authority to institute corrective actions including the shut-down of operations when necessary in an emergency ~~[situations]~~ or unsafe conditions; ~~[and]~~

(E) ensuring that corrective actions for violations issued by the department are implemented to avoid a repeat violation; and

(F) ~~[(E)]~~ maintaining records as required by this chapter.

(2) The RSO shall ensure that personnel are adequately trained and complying with this chapter, the conditions of the certificate of registration, and the operating and safety procedures of the registrant.

(3) The RSO shall make entries of the records in paragraph (1) of this subsection at intervals not to exceed 30 days after receipt of a monitoring report.

(o) Responsibilities of assemblers and ~~[and/or]~~ installers.

(1) No person shall provide radiation machine services for a person who cannot produce evidence of a completed application for registration or a valid certificate of registration issued by the department ~~[agency]~~ except for the initial installation of the first machine(s) for a new certificate of registration.

(2) Persons who assemble or install radiation machines shall notify the department ~~[agency]~~ of the following information within 30 days after assembly or ~~[of]~~ installation:

(A) the name, address, and certificate of registration number, except in the case of initial machine installation, of persons who have received the machines;

(B) the type of radiation machine, the manufacturer's name, model number, and control panel serial number of each radiation machine; and

(C) the date of transfer or disposal of each radiation machine.

(3) Persons who assemble, install, or repair radiation machines, or components of the machines, shall ensure the radiation machines meet the applicable requirement of this chapter when the machines are placed in operation.

(4) Persons assembling, installing, and repairing radiation machines shall keep a daily log to include the following information:

(A) date of service;

(B) name of customer;

(C) customer's certificate of registration number unless the installation is an initial installation described in paragraph (1) of this subsection; and

(D) records of assembling, installing and repairing of the machines shall be made and maintained for inspection by the department per [~~agency in accordance with~~] subsection (v) of this section.

(5) Equipment performance evaluations shall be performed as follows:

(A) on all medical, chiropractic or podiatric radiation machines within 30 days after the initial installation, re-installation, and after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, power supply, and thereafter, per [~~in accordance with~~] §289.227(o)(1) of this title; and

(B) on all dental radiation machines and radiation machines used in veterinary medicine within 30 days after the initial installation, re-installation, and after repair of a machine component that would affect the radiation output that includes [~~but is not limited to~~] the timer, tube, and power supply, and thereafter, per §289.232(j)(5)(J)(i) [in accordance with §289.232(i)(7)] and §289.233(j)(5)(N)(i)(I)-(III) [§289.232(i)(5)(N)] of this title, as applicable.

(6) Radiation air kerma rate [~~exposure rate (air kerma rate)~~] or dose measurements for fluoroscopy and computed tomography (CT) radiation machines, as required by §289.227 and §289.233 of this title shall be performed by a licensed medical physicist with a specialty in diagnostic medical physics.

(7) Radiation entrance exposure [~~(air kerma)~~] data required during EPEs on general radiographic and special purpose radiation machines, as defined in §289.227(e) and §289.233(d) of this title, shall be performed by or under the

supervision of a licensed medical physicist with a specialty in diagnostic medical physics. The physicist shall:

(A) establish written procedures for non-physicists that document entrance exposure [~~(air kerma)~~] data;

(B) calculate the entrance exposure [~~(air kerma)~~];

(C) verify the entrance exposure [~~(air kerma)~~] meets compliance with §289.227(j) of this title;

(D) retest the machine, by measuring entrance exposure, at the facility's specified technique after repair or adjustment by a service technician; [sign the EPE reports.]

(E) submit any test or EPE results to the facility within 30 days after completion of testing. Documentation shall include:

(i) name of the facility;

(ii) address of facility; if satellite facility, address of where the radiation machine is located;

(iii) business email address;

(iv) registration number of the facility;

(v) make, model, and serial number from the machine control panel;

(vi) registration number of physicist and service company performing EPE;

(vii) mailing/business address of physicist performing EPE;

(viii) date of the last calibration of testing equipment;

(ix) signature of physicist that performed the EPE;

(F) retain documentation of subparagraph (E) of this paragraph according to subsection (v) of this section; and

(G) maintain a calibrated dosimetry system available for use:

(i) The system shall be calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL).

(ii) The calibration shall be performed within the previous 24 months and after any servicing that may have affected system calibration.

(p) Expiration of certificates of registration.

(1) Except as provided by subsection (r) of this section, each certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration.

(2) If a registrant does not submit an application for renewal of the certificate of registration per [~~in accordance with~~] subsection (r) of this section, as applicable, on or before the expiration date specified in the certificate of registration, the registrant shall:

(A) terminate use of all radiation machines and [~~and/or~~] terminate radiation machine servicing or radiation services as applicable; and

(B) pay any outstanding fees per [~~in accordance with~~] §289.204 of this title.

(3) The expiration [~~Expiration~~] of the certificate of registration does not relieve the registrant of the requirements of this chapter.

(q) Termination of certificates of registration.

(1) When a registrant decides to terminate all activities involving radiation machines or services authorized under the certificate of registration, the registrant shall immediately:

(A) request termination of the certificate of registration in writing signed by the RSO, owner, or an individual authorized to act on behalf of the registrant; and

(B) submit to the department [~~agency~~] a record of the disposition of the radiation machines, if applicable; and if transferred, to whom they are transferred.

(2) The registrant shall pay any outstanding fees per [~~in accordance with~~] §289.204 of this title.

(r) Renewal of certificates of registration.

(1) An application for renewal of a certificate of registration shall be filed per [~~in accordance with~~] subsection (e) of this section and applicable paragraphs of subsections (f) - (j) of this section.

(2) If a registrant applies [~~files an application~~] for [~~a~~] renewal in proper form before the existing certificate of registration expires, such [~~existing~~] certificate of registration shall not expire until the application status has been determined by the department [~~agency~~].

(s) Modification, suspension, and revocation of certificates of registration.

(1) The terms and conditions of all certificates of registration shall be subject to revision or modification. A certificate of registration may be suspended or revoked because [~~by reason~~] of amendments to the Act, because of amendments to the [~~by reason of~~] rules in this chapter, or orders issued by the department [~~agency~~].

(2) Any certificate of registration may be revoked, suspended, or modified, in whole or in part, for:

(A) any material false statement in the application or any statement of fact required under provisions of the Act;

(B) conditions revealed by such application or statement of fact or any report, record, or inspection, or other means that would warrant the department [~~agency~~] to refuse to grant a certificate of registration on an original application;

(C) violation of, or failure to observe any of the terms and conditions of the Act, this chapter, the certificate of registration, or order of the department [~~agency~~]; or

(D) existing conditions that constitute a substantial threat to [~~the~~] public health or safety or the environment.

(3) Each certificate of registration revoked by the department [~~agency~~] ends at the end of the day on the date of the department's [~~agency's~~] final determination to revoke the certificate of registration, or on the revocation date stated in the determination, or as otherwise provided by the department [~~agency~~] order.

(4) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of registration shall be suspended or revoked unless, before [~~prior to~~] the institution of proceedings, therefore, facts or conduct that may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been allowed [~~afforded an opportunity~~] to demonstrate compliance with all lawful requirements.

(t) Reciprocal recognition of out-of-state certificates of registration.

(1) Whenever any radiation machine is to be brought into the state for any temporary use, the person proposing to bring the machine into the state shall apply for and receive a notice from the department [~~agency~~] granting reciprocal recognition before [~~prior to~~] beginning operations. The request for reciprocity shall include a:

(A) completed RC Form 226-1 (Business Information Form);

(B) completed RC Form 226-3 (Application for Registration of Industrial Radiation Machines);

(C) RSO qualifications per subsection (e)(3) of this section.

~~(D) [(C)]~~ completed RC [~~BRC~~] Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);

~~(E) [(D)]~~ completed qualification forms (RC [~~BRC~~] Forms 255-E, 255-T or [~~and/or~~] 255-OS) for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;

~~[(E) name and Texas licensing board number of the practitioner if the radiation machines are used on humans;]~~

(F) copy of the applicant's current certificate of registration or equivalent document;

(G) copy of the applicant's current operating and safety procedures pertinent to the proposed use; and

(H) the fee as specified in §289.204(d) of this title. ~~[, and]~~

~~[(I) qualifications of personnel who will be operating the machines for human use.]~~

(2) Upon a determination that the request for reciprocity meets the requirements of the department [~~agency~~], the department [~~agency~~] may issue a notice granting reciprocal recognition authorizing the proposed use.

(3) Once reciprocity is granted, the out-of-state registrant shall file a RC [~~BRC~~] Form 252-3 with the department ~~before~~ [~~agency prior to~~] each entry into the state. This form shall be filed at least three [~~3~~] working days before the radiation machine is to be used in the state. If, for a specific case, the three-day [~~3-day~~] period would impose an undue hardship, the out-of-state registrant may, at the determination of the department [~~agency~~], obtain permission to proceed sooner.

(4) When radiation machines are used as authorized under reciprocity, the out-of-state registrant shall have the following in its possession at all times for inspection by the department [~~agency~~]:

(A) completed RC [~~BRC~~] Form 252-3;

(B) copy of the notice from the department [~~agency~~] granting reciprocity;

(C) copy of the out-of-state registrants operating and safety procedures; and

(D) copy of the applicable rules as specified in the notice granting reciprocity.

(5) If the state from which the radiation machine is proposed to be brought does not issue certificates of registration or equivalent documents, a certificate of registration shall be obtained from the department per [agency in accordance with] the requirements of this section.

(6) The department [agency] may withdraw, limit, or qualify its acceptance of any certificate of registration or equivalent document issued by another department [agency] upon determining that the action is necessary [~~in order~~] to prevent an undue hazard to occupational and public health and safety or property.

(7) Reciprocal recognition will expire two [2] years from the date it is granted. A new request for reciprocity shall be submitted to the department [agency] every two [2] years. Reciprocity requests made after the initial request shall include the following:

(A) completed RC Form 226-1(Business Information Form);

(B) completed RC Form 226-3 (Application for Registration of Industrial Radiation Machines);

(C) RSO qualifications in accordance with subsection (e)(3) of this section.

(D) [(C)] completed RC [BRC] Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);

(E) [(D)] completed qualification forms RC [(BRC) Forms 255-E, 255-T or [and/or] 255-OS for each radiographer who will be working in Texas if the reciprocity request is for industrial radiography;

[(E) name and Texas licensing board number of the practitioner if the radiation machines are used on humans;]

(F) copy of the applicant's current certificate of registration or equivalent document;

(G) copy of the applicant's current operating and safety procedures pertinent to the proposed use; and

(H) the fee as specified in §289.204(d) of this title. ~~[, and]~~

~~[(I) qualifications of personnel who will be operating the machines.]~~

(8) Radiation services provided by a person from out-of-state will not be granted reciprocity. Whenever radiation services are to be provided by a person from out-of-state, that person shall apply for and receive a certificate of registration from the

department [~~agency~~] before providing radiation services. The application shall be filed per [~~in accordance with~~] subsections (e), (i), and (j) of this section, as applicable.

(u) Medical research and investigational devices.

(1) Any research using radiation machines on humans shall be approved by an Investigational Review Board (IRB) as required by Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one physician to direct any use of radiation per [~~in accordance with~~] §289.231(b) of this title.

(2) Facilities with radiation machines with investigational device exemptions that are involved in clinical studies shall comply with primary regulations that govern the conduct of clinical studies and that apply to the manufacturers, sponsors, clinical investigators, institutional review boards, and the medical device. These regulations include:

(A) 21 CFR, Part 812, Investigational Device Exemptions;

(B) 21 CFR, Part 50, Protection of Human Subjects;

(C) 21 CFR, Part 56, Institutional Review Boards;

(D) 21 CFR, Part 54, Financial Disclosure by Clinical Investigators; and

(E) 21 CFR, Part 820 [~~821~~], Subpart C, Design Controls of the Quality System Regulation.

(v) Record/document retention requirements for registration of radiation machines.

(1) Each registrant shall maintain the following records/documents at each site, including authorized records sites for mobile services, at the time intervals specified for inspection by the department [~~agency~~].

Figure: 25 TAC §289.226(v)(1)

	Name of Records/Documents	Rule Cross Reference	Time Interval for Keeping Records/Documents
(A)	Records of training and experience	§289.226(j)(8)	Until termination of registration or 5 years after the individual terminates employment with the facility
(B)	Inventory of radiation machines	§289.226(m)(9)	<u>Until next routine on-site inspection [3-years]</u>
(C)	Receipt, transfer, and disposal of radiation machines	§289.226(m)(10)	Until termination of registration
(D)	Radiation machine log for providers of equipment	§289.226(m)(12)(B)	10 years
(E)	Demonstration and sale log for radiation machines	§289.226(m)(13)(B)	10 years
(F)	RSO annual review of operating and safety procedures	§289.226(n)(1)(A)	3 years
(G)	Assemble, installation, and repair log for radiation machines	§289.226(o)(4)(D)	10 years
(H)	<u>Equipment performance evaluations and corrections</u>		
	(i) <u>Healing Arts</u>	§289.227(o)(3) and (o)(4)(B)	<u>10 years</u>
	(ii) <u>Dental</u>	§289.232(j)(5)(J)(iii)	<u>10 years</u>
	(iii) <u>Veterinary</u>	§289.233(j)(5)(N)(ii)	<u>10 years</u>
	(iv) <u>Service Companies</u>	§289.226(o)(7)(F)	<u>10 years</u>

(2) Records listed in paragraph (1) of this subsection may be maintained in electronic format.