

25 TEXAS ADMINISTRATIVE CODE

§289.232

RADIATION CONTROL REGULATIONS FOR DENTAL RADIATION MACHINES

TEXAS REGULATIONS FOR CONTROL OF RADIATION

(revisions effective September 1, 2004, are shown as shaded text)

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§289.232. Radiation Control Regulations for Dental Radiation Machines.

(a) Purpose. This section establishes the following.

(1) Fees for certificates of registration for dental facilities and provisions for their payment.

(2) Requirements for the registration of persons using radiation machines. No person shall use radiation machines except as authorized in a certificate of registration issued by the agency in accordance with the requirements of this section. 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.

(3) **Requirements** intended to control the receipt, possession, use, and transfer of radiation machines by any person so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this section. However, nothing in this section shall be construed as limiting actions that may be necessary to protect health and safety in an emergency.

(4) Requirements for the use of dental radiation machines. The registrant shall assure that the requirements of this section are met in the operation of such radiation machines.

(5) Specific record keeping requirements and general provisions for records and reports.

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SUMMARY OF DENTAL RULE

These rules are for dentists who use x-ray machines.

This rule explains:

- **how you register your x-ray machine**
- **how to safely use your x-ray machine**
- **how to keep your x-ray machine in safe working condition**
- **what records to keep**
- **the rights of your employees who operate the x-ray machine**
- **actions the agency can take**

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(6) Requirements for providing notices to employees and instructions and options available to such individuals in connection with agency inspections of registrants to ascertain compliance with the provisions of the Texas Radiation Control Act, Health and Safety Code, Chapter 401, and requirements of this chapter, orders, and certificates of registration issued thereunder regarding radiological working conditions.

(7) Governing of the following in accordance with the Texas Radiation Control Act, the Texas Administrative Procedure Act, Health and Safety Code, Chapter 401; Texas Government Code, Chapter 2001; Title 1 Texas Administrative Code (TAC), Chapter 155; and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title:

(A) proceedings for the granting, denying, renewing, transferring, amending, suspending, revoking, or annulling of a certificate of registration;

(B) determining compliance with or granting of exemptions from agency rule, order, or condition of certificate of registration;

(C) assessing administrative penalties; and

(D) determining propriety of other agency orders.

(b) Scope.

§289.232(b)(1)

(1) Except as specifically provided in other sections of this chapter, this section applies to persons who receive, possess, use, or transfer dental radiation machines. The dose limits in this section do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of dental diagnosis, to exposure from individuals administered radioactive material and released in accordance with this chapter, or to voluntary participation in medical research programs. **No radiation may be deliberately applied to human beings except by or under the supervision of a dentist licensed by the Texas State Board of Dental Examiners.**

(2) Persons who are also registered by the agency to receive, possess, acquire, transfer, or use class IIIb and class IV lasers in dentistry shall also comply with the requirements of §289.301 of this title (relating to Registration and Radiation Safety Requirements for Lasers).

(3) Dental radiation machines located in a facility that also has other healing arts radiation machines will be inspected at the intervals specified in §289.231(l)(1) of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation) and equipment performance evaluations shall be performed at the interval specified for a medical facility in subsection §289.227(q)(1) of this title (relating to Use of Radiation Machines in the Healing Arts and Veterinary Medicine).

(4) The agency may, **by requirements in this chapter, an order, or a condition of certificate of registration,** impose upon any registrant such requirements in addition to those established in this chapter as it deems appropriate or necessary to minimize danger to public health and safety or the environment.

These are the only radiation rules that apply to dentists using x-ray machines.

Dentists who use lasers must follow additional rules found in another section.

The agency may add requirements if necessary to protect public health, safety, and the environment.

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(5) Registrants who are also licensed by the agency to receive, possess, use, and transfer radioactive materials must also comply with the applicable requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials), §289.252 of this title (relating to Licensing of Radioactive Material), §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(c) Definitions. The following words and terms when used in this section shall have the following meaning, unless the context clearly indicates otherwise.

(1) Absorbed dose - The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) Accessible surface - The external surface of the enclosure or housing provided by the manufacturer.

(3) Act - Texas Radiation Control Act, Health and Safety Code, Chapter 401.

(4) Administrative law judge (ALJ) - A judge employed by the State Office of Administrative Hearings.

The definitions are self-explanatory.

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(5) Administrative penalty - A monetary penalty assessed by the agency in accordance with the Texas Radiation Control Act, **Health and Safety Code**, §401.384, to emphasize the need for lasting remedial action and to deter future violations.

(6) Adult - An individual 18 or more years of age.

(7) Agency - The Texas Department of Health **or its successor**.

(8) Agreement State - Any state with which the United States Nuclear Regulatory Commission (NRC) has entered into an effective agreement under **§274b. of** the Atomic Energy Act of 1954 (42 United States Code et seq.), as amended (**73 Stat. 689**).

(9) As low as is reasonably achievable (ALARA) - Making every reasonable effort to maintain exposures to radiation as far below the dose limits in this section as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of ionizing radiation and radiation machines in the public interest.

(10) Automatic exposure control - A device that automatically controls one or more technique factors in order to obtain a required quantity of radiation at preselected locations (See definition for phototimer).

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(11) Background radiation - Radiation from cosmic sources; non-technologically enhanced naturally occurring radioactive material, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl, that contribute to background radiation and are not under the control of the registrant. "Background radiation" does not include radiation from sources of radiation regulated by the agency.

(12) Barrier - (See definition for protective barrier.)

(13) Beam-limiting device - A device that provides a means to restrict the dimensions of the x-ray field.

(14) Beam quality (diagnostic x-ray) - A term that describes the penetrating power of the x-ray beam. This is identified numerically by half-value layer and is influenced by kilovolt peak (kVp) and filtration.

(15) Board - The Texas Board of Health or its successor.

(16) Certificate of registration - A form of permission given by the agency to an applicant who has met the requirements for registration set out in the Texas Radiation Control Act and this section.

(17) Certified equipment - Equipment that has been certified in accordance with Title 21, Code of Federal Regulations.

(18) Coefficient of variation or C - The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^n \frac{(X_i - \bar{X})^2}{n-1} \right]^{1/2}$$

where : s = estimated standard deviation of the population

\bar{X} = mean value of observations in sample

X_i = ith observation in sample

n = number of observations in sample

(19) Collective dose - The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(20) Contested case - A proceeding in which the agency determines the legal rights, duties, or privileges of a party after an opportunity for adjudicative hearing.

(21) Continuous pressure type switch - A switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(22) Control panel - The part of the radiation machine control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

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(23) Declared pregnant woman - A woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman voluntarily withdraws the declaration in writing or is no longer pregnant.

(24) Deep dose equivalent, that applies to external whole body exposure - The dose equivalent at a tissue depth of 1 centimeter (1000 milligrams per square centimeter).

(25) Dentist - An individual licensed by the Texas State Board of Dental Examiners.

(26) Diagnostic source assembly - The tube housing assembly with a beam-limiting device attached.

(27) Dose - For external exposure to x-ray radiation from radiation machines, a generic term that means absorbed dose, dose equivalent, or total effective dose equivalent. For purposes of this section, "radiation dose" is an equivalent term.

(28) Dose equivalent - The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(29) Dose limits - The permissible upper bounds of radiation doses established in accordance with this chapter. For purposes of this chapter, "limits" is an equivalent term.

(30) Embryo/fetus - The developing human organism from conception until the time of birth.

(31) Enforcement conference - A meeting held by the agency with a person to discuss the following:

(A) safety, safeguards, or environmental problems;

(B) compliance with regulatory or registration condition requirements;

(C) proposed corrective measures including, but not limited to, schedules for implementation; and

(D) enforcement options available to the agency.

(32) Entrance exposure - The exposure expressed in roentgens (R), measured in air with the specified technique, calculated or adjusted to represent the exposure at the point where the center of the useful beam enters the patient.

(33) Exposure - The quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The International System of Units (SI) unit of exposure is the coulomb per kilogram. For purposes of this section, this term is used as a noun.

(34) Exposure rate - The exposure per unit of time.

(35) External dose - That portion of the dose equivalent received from any source of radiation outside the body.

(36) Extremity - Hand, elbow, arm below the elbow, foot, knee, and leg below the knee. The arm above the elbow and the leg above the knee are considered part of the whole body.

(37) Field emission equipment - Equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(38) Filter - Material placed in the useful beam to preferentially absorb selected radiations.

(39) Gray - The SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram or 100 rad.

(40) Half-value layer - The thickness of a specified material that attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value.

(41) Healing arts - Any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

(42) Hearing - A proceeding to examine an application or other matter before the agency in order to adjudicate rights, duties, or privileges.

(43) Human use - For exposure to x-ray radiation from radiation machines, the external administration of radiation to human beings for healing arts purposes or research and/or development specifically authorized by the agency.

(44) Image receptor - Any device, such as a fluorescent screen or radiographic film, that transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

(45) Individual - Any human being.

(46) Individual monitoring - The assessment of dose equivalent to an individual by the use of:

(A) individual monitoring devices; or

(B) survey data.

(47) Individual monitoring devices - Devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this section, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters, optically stimulated luminescence dosimeters, pocket ionization chambers (pocket dosimeters), and electronic personal dosimeters.

(48) Inspection - An official examination and/or observation including, but not limited to, records, tests, surveys, and monitoring to determine compliance with the Texas Radiation Control Act and agency rules, orders, requirements, and conditions of the certificate of registration.

(49) Institutional Review Board - Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(50) Ionizing radiation - Any electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in its passage through matter. Ionizing radiation includes gamma rays and x rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles.

(51) kV - Kilovolt.

(52) kVp - Kilovolt peak (See definition for peak tube potential).

(53) kW - Kilowatt-second. It is equivalent to 10^3 watt-second, where 1 watt-second = 1 kilovolt x 1 milliamper x 1 second.

(54) Lead equivalent - The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(55) Leakage radiation - Radiation emanating from the diagnostic assembly except for the useful beam and radiation produced when the exposure switch or timer is not activated.

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(56) Lens dose equivalent - The external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeters (300 milligrams per square centimeter).

(57) License - A form of permission given by the agency to an applicant who has met the requirements for licensing set out in the Texas Radiation Control Act and this chapter.

(58) Licensed material - Radioactive material received, possessed, used, or transferred under a general or specific license issued by the agency.

(59) Licensed medical physicist - An individual holding a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602.

(60) Licensee - Any person who is licensed by the agency in accordance with the Texas Radiation Control Act and this chapter.

(61) Licensing state - Any state with rules equivalent to the Suggested State Regulations for Control of Radiation relating to, and having an effective program for, the regulatory control of naturally occurring or accelerator-produced radioactive material (NARM) and has been designated as such by the Conference of Radiation Control Program Directors, Inc.

(62) mA - Milliampere.

(63) mAs - Milliampere-second.

(64) Medical research - The investigation of various health risks and diseases.

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(65) Member of the public - Any individual, except when that individual is receiving an occupational dose.

(66) Minor - An individual less than 18 years of age.

(67) Mobile service operation - The provision of radiation machines and personnel at temporary sites for limited time periods. The radiation machines may be fixed inside a motorized vehicle or may be a portable radiation machine that may be removed from the vehicle and taken into a facility for use.

(68) Monitoring - The measurement of radiation and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this chapter, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(69) Non-certified equipment - Equipment manufactured and assembled prior to certification requirements of Title 21, Code of Federal Regulations (CFR), effective as specified in Title 21, CFR, §1020.30(a).

(70) Notice of violation - A written statement of one or more alleged infringements of a legally binding requirement. The notice requires the person receiving the notice to provide a written statement describing the following:

(A) corrective steps taken by the person and the results achieved;

(B) corrective steps to be taken to prevent recurrence; and

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(C) the projected date for achieving full compliance.
The agency may require responses to notices of violation to be under oath.

(71) Occupational dose - The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter or from voluntary participation in medical research programs, or as a member of the public.

(72) Order - A specific directive contained in a legal document issued by the agency.

(73) Party - A person designated as such by the ALJ. A party may consist of the following:

(A) the agency; **and**

(B) an applicant, licensee, registrant, accredited mammography facility, or certified industrial radiographer.

(74) Patient - An individual subjected to dental examination, diagnosis, or treatment.

(75) Peak tube potential - The maximum value of the potential difference in kilovolts across the x-ray tube during an exposure.

(76) Person - Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, local government, any other state or political subdivision or agency thereof, or any other legal entity, and any legal successor, representative, agent, or agency of the foregoing, other than the United States Nuclear Regulatory Commission, and other than federal government agencies licensed or exempted by the United States Nuclear Regulatory Commission.

(77) Personnel monitoring equipment - (See definition for individual monitoring devices).

(78) Phototimer - A method for controlling radiation exposures to image receptors by the amount of radiation that reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit that controls the duration of time the tube is activated (See definition for automatic exposure control).

(79) Portable x-ray equipment - (See definition for x-ray equipment).

(80) Primary protective barrier - (See definition for protective barrier).

(81) Protective barrier - A barrier of radiation absorbing materials used to reduce radiation exposure. The types of protective barriers are as follows:

(A) Primary protective barrier - A barrier sufficient to attenuate the useful beam to the required degree; or

(B) Secondary protective barrier - A barrier sufficient to attenuate the stray radiation to the required degree.

(82) Public dose - The dose received by a member of the public from exposure to radiation from licensed/registered and unlicensed/unregistered sources of radiation, whether in the possession of the licensee/registrant or other person. It does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with this chapter or from voluntary participation in medical research programs, or as a member of the public.

(83) Rad - The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 gray).

(84) Radiation - One or more of the following:

(A) gamma and x rays; alpha and beta particles and other atomic or nuclear particles or rays;

(B) radiation emitted to energy density levels that could reasonably cause bodily harm from an electronic device; or

(C) sonic, ultrasonic, or infrasonic waves from any electronic device or resulting from the operation of an electronic circuit in an electronic device in the energy range to reasonably cause detectable bodily harm.

(85) Radiation area - Any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 millisievert) in one hour at 30 centimeters from the radiation machine or from any surface that the radiation penetrates.

(86) Radiation machine - Any device capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation.

(87) Radiation safety officer - An individual who has a knowledge of and the authority and responsibility to apply appropriate radiation protection rules, standards, and practices, who shall be specifically authorized on a certificate of registration, and who is the primary contact with the agency.

(88) Radiograph - An image receptor on which the image is created directly or indirectly by an x-ray exposure and results in a permanent record.

(89) Registrant - Any person issued a certificate of registration by the agency in accordance with the Texas Radiation Control Act and this chapter.

(90) Regulation (See definition for rule.)

(91) Rem - The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

(92) Remote inspection - An examination by the agency of information submitted by the registrant on a form provided by the agency.

(93) Research and development - Research and development is defined as:

(A) theoretical analysis, exploration, or experimentation; or

(B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

(94) Restricted area - An area, access to which is limited by the registrant for the purpose of protecting individuals against undue risks from exposure to radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(95) Roentgen (R) - The special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air. (See definition for exposure.)

(96) Rule - Any agency statement of general applicability that implements, interprets, or prescribes law or policy, or describes the procedure or practice requirements of an agency. The term includes the amendment or repeal of a prior section but does not include statements concerning only the internal management or organization of any agency and not affecting private rights or procedures. The word "rule" was formerly referred to as "regulation."

(97) Scattered radiation - Radiation that has been deviated in direction during passage through matter.

(98) Secondary protective barrier (See definition for protective barrier).

(99) Severity level - A classification of violations based on relative seriousness of each violation and the significance of the effect of the violation on the occupational or public health or safety.

(100) Shallow dose equivalent - The dose equivalent at a tissue depth of 0.007 centimeters (7 milligrams per square centimeter) that applies to the external exposure of the skin of the whole body or the skin of an extremity.

(101) SI - The abbreviation for the International System of Units.

(102) Sievert - The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 sievert = 100 rem).

(103) Source of radiation - Any radioactive material, or any device or equipment emitting or capable of producing radiation.

(104) Source-to-image receptor distance - The distance from the source to the center of the input surface of the image receptor.

(105) Source-to-skin distance - The distance from the source to the skin of the patient.

(106) Special units - The conventional units historically used by registrants, i.e., rad (absorbed dose), and rem (dose equivalent).

(107) Stationary x-ray equipment - (See definition for x-ray equipment).

(108) Stray radiation - The sum of leakage and scattered radiation.

(109) Supervision - The delegating of the task of applying radiation in accordance with this section to persons not licensed in dentistry, who perform tasks under the dentist's control. The dentist assumes full responsibility for these tasks and shall assure that the tasks will be administered correctly.

(110) Survey - An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, and/or disposal of radiation machines. When appropriate, such survey includes, but is not limited to, tests, physical examination of location of equipment or radiation machines, and measurements of levels of radiation present, and evaluation of administrative and/or engineered controls.

(111) Technique chart - A chart that provides all necessary generator control settings and geometry needed to make clinical radiographs when the radiation machine is in manual mode.

(112) Technique factors - The conditions of operation that are specified as follows:

(A) for capacitor energy storage equipment, peak tube potential in kilovolt and quantity of charge in milliampere-second;

(B) for field emission equipment rated for pulsed operation, peak tube potential in kilovolt and number of x-ray pulses; and

(C) for all other equipment, peak tube potential in kilovolt and either tube current in milliamperes and exposure time in seconds or the product of tube current and exposure time in milliampere-second.

(113) Termination - A release by the agency of the obligations and authorizations of the registrant under the terms of the certificate of registration. It does not relieve a person of duties and responsibilities imposed by law or rule.

(114) Texas Regulations for Control of Radiation (TRCR) - All sections of Title 25 Texas Administrative Code, Chapter 289.

(115) Total effective dose equivalent - For external exposures only to x-ray radiation from radiation machines, the total effective dose equivalent is equal to the deep dose equivalent.

(116) Traceable to a national standard - This indicates that a quantity or a measurement has been compared to a national standard, for example, the National Institute of Standards and Technology, directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

(117) Tube - An x-ray tube, unless otherwise specified.

(118) Tube housing assembly - The tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

(119) Unrestricted area (uncontrolled area) - An area, access to which is neither limited nor controlled by the registrant. For purposes of this section, "uncontrolled area" is an equivalent term.

(120) Useful beam - Radiation that passes through the window, aperture, core, or other collimating device of the source housing. Also referred to as the primary beam.

(121) Violation - An infringement of any rule, license or registration condition, order of the agency, or any provision of the Texas Radiation Control Act.

(122) X-ray control - A device that controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes components such as timers, phototimers, automatic brightness stabilizers, and similar devices that control the technique factors of an x-ray exposure.

(123) X-ray equipment - An x-ray system, subsystem, or component thereof. For the purposes of this rule, types of x-ray equipment are as follows:

(A) portable x-ray equipment - x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled or equipment designed to be hand-carried; or

(B) stationary x-ray equipment - x-ray equipment that is installed in a fixed location.

(124) X-ray field - That area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(125) X-ray high-voltage generator - A device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tubes, high-voltage switches, electrical protective devices, and other appropriate elements.

(126) X-ray system - An assemblage of components for the controlled production of x rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

(127) X-ray subsystem - Any combination of two or more components of an x-ray system.

(128) X-ray tube - Any electron tube that is designed to be used primarily for the production of x rays.

(129) Whole body - For purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(130) Worker - An individual engaged in work under a certificate of registration issued by the agency and controlled by a registrant, but does not include the registrant.

(131) Year - The period of time beginning in January used to determine compliance with the provisions of this chapter. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(d) Exemptions.

(1) The agency may, upon application therefor or upon its own initiative, exempt a source of radiation or a kind of use or user from the requirements of this section if the agency determines that the exemption is not prohibited by law and will not result in a significant risk to public health and safety. In determining such exemptions, the agency will consider:

(A) state of technology;

(B) economic considerations in relation to benefits to the public health and safety; and

(C) other societal, socioeconomic, or public health and safety considerations.

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Under certain conditions, the agency may exempt an x-ray machine or use of an x-ray machine from these rules.

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§289.232(d)(2)

(2) 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 does not exceed 0.5 millirem per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(3) 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. Facilities that have placed all radiation machines in storage, including storage in place, and have notified the 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.

(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) Financial institutions that take possession of radiation machines as the result of foreclosure, bankruptcy, or other default of payment are exempt from the requirements in this section to the extent that they demonstrate that the radiation machine is operable for the sole purpose of selling, leasing, or transferring.

(6) No individual monitoring shall be required for personnel operating only dental radiation machines for dental diagnostic purposes.

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These rules do not apply to certain electronic equipment such as televisions.

If you have notified the agency in writing that all of your x-ray machines are in storage, these rules do not apply to you. But, if you energize an x-ray machine in storage, the rules apply.

These rules do not apply to x-ray machines that will not work when plugged in without being repaired.

These rules do not apply to financial institutions that have x-ray machines because of a client's bankruptcy or foreclosure. They may use the machine only to show that the machines work in order to sell, lease or transfer them.

Individuals who use dental x-ray machines do not have to use radiation monitoring badges.

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§289.232(d)(7)

(7) Portable radiation machines designed to be hand-held are exempt from the requirements of subsection (i)(6)(C) of this section. The portable radiation machines shall be held by the tube housing support or handle.

(8) Individuals who are sole practitioners and sole operators and the only occupationally exposed individual are exempt from the following requirements:

- (A) subsection (i)(3) of this section;
- (B) subsection (i)(4)(D) of this section; and
- (C) subsection (i)(5)(B) and (C) of this section.

(9) In accordance with the Dental Practice Act, Texas Occupations Code, §258.054, dental practices are exempt from the Medical Physics Practice Act, Texas Occupations Code, Chapter 602. Registrants required to have tests performed in accordance with subsection (i)(7)(A) of this section may select any qualified person authorized by registration through the Bureau of Radiation Control.

(e) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under them should be mailed by postal service to the Bureau of Radiation Control, Texas Department of Health, 1100 West 49th Street, Austin, Texas, 78756-3189. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas.

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Portable x-ray machines that are designed to be hand-held must be held by the tube housing support or the handle.

A dentist who practices alone, who is the only person operating the x-ray machines, and the only worker exposed to radiation, does not have to have operating and safety procedures, give instructions to workers, or post notices required by this rule.

Dentists are not required to have a licensed medical physicist perform tests on their x-ray machines.

Mail Correspondence to:

**Bureau of Radiation Control
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3189**

**Deliver correspondence to our office at:
8407 Wall Street, Austin TX**

We consider correspondence received on the date of the postmark, telegram, fax, or electronic mail.

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(2) Documents received by the agency will be deemed to have been received on the date of the postmark, telegram, telefacsimile, or electronic media transmission.

(f) Interpretations. Except as specifically authorized by the agency in writing, no interpretation of the meaning of this chapter by any officer or employee of the agency other than a written **legal** interpretation by the **agency**, will be considered binding upon the agency.

(g) Fees for Certificates of Registration for Dental Facilities.

(1) Payment of fees.

(A) Each application for a certificate of registration shall be accompanied by a nonrefundable fee of \$300. No application will be accepted for filing or processed prior to payment of the full amount specified.

(B) A nonrefundable fee of \$300 shall be paid for each certificate of registration for radiation machines used in dentistry. The fee shall be for the two-year term of the certificate of registration. The fee shall be paid in full on or before the last day of the expiration month and year of the certificate of registration.

(j) For each additional use location authorized on a single certificate of registration, the registrant will pay an additional \$90.

Any correspondence you send to the agency may be an "open record" and can be viewed by the public. You may request that your correspondence be kept confidential, but you have to justify why. The specific instructions you must follow in order to keep your documents confidential are on pages 232-71 through 232-74.

Official interpretations of these rules must be made by the agency.

Send in a fee when you send in your application for a certificate of registration. After you are registered you will be billed every two years.

The fee is nonrefundable.

(ii) In the case of a single certificate of registration that authorizes more than one category of use, the category listed in §289.204(h) of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services) and assigned the higher fee will be used. If this certificate of registration also has additional authorized use sites, the registrant shall pay an additional 30% of the highest fee category.

(C) Each application for reciprocal recognition of an out-of-state registration in accordance with subsection (h)(9) of this section shall be accompanied by the \$300 fee, provided that no such fee has been submitted within 24 months of the date of commencement of the proposed activity.

(D) Fee payments shall be in cash or by check or money order made payable to the Texas Department of Health. The payments may be made by personal delivery to the central office, Bureau of Radiation Control, Texas Department of Health, 1100 West 49th Street, Austin, Texas, or mailed to the Bureau of Radiation Control, Texas Department of Health, 1100 West 49th Street, Austin, Texas, 78756-3189.

(2) Failure to pay prescribed fees.

(A) In any case where the agency finds that an applicant for a certificate of registration has failed to pay the fee prescribed in this section, the agency will not process that application until such fee is paid.

Out-of-state dentists who practice in Texas and use an x-ray machine pay \$300.00.

You may pay your fee with cash, check, or money order. Payments can be mailed or you may pay in person.

If you do not send in the fee with your application, the application will not be processed.

§289.232(g)(2)(B)

(B) In any case where the agency finds that a registrant has failed to pay a fee prescribed by this section by the due date, the certificate of registration expires and the agency may implement compliance procedures as provided in subsection (k)(2)(C) of this section.

(3) Fees for Texas Online participation. 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.

(h) Registration of Radiation Machine Use.

(1) Application for registration.

(A) Each person having a radiation machine used in dentistry shall apply for registration with the agency within 30 days after beginning use of the radiation machine, except for mobile services that shall be registered in accordance with paragraph (2) of this subsection and clinical trial evaluations that shall be registered in accordance with paragraph (5)(B) of this subsection.

(B) Application for registration shall be completed on forms prescribed by the agency and shall contain all the information required by the form and accompanying instructions.

(C) The applicant shall be qualified by reason of training and experience to use the radiation machines for the purpose requested in accordance with this section in such a manner as to minimize danger to public health and safety.

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If you do not pay your fee, your certificate is expired and you will be in violation of the rules.

The agency will be collecting subscription and convenience fees for all applications and renewal applications. The cost is to be determined by the Texas Online Authority,

Send in an application for registration within 30 days from the day you first use your x-ray machine.

Fill out the agency application. The instructions on the application explain how to fill it out. Also send in BRC Form 226-1 with your application. The forms can be downloaded from the agency website.

www.tdh.state.tx.us/radiation/forms.htm

You must have training and experience to safely use x-ray machines.

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§289.232(h)(1)(D)

(D) A radiation safety officer shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application. The radiation safety officer shall meet the applicable requirements of paragraph (10) of this subsection and carry out the responsibilities of paragraph (11) of this subsection.

(E) An application for use of a dental radiation machine shall be signed by a licensed dentist. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed dentist's signature if the facility has more than one licensed dentist who may direct the operation of radiation machines. The application shall also be signed by the radiation safety officer if the radiation safety officer is someone other than the licensed dentist.

(F) The agency may at any time after the filing of the original application require further statements in order to enable the agency to determine whether the certificate of registration should be issued or denied.

(G) An application for a certificate of registration may include a request for a certificate of registration authorizing one or more activities. If an application includes a request for an additional authorization other than use of a dental radiation machine, compliance with other applicable sections of this chapter will be required.

(H) Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection in accordance with subsection (j)(1)(K) and (L) of this section.

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You must name a radiation safety officer (RSO) for your office. That person must have the qualifications listed on page 232-44 and must perform the duties listed on page 232-47. Send in the qualifications of the person with the application.

Your application must be signed by a licensed dentist and the RSO.

The agency may ask for more information after you have sent in your application.

Your application may include a request for use of x-ray machines other than dental x-ray machines. If so, other rules will apply.

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§289.232(h)(1)(I)

(I) Each application for a certificate of registration shall be accompanied by the fee prescribed in subsection (g) of this section.

(J) Each application shall be accompanied by a completed BRC Form 226-1, Business Information Form.

(K) The applicant's proposed radiation machines, facilities, and operating and safety procedures shall be adequate to minimize danger to occupational and public health and safety.

(2) Application for registration of mobile service operation used in dentistry. In addition to the requirements of paragraph (1) of this subsection, each applicant shall apply for and receive authorization for mobile service operation before beginning mobile service operation. 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 radiation machine inside, furnish the floor plan indicating protective shielding and the operator's location.

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

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Your x-ray machines, facility, and procedures must adequately protect occupational and public health and safety.

You must get approved for mobile x-ray services before you begin using them. Send in the following information with your request for approval:

- **A main office where your x-ray machines and records can be inspected by the agency.**
- **An explanation of how the x-ray machine, the operator, and any other personnel are typically positioned during an x-ray.**
- **Your operating and safety procurers for mobile x-ray operations.**

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(3) Issuance of certificate of registration.

(A) Upon a determination that an application meets the requirements of the Texas Radiation Control Act and the requirements of this chapter, the agency may issue a certificate of registration authorizing the proposed activity in such form and containing such conditions and limitations as the agency deems appropriate or necessary.

(B) The agency may incorporate in the certificate of registration at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the registrant's possession, use, and transfer of radiation machines subject to this section as it deems appropriate or necessary in order to:

(i) minimize danger to occupational and public health and safety;

(ii) require additional records and the keeping of additional records as may be appropriate or necessary; and

(iii) prevent loss or theft of radiation machines subject to this section.

(4) Specific terms and conditions of certificates of registration.

(A) Each certificate of registration issued in accordance with this section shall be subject to the applicable provisions of the Texas Radiation Control Act, now or hereafter in effect, and to the applicable requirements of this chapter and orders of the agency.

Your certificate of registration will be issued if your application is complete and meets all the requirements and the fee is paid.

The agency may add conditions to your certificate of registration if necessary to protect occupational and public health and safety.

§289.232(h)(4)(B)

(B) 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 agency authorizes the transfer in writing.

(C) Each person registered by the agency for radiation machine use 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.

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

(E) No person shall use radiation machines that are not authorized in the certificate of registration issued by the agency.

(F) In making a determination whether to grant, deny, amend, renew, revoke, suspend, or restrict a certificate of registration, the 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 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 agency actions have been issued against the applicant, within the previous six years, that assess administrative or civil penalties against the applicant, or that revoke or suspend the certificate of registration.

(G) No registrant shall engage any person for services described in §289.226(j) of this title (relating to Registration of Radiation Machine Use and Services) until such person provides evidence to the registrant of registration with the agency.

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Your compliance history will be reviewed.

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(5) Responsibilities of the registrant.

(A) The registrant shall notify the agency **in writing** within 30 days of any **of the following** changes that would render the information contained in the application for registration and/or the certificate of registration inaccurate:

(i) name and mailing address;

(ii) street address where machine will be used;

(iii) RSO; or

(iv) name of entity contracted for "provider of equipment" registered in accordance with §289.226 of this title.

(B) The following criteria applies to **loaner or demonstration** radiation machines and radiation machines used for clinical trial evaluations. **For persons having a valid certificate of registration, radiation machines used for clinical trial evaluations and loaner or demonstration radiation machines may be used for up to 60 days. After 60 days, the registrant shall notify the agency of the following:**

(i) any change in the category(ies) of machine type or type of use as authorized in the certificate of registration (for example, addition of a computerized tomography machine to the authorized dental radiographic machine); or

If any of the information in your application changes, such as your name, address, RSO, etc., tell the agency in writing within 30 days of the change.

If you use an x-ray machine on loan to you or a machine for clinical trial evaluation, you must tell the agency how long you are going to use it. If you use the machine for more than 60 days, you must add it to your certificate of registration.

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

(C) The following applies to voluntary or involuntary petitions for bankruptcy.

(i) Each registrant shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by the registrant or its parent company. This notification shall include:

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

(II) the date of the filing of the petition.

(ii) A copy of the "petition for bankruptcy" shall be submitted to the agency along with the written notification.

(D) Inventory.

(i) Each registrant shall inventory all radiation machines at an interval not to exceed one year. The inventory shall be made and maintained for inspection by the agency in accordance with subsection (k)(1)(X)(i) of this section and shall include:

(I) manufacturer's name;

Let the agency know in writing if you claim bankruptcy.

Also tell the agency in writing, the bankruptcy court in which you filed and the date you filed.

Include a copy of your petition for bankruptcy with your written notice.

You must inventory all of your x-ray machines each year. Keep a record of the inventory and include the manufacturer's name, the model and serial number from the control panel, and where the x-ray machines are located.

§289.232(h)(5)(D)(i)(II)

(II) model and serial number of the control panel; and

(III) location of radiation machine(s), for example, room number.

(ii) Notification to the agency concerning radiation machine inventory is required within 30 days of either of the following:

(I) any change in the category(ies) of machine type or type of use as authorized in the certificate of registration (for example, addition of a computerized tomography machine to the authorized dental radiographic machine); or

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

(E) Receipt, transfer, and disposal of radiation machines. The registrant shall ensure that records of receipt, transfer, and disposal of radiation machines are made and/or maintained for each radiation machine in accordance with subsection (k)(1)(X)(i) of this section for inspection by the agency. Records of receipt, transfer, and disposal of radiation machines shall include the following:

(i) manufacturer's name and model and serial number from the control panel;

(ii) date of the receipt, transfer, and disposal; and

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Notify the agency within 30 days if your inventory changes because you changed the category(ies) of machine type or type of use as authorized in the certificate of registration or if you added a machine.

Keep records of the machines you received, transferred or disposed of. Your record must include:

- **manufacturer's name**
- **model and serial number of control panel**
- **date you received, transferred, or disposed of the machine**
- **name of the person who recorded the information**

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(iii) name of the individual recording the information.

(F) Records of training and experience required by this section shall be maintained for inspection by the agency until disposal is authorized by the agency.

(6) Expiration of certificates of registration.

(A) Effective September 1, 2004, the term of the certificate of registration is two years. Each certificate of registration expires at the end of the day, in the month and year stated in the certificate of registration. Upon payment of the fee required by subsection (g)(1)(B) of this section, and if the agency does not deny the renewal in accordance with subsection (h)(4)(F) of this section, the certificate of registration will be renewed.

(B) If the fee is not paid and the certificate of registration is not renewed in accordance with subparagraph (A) of this paragraph, the certificate of registration expires, and the registrant is in violation of the requirements in this chapter and is subject to administrative penalties in accordance with §289.205 of this title.

(i) If the registrant pays the fee required by §289.204 of this title within 30 days after expiration of the certificate of registration, the certificate of registration will be reinstated and the registrant will not be required to file an application in accordance with subsection (h) of this section.

Keep records of training and experience for all employees.

As of September 1, 2004, the certificate of registration is valid for two years. The certificate expires at the end of the day of the month and year indicated on the certificate.

Your certificate will be renewed if the fee is paid and if the agency does not deny the renewal.

Your certificate will expire if you do not pay your fee and if the certificate is not renewed.

Pay your fee on time to avoid having to file an application.

(ii) If the registrant fails to pay the fee within 30 days after expiration of the certificate of registration, the registrant shall file an application in accordance with subsection (h) of this section.

(C) If a registrant does not pay the fee required by subsection (g) of this section and the certificate of registration is not renewed, the registrant shall:

(i) terminate use of all radiation machines within 30 days following the expiration date; and

(ii) submit to the agency a record of the disposition of the radiation machines and if transferred, to whom transferred, within 30 days following the expiration date.

(D) Expiration of the certificate of registration does not relieve the registrant of the requirements of this chapter.

(7) Termination of certificates of registration. When a registrant decides to terminate all activities involving radiation machines authorized under the certificate of registration, the registrant shall notify the agency immediately and:

(A) request termination of the certificate of registration in writing;

(B) submit to the agency a record of the disposition of the radiation machines and if transferred, to whom transferred; and

(C) pay any outstanding fees in accordance with subsection (g) of this section.

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The certificate will not be renewed if the fee is not paid and you must then do the following:

- **stop using x-ray machines**
- **tell us in writing what you will do with your x-ray machine and if the machine is transferred, who the machine is transferred to**

When you decide to quit using x-ray machines, you must do the following things:

- **request termination of your certificate of registration, in writing**
- **tell us in writing what you will do with your x-ray machine and if the machine is transferred, who the machine is transferred to**
- **pay any outstanding fees**

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§289.232(h)(8)

(8) Modification, suspension, and revocation of certificate of registration.

(A) 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 by reason of amendments to the Act, by reason of requirements of this chapter or orders issued by the agency.

(B) Any certificate of registration may be revoked, suspended, or modified, in whole or in part, for any of the following:

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

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

(iii) 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 agency; or

(iv) existing conditions that constitute a substantial threat to the public health or safety or the environment.

Your certificate may be modified, suspended, or revoked.

§289.232(h)(8)(C)

(C) Each certificate of registration revoked by the agency ends at the end of the day on the date of the 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 agency order.

(D) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of registration shall be suspended or revoked unless, 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 afforded an opportunity to demonstrate compliance with all lawful requirements.

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

(A) 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 agency granting reciprocal recognition prior to beginning operations. The request for reciprocity shall include the following:

(i) completed BRC Form 226-1 (**Business Information Form**);

(ii) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);

(iii) name and Texas licensing board number of the dentist if the radiation machines are used to irradiate humans;

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This applies only to dental machines brought in to Texas from out-of-state for temporary use.

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§289.232(h)(9)(A)(iv)

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

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

(vi) the fee as specified in subsection (g)(2) of this section; and

(vii) qualifications of personnel who will be operating the machines.

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

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

(D) 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 agency:

(i) completed BRC Form 252-3;

(ii) copy of the notice from the agency granting reciprocity;

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(iii) copy of the out-of-state registrant's operating and safety procedures; and

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

(E) 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 agency in accordance with the requirements of this section.

(F) The agency may withdraw, limit, or qualify its acceptance of any certificate of registration or equivalent document issued by another agency upon determining that such action is necessary in order to prevent undue hazard to occupational and public health and safety.

(G) Reciprocal recognition will expire one year from the date it is granted. A new request for reciprocity shall be submitted to the agency each year. Reciprocity requests made after the initial request shall include only the following:

(j) completed BRC Form 226-1 (Business Information Form);

(ii) completed BRC Form 252-3 (Notice of Intent to Work in Texas Under Reciprocity);

(iii) name and Texas licensing board number of the dentist if the radiation machines are used to irradiate humans;

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

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

(vi) the fee as specified in subsection (g)(1) of this section; and

(vii) qualifications of personnel who will be operating the machines.

(H) 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 agency before providing radiation services. The application shall be filed in accordance with this subsection, as applicable.

(10) A radiation safety officer (RSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application.

(A) The RSO shall have the following qualifications:

(j) knowledge of potential hazards and emergency precautions; and

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

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You must have these qualifications to be a radiation safety officer (RSO):

- **knowledge of possible hazards**
- **radiation safety training**
- **experience with the x-ray machine**

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

(B) In addition to the qualifications in subparagraph (A) of this paragraph, documentation of the following shall be submitted to the agency:

(j) dentist radiation safety officers shall provide documentation of licensing board number and their signature on the application; or

(ii) non-practitioner radiation safety officers shall provide any one of the following:

(I) 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 use of radiation machines;

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

(III) 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 use of radiation machines;

RSOs who are dentists must send in their licensing board number and sign the application.

RSOs who are not dentists must send in:

- **a copy of their registration with the Board of Dental Examiners or Dental Hygienist Board**
- **documentation showing 4 years of working with dental x-ray machines**

§289.232(h)(10)(B)(ii)(IV)

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

(V) evidence of registration with the Board of Nurse Examiners as a Registered Nurse or a Registered Nurse with an extended scope of practice (Nurse Practitioner) performing radiologic procedures, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;

(VI) evidence of registration with the Texas State Board of Physician Assistant Examiners, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;

(VII) evidence of:

(-a-) registration with the Texas State Board of Dental Examiners to perform radiologic procedures under a dentist's instruction and direction or evidence of a valid certificate as a registered dental hygienist; and

(-b-) at least four years of supervised use of radiation machines in the respective dentists' specialty;

(VIII) evidence of bachelor's (or higher) degree in a natural or physical science, health physics, radiological science, nuclear medicine, or nuclear engineering; or

(IX) evidence of a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, in medical health physics, diagnostic radiological physics, or medical nuclear physics for diagnostic x-ray facilities.

(C) Academic institutions and/or research and development facilities shall have radiation safety officers who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. (This individual may also serve as the radiation safety officer over the dental section of the facility).

(D) The radiation safety officer identified on a certificate of registration issued before September 1, 1993, need not comply with the qualification requirements in this subsection.

(11) Responsibilities of radiation safety officers. Specific duties of the radiation safety officer include, but are not limited to, the following:

(A) establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable, and to review them regularly to ensure that the procedures are current and conform with this section;

(B) investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this section and each theft or loss of radiation machines, determining the cause, and taking steps to prevent its recurrence;

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Radiation safety officers are responsible for:

- **preparing operating and safety procedures and keeping them updated**
- **telling us about lost or stolen x-ray machines or overexposures**
- **knowing policies and procedures**
- **stopping unsafe practices**
- **keeping records**
- **training employees**
- **making sure the rules are followed**

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(C) having a thorough knowledge of management policies and administrative procedures of the registrant;

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

(E) maintaining records as required by this section;
and

(F) ensuring that personnel are adequately trained and complying with this section, the conditions of the certificate of registration, and the operating and safety procedures of the registrant.

(i) Use of Dental Radiation Machines.

(1) As low as reasonably achievable. The registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as reasonably achievable.

(2) Prohibited uses.

(A) The agency may prohibit use of dental radiation machines that pose significant threat or endanger occupational and public health and safety, in accordance with subsections (a)-(f) and (k)(2) of this section and paragraphs (1) and (2) of this subsection.

§289.232(i)(2)(B)

(B) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a dentist. This provision specifically prohibits deliberate exposure for the following purposes:

(i) exposure of an individual for training, demonstration, or other non-healing arts purposes;

(ii) exposure of an individual for the purpose of research except as authorized by subsection (i)(7) of this section.

(3) Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures. These procedures shall be made available to each individual operating a radiation machine, including any restrictions of the operating technique required for the safe operation of the particular x-ray system.

(A) The registrant shall document that each individual operating a radiation machine has read the operating and safety procedures and shall maintain this documentation for inspection by the agency in accordance with subsection (k)(1)(X)(i) of this section. The documentation shall include the following:

(i) name and signature of individual;

(ii) date individual read the operating and safety procedures; and

(iii) initials of the RSO.

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You cannot use your x-ray machine on a person for training or demonstration.

You cannot use your x-ray machine on a person for research unless approved by the agency.

Operating and safety procedures must be in writing and shall include certain items.

The agency has sample operating and safety procedures you may use to develop your own procedures. You can download these sample procedures at:

www.tdh.state.tx.us/radiation/regguide.htm

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(B) The operating and safety procedures shall include, but are not limited to, the following procedures as applicable.

(i) use of a technique chart in accordance with paragraph (6)(A) of this subsection;

(ii) radiation dose requirements in accordance with paragraph (4)(A) of this subsection;

(iii) holding of patients or film in accordance with paragraph (13)(A), (C), and (D) of this subsection;

(iv) film processing program or digital image processing in accordance with paragraphs (14)-(16) of this subsection;

(v) posting notices to workers in accordance with paragraph (5)(B) of this subsection;

(vi) instructions to workers in accordance with paragraph (4)(D) of this subsection;

(vii) notifications and reports to individuals in accordance with subsection (j)(2)(B) and (C) of this section;

(viii) ordering x-ray exams in accordance with subsection (b)(1) of this section; and

(ix) posting of a radiation area in accordance with paragraph (5)(D) and (E) of this subsection.

(4) Personnel requirements.

(A) Occupational dose limits.

(i) The registrant shall control the occupational dose to individuals, to the following dose limits.

(I) An annual limit shall be the total effective dose equivalent being equal to 5 rems (0.05 sievert).

(II) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of any extremities shall be:

(-a-) a lens dose equivalent of 15 rems (0.15 sievert); and

(-b-) a shallow dose equivalent of 50 rems (0.5 sievert) to the skin of the whole body or to the skin of any extremity.

(III) The annual limits for a minor shall be 10% of the annual occupational dose limits specified in subclauses (I) and (II) of this clause.

(IV) If a woman declares her pregnancy, the registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 millisievert). If a woman chooses not to declare pregnancy, the occupational dose limits specified in subclauses (I) and (II) of this clause are applicable to the woman.

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There are radiation dose limits for workers, pregnant women, and the public.

Historically, safely using dental x-ray machines does not cause these dose limits to be exceeded which is why personnel monitoring is not required for dental office.

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(V) The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in clause (i) of this subparagraph. The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

(ii) The assigned deep dose equivalent shall be for the portion of the body receiving the highest exposure. The assigned shallow dose equivalent shall be the dose averaged over the contiguous 10 cm² of the skin receiving the highest exposure.

(iii) The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or radiation measurements for the purpose of demonstrating compliance with the occupational dose limits.

(iv) The registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received from radiation machines or radioactive materials while employed by any other person.

(B) Dose limits for individual members of the public.

(i) Each registrant shall conduct operations so that:

§289.232(i)(4)(B)(i)(I)

(I) the total effective dose equivalent to individual members of the public from exposure to radiation from radiation machines does not exceed 0.5 rem (5 millisieverts) in a year, exclusive of the dose contribution from background radiation, exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs; and

(II) the dose in any unrestricted area from external exposure to radiation from radiation machines does not exceed 0.002 rem (0.02 millisieverts) in any one hour.

(ii) If the registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

(iii) The agency may impose additional restrictions on radiation levels in unrestricted areas in order to restrict the collective dose.

(C) Occupational doses from other sources of radiation. Individuals who receive occupational doses from sources of radiation other than dental radiation machines may be required to comply with the requirements of §289.231(n) and (q)-(s) of this title.

(D) Instructions to workers. The registrant shall provide instructions to radiation workers prior to beginning initial work in restricted areas. These instructions shall include the following:

(i) precautions or procedures to minimize exposure;

Train your employees in how to keep radiation exposures at a minimum and report unsafe radiation conditions.

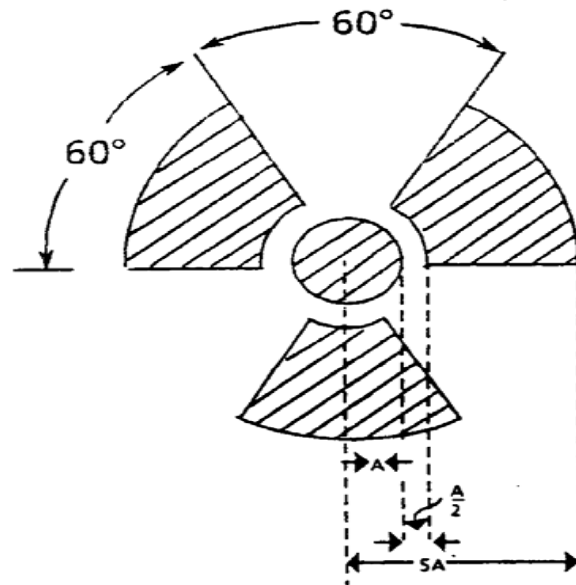
§289.232(i)(4)(D)(ii)

(ii) the applicable provisions of agency requirements and certificates of registration for the protection of personnel from exposures to radiation occurring in such areas; and

(iii) the radiation worker's responsibility to report promptly to the registrant any condition that may constitute, lead to, or cause a violation of agency requirements or certificate of registration conditions, or unnecessary exposure to radiation.

(5) Facility requirements.

(A) Caution signs. Unless otherwise authorized by the agency, the standard radiation symbol prescribed shall use the colors magenta or purple or black on yellow background. The standard radiation symbol prescribed is the three-bladed design as follows:



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Post the room where the x-ray machine is with a sign that has the radiation symbol and the words: "CAUTION, RADIATION AREA."

However, if someone is in continuous control of the room and the x-ray machine, then caution signs don't have to be posted.

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(j) the cross-hatched area of the symbol is to be magenta, or purple, or black; and

(ii) the background of the symbol is to be yellow.

(B) Posting of notices to workers.

(i) Each registrant shall post current copies of the following documents:

(I) this section;

(II) the certificate of registration and conditions or documents incorporated into the certificate of registration by reference, and amendments thereto;

(III) the operating procedures applicable to work under the certificate of registration; and

(IV) any notice of violation, if applicable, involving radiological working conditions, or order issued in accordance with subsections (b) and (k)(2) of this section and documentation of the corrections of any violations.

(i) If posting of a document specified in clause (j) of this subparagraph is not practicable, the registrant shall post a notice that describes the document and states where it may be examined.

Post a note stating where employees can find these documents:

- **current rules**
- **operating and safety procedures**
- **certificate of registration**
- **last notice of violation from the agency**

§289.232(i)(5)(B)(iii)

(iii) Bureau of Radiation Control (BRC) Form 232-1, "Notice to Employees," as contained in subparagraph (C) of this paragraph, or an equivalent document containing at least the same wording as BRC Form 232-1, shall be posted by each registrant as required by this section.

(iv) Documents, notices, or forms posted in accordance with this subsection shall:

(I) appear in a sufficient number of places to permit individuals engaged in work under the certificate of registration to observe them on the way to or from any particular work location to which the document applies;

(II) shall be conspicuous; and

(III) shall be replaced if defaced or altered.

(C) Notice to employees. The following form, or an equivalent as stated in subparagraph (B)(ii) of this paragraph, shall be posted.

(D) Posting requirements. The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

Post the "Notice to Employees," BRC Form 232-1, where all employees can see it.

BRC Form 232-1, "Notice to Employees," is located at the end of this rule.

§289.232(i)(5)(E)

(E) Exceptions to posting requirements. Registrants are exempt from the posting of the radiation area requirements in subparagraph (D) of this paragraph provided that the operator has continuous surveillance and access control of the radiation area.

(6) Radiation machine requirements.

(A) Technique chart.

(i) A technique chart relevant to the particular x-ray machine shall be provided or electronically displayed in the vicinity of the control panel and used by all operators.

(ii) Technique and exposure indicators.

(J) The technique factors to be used during an exposure shall be indicated before the exposure begins except when automatic exposure controls are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(II) On radiation machines having fixed technique factors, the requirement of subclause (I) of this clause may be met by permanent markings.

(III) The x-ray control shall provide visual indication of the production of x rays.

You must have a technique chart for each x-ray machine and follow that chart.

The x-ray machine control panel must show when x-rays are produced. It must also have a label that says x-rays are produced when the machine is on.

§289.232(i)(6)(A)(i)(IV)

(IV) The indicated technique factors shall be accurate to within manufacturer's specifications. If these specifications are not available from the manufacturer, the factors shall be accurate to within $\pm 10\%$ of the indicated setting.

(B) Labeling radiation machines. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner that cautions individuals that radiation is produced when it is energized. This label shall be affixed in a clearly visible location on the face of the radiation machine.

(C) Mechanical support of tube head. The tube housing assembly shall be adjusted to remain stable during an exposure unless tube housing movement is a designed function of the x-ray system. The tube housing assembly supports shall not be hand-held.

(D) Battery charge indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(E) Beam quality. The following requirements apply to beam quality.

(i) Half-value layer.

(J) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in the following Table I. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table I, linear interpolation may be made.

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The x-ray machine tube head shall be stable. Do not hold the tube head during exposures.

The x-ray beam must be filtered. Most dental x-ray machines are manufactured with the correct filters.

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TABLE I. HALF-VALUE LAYER FOR SELECTED KILOVOLT PEAK

X-ray tube voltage (kilovolt peak)		Measure Half-Value Layer (millimeters of aluminum)
Designed operating range	Measured operating potential	
Below 51 -----	30	0.3
	40	0.4
	50	0.5
51 to 70 -----	51	1.2
	60	1.3
	70	1.5
Above 70 -----	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

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(II) For capacitor energy storage equipment, compliance with the requirements of this subparagraph shall be determined with the maximum quantity of charge per exposure.

(ii) Filtration controls. For x-ray systems that have variable kilovolt peak and variable filtration for the useful beam, a device shall link the kilovolt peak selector with the filters and shall prevent an exposure unless the minimum amount of filtration required by clause (i) of this subparagraph is in the useful beam for the given kilovolt peak that has been selected.

(iii) Any other system having removable filters shall be required to have the minimum amount of filtration as required by clause (i)(I) of this subparagraph permanently located in the useful beam during each exposure.

(F) Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected.

(G) X-ray control. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less. The exposure switch shall be of the continuous pressure type.

If your x-ray machine has more than one tube head, the control panel and the tube head must show which tube head is being used.

The exposure switch must require continuous pressure for the machine to produce x-rays. The operator must be able to stop the exposure.

(H) Timer.

(j) The accuracy of the timer shall meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer accuracy shall be $\pm 10\%$ of the indicated time with testing performed at 0.5 second.

(ii) Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(I) Exposure **interval** reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

(J) Kilovolt peak. If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine shall meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak shall be accurate to within $\pm 10\%$ of the indicated setting(s). For radiation machines with fewer than three fixed kilovolt peak settings, the radiation machine shall be checked at those settings.

The x-ray timer must be accurate and shall stop x-ray production at a pre-set time.

The exposure from an x-ray machine must be consistent at each setting.

The kilovoltage (kVp) of the x-ray machine must be accurate.

§289.232(i)(6)(K)

(K) Tube stability. The x-ray tube shall remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant shall assure proper and free movement of the radiation machine.

(L) Collimation. Field limitation shall meet the requirements of paragraph (12) of this subsection.

(M) Radiographic entrance exposure limits for dental facilities. The in-air exposure determined for the technique used **by the registrant** for the specified average human adult patient thickness for routine intraoral (bite wing) dental radiography shall not exceed the following entrance exposure limits.

(i) 450 millirem for dental intraoral at 60 kilovolt peak and above; and

(ii) 600 millirem for dental intraoral less than 60 kilovolt peak.

(N) Security and control of radiation machines.

(i) The registrant shall secure radiation machines from unauthorized removal.

(ii) The registrant shall use devices and/or administrative procedures to prevent unauthorized use of radiation machines.

The x-ray tube must stay stable during an exposure.

Limit the x-ray beam to the receptor, such as the x-ray film.

The exposure from the intraoral x-ray machine must not exceed these limits:

- **450 mrem for 60 kVp and above**
- **600 mrem for less than 60 kVp**

(7) Equipment performance evaluations.

(A) For all dental radiation machines, the registrant shall perform, or cause to be performed, tests necessary to assure proper function of equipment with the indicated standard for each item specified in paragraph (6)(H)-(M) of this subsection. After installation, the tests listed shall be performed every four years.

(B) Records of the test results, including any numerical readings shall be maintained by the registrant in accordance with subsection (k)(1)(X)(i) of this section.

(C) Any items not meeting the specifications of the tests shall be corrected or repaired. Correction or repair shall begin within 30 days following the check and shall be performed according to a plan designated by the registrant. Correction or repair shall be completed no longer than 90 days from discovery unless authorized by the agency. Records of corrections or repairs shall be maintained by the registrant in accordance with subsection (k)(1)(X)(i) of this section for inspection by the agency.

(D) Measurements of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated within the preceding 24 months and the calibration shall be traceable to a national standard. During the calendar year in which the dosimetry system is not calibrated, an intercomparison to a system calibrated within the previous 12 months shall be performed.

Every 4 years you must test these equipment performance evaluation items.

- **timer**
- **exposure reproducibility**
- **kVp**
- **tube stability**
- **collimation**
- **entrance exposure limits**

Keep a record of these tests.

Begin to correct any time that fails a test and complete the correction in 90 days. Keep a record of your corrections.

Make sure that the entrance exposure limit is tested with a calibrated dosimetry system.

(8) Dental research. In addition to the requirements of subsection (h)(1) of this section, any research using radiation machines on humans shall receive prior approval from the agency and shall be approved by an Institutional Review Board as required by Title 45, CFR, Part 46 and Title 21, CFR, Part 56. The Institutional Review Board shall include at least one dentist to direct any use of radiation in accordance with subsection (a)(4) of this section.

(9) Educational facilities. Facilities conducting training using non-humans are held to all the requirements of this section except for paragraphs (14) and (15) of this subsection concerning film processing and paragraph (7) of this subsection concerning equipment performance evaluation.

(10) Certified radiation machines for dental facilities. In addition to the requirements of this section, the registrant shall not make, nor cause to be made, any modification of components or installations of components certified in accordance with the United States Food and Drug Administration Title 21, CFR, Part 1020, "Performance Standards for Ionizing Radiation Emitting Products," as amended, in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in Title 21, CFR, Part 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, United States Food and Drug Administration. A copy of the variance shall be maintained by the registrant in accordance with subsection (k)(1)(X)(i) of this section for inspection by the agency.

If your x-ray machine is in an educational facility and you do not use it on people, only some of these requirements apply.

Do not modify your machine.

§289.232(i)(11)

(11) Additional requirements for dental intraoral systems.

(A) Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(i) 18 centimeters if operable above 50 kilovolt peak; or

(ii) 10 centimeters if not operable above 50 kilovolt peak.

(B) Field limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) if the minimum source-to-skin distance is 18 centimeters or more, the x-ray field at the minimum source-to-skin distance shall be restricted to a dimension of no more than 7 centimeters; and

(ii) if the minimum source-to-skin distance is less than 18 centimeters, the x-ray field at the minimum source-to-skin distance shall be restricted to a dimension of no more than 6 centimeters.

(12) Additional requirements for dental extraoral systems.

(A) Field limitation. Dental rotational panoramic systems shall be provided with means to restrict the x-ray beam to the following:

If you use an intraoral x-ray machine, there are specific requirements for the size of the x-ray beam and the distance from the source of the x-rays to the patient's skin. Most dental x-ray machines are manufactured to meet these requirements.

§289.232(i)(12)(A)(i)

(j) the imaging slit in the transverse axis;
and

(ii) no more than a total of 0.5 inches larger than the imaging slit in the vertical axis.

(B) All other dental extraoral radiographic systems (e.g., cephalometric) shall be provided with means to restrict the x-ray field to the image receptor. The x-ray field shall not exceed the image receptor by more than:

(i) 2.0% of the source-to-image receptor distance for the length or width of the image receptor for rectangular collimation; or

(ii) 2.0% of the source-to-image receptor distance for the diagonal of the image receptor for circular or polygon collimation.

(13) Additional operational controls.

(A) When a patient or image receptor must be held in position during radiography, mechanical supporting or restraining devices shall be used **when the exam permits** except in individual cases in which the registrant has determined that the holding devices are contraindicated.

(B) The registrant's written operating and safety procedures required by paragraph (3) of this subsection shall include the following:

If you use a panoramic or cephalometric x-ray machine, there are specific requirements to limit the size of the x-ray beam.

Don't hold patients or film unless mechanical holders cannot be used. If you must hold patients or film on occasion, keep procedures for doing this in your operating and safety procedures.

§289.232(i)(13)(B)(i)

(j) a list of circumstances in which mechanical holding devices cannot be routinely utilized; and

(ii) a procedure used for selecting an individual to hold or support the patient or image receptor.

(C) The operator position during the exposure shall be such that the operator's exposure is as low as reasonably achievable and the operator is a minimum of six feet from the useful beam or behind a protective barrier. The operator shall maintain verbal, aural, and visual contact with the patient.

(D) In no case shall an individual hold the tube or tube housing assembly support during any radiographic exposure.

(14) Automatic and manual film processing for dental facilities and mobile dental services.

(A) Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer. The specified developer temperature for automatic processing and the time-temperature chart for manual processing shall be posted in the darkroom. If the registrant determines an alternate time-temperature relationship is more appropriate for a specific facility, that time-temperature relationship shall be documented and posted.

(B) Chemicals shall be replaced according to the chemical manufacturer's or supplier's recommendations or at an interval not to exceed three months.

Stand at least 6 feet from the x-ray beam or behind a barrier. You must still be able to hear, see, and talk to the patient.

Use the time and temperatures recommended by the film manufacturer when you process x-ray films.

If you process your films at a different time and temperature, write it down and post it.

Change your chemicals at the times recommended by the manufacturer or supplier or at least every 3 months.

§289.232(i)(14)(C)

(C) Darkroom light leak tests shall be performed and any light leaks corrected at intervals not to exceed six months.

(D) Lighting in the film processing/loading area shall be maintained with the filter, bulb wattage, and distances recommended by the film manufacturer for that film emulsion or with products that provide an equivalent level of protection against fogging.

(E) Corrections or repairs of the light leaks or other deficiencies in subparagraphs (B)-(D) of this paragraph shall be initiated within 72 hours of discovery and completed no longer than 15 days from detection of the deficiency unless a longer time is authorized by the agency. Records of the corrections or repairs shall include the date and initial of the individual performing these functions and should be maintained in accordance with subsection (k)(1)(X)(i) of this section for inspection by the agency.

(F) Documentation of the items in subparagraphs (B), (C), and (E) of this paragraph shall be maintained at the site where performed and shall include the date and initials of the individual completing these items. These records shall be maintained in accordance with subsection (k)(1)(X)(i) of this section for inspection by the agency.

(15) Alternative processing systems. Users of daylight processing systems, laser processors, self-processing film systems, or other alternative processing systems shall follow manufacturer's recommendations for image processing. Documentation that the registrant is following manufacturer's recommendations shall include the date and initials of the individual completing the document and shall be made and maintained at the site where performed in accordance with subsection (k)(1)(X)(i) of this section for inspection by the agency.

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If you have a darkroom, check for light leaks at least every 6 months and fix any you find.

If you have a darkroom, use the correct filter, bulb wattage, and distance recommended by the film manufacturer.

Keep a record of when you changed chemicals, when you checked for lights leaks and repairs of light leaks.

If you have any other kind of film processing system besides a darkroom, follow the manufacturer's instructions for processing.

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(16) Digital imaging acquisition systems. Users of digital imaging acquisition systems shall follow quality assurance/quality control protocol for image processing established by the manufacturer or, if no manufacturer's protocol is available, by the registrant. The registrant shall include the protocols, whether established by the registrant or the manufacturer, in its operating and safety procedures. The registrant shall document the frequency at which the quality assurance/quality control protocol is performed. Documentation shall include the date and initials of the individual completing the document and shall be maintained at the site where performed in accordance with subsection (k)(1)(X)(i) of this section for inspection by the agency.

(j) Records and reports.

(1) General provisions for records and reports.

(A) All records required by this section shall be accurate and factual.

(B) Records are only valid if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures.

(C) Each registrant shall use the SI units gray, sievert, and coulomb per kilogram, or the special units rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this section.

If you have a digital imaging system, follow the instructions for quality assurance/quality control provided by the manufacturer. However, if the manufacturer does not provide instructions, then you must develop your own.

You must keep the instructions in your operating and safety procedures.

Your records must be accurate and be signed and dated.

§289.232(j)(1)(D)

(D) The registrant shall make a clear distinction among the quantities entered on the records required by this section, such as, total effective dose equivalent, shallow dose equivalent, lens dose equivalent, and deep dose equivalent.

(E) Each record required by this section shall be legible throughout the specified retention period.

(F) The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

(G) The record may also be stored in electronic format with the capability for producing legible, accurate, and complete records during the required retention period.

(H) Each registrant shall maintain records of receipt, transfer, and disposal of radiation machines for inspection by the agency. The records shall include the following information and shall be kept until disposal is authorized by the agency:

(i) manufacturer's name;

(ii) model and serial number from the control panel;

(iii) date of the receipt, transfer, and disposal; and

You may keep your records in an electronic format.

(iv) name of the individual recording the information.

(I) Copies of records required in subsections (h)(5)(D) and (E), (i)(7), and (i)(14)(F) of this section and by certificate of registration condition that are relevant to operations at an additional authorized use location shall be maintained at that location in addition to the main location specified on a certificate of registration in accordance with subsection (k)(1)(X)(i) of this section.

(J) The registrant shall maintain adequate safeguards against tampering with and loss of records.

(K) Subject to the limitations provided in the Texas Public Information Act, Government Code, Chapter 552, all information and data collected, assembled, or maintained by the agency are public records open to inspection and copying during regular office hours.

(L) Any person who submits written information or data to the agency and requests that the information be considered confidential, privileged, or otherwise not available to the public under the Texas Public Information Act, shall justify such request in writing, including statutes and cases where applicable, addressed to the agency.

(i) Documents containing information that is claimed to fall within an exception to the Texas Public Information Act shall be marked to indicate that fact. Markings shall be placed on the document on origination or submission.

If you have another office, keep the following records at that office:

- **x-ray machine inventory**
- **x-ray machines received, transferred, or disposed of**
- **equipment performance evaluations**
- **when you change film processing chemicals**
- **when you check for light leaks**
- **any repairs of light leaks**

All records sent to the agency are available to the public except for certain information justified to be kept confidential.

§289.232(j)(1)(L)(i)(I)

(I) The words "NOT AN OPEN RECORD" shall be placed conspicuously at the top and bottom of each page containing information claimed to fall within one of the exceptions.

(II) The following wording shall be placed at the bottom of the front cover and title page, or first page of text if there is no front cover or title page:

"INFORMATION FALLING WITHIN EXCEPTION OF THE TEXAS PUBLIC INFORMATION ACT, GOVERNMENT CODE, CHAPTER 552
---- CONFIDENTIAL

This document contains information submitted to the Texas Department of Health, Bureau of Radiation Control by

(Name of Company)(Name of Submitter)

that is claimed to fall within the following exception to the Texas Public Information Act, Government Code, Chapter 552, Subchapter C

(Appropriate Subsection)

WITHHOLD FROM PUBLIC DISCLOSURE

(Signature and Title)(Office)(Date)"

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§289.232(j)(1)(L)(i)

(ii) The agency requests, whenever possible, that all information submitted under the claim of an exception to the Texas Public Information Act be extracted from the main body of the application and submitted as a separate annex or appendix to the application.

(iii) Failure to comply with any of the procedures described in subparagraphs (A) and (B) of this paragraph may result in all information in the agency file being disclosed upon an open records request.

(M) The agency will determine whether information falls within one of the exceptions to the Texas Public Information Act. The agency will determine whether or not there has been a previous determination that the information falls within one of the exceptions to the Texas Public Information Act. If there has been no previous determination and the agency believes that the information falls within one of the exceptions, an opinion of the Attorney General will be requested. If the agency agrees in writing to the request, the information shall not be open for public inspection unless the Attorney General's office subsequently determines that it is not an exception.

(N) Requests for information.

(i) All requests for open records information shall be in writing and refer to documents currently in possession of the agency.

(ii) The agency will ascertain whether the information may be released or whether it falls within an exception to the Texas Public Information Act.

§289.232(j)(1)(N)(ii)(J)

(J) The agency may take a reasonable period of time to determine whether information falls within one of the exceptions to the Texas Public Information Act.

(II) If the information is determined to be public, it will be presented for inspection and/or copies of documents will be furnished within a reasonable period of time. A fee will be charged to recover agency costs for copies.

(iii) Original copies of public records may not be removed from the agency. Under no circumstances shall material be removed from existing records.

(2) Reports.

(A) Reports of stolen, lost, or missing radiation machines.

(i) Each registrant shall report to the agency by telephone a stolen, lost, or missing radiation machine immediately after its occurrence becomes known to the registrant.

(ii) Each registrant required to make a report in accordance with clause (i) of this subparagraph shall, within 30 days after making the telephone report, make a written report to the agency that includes the following information:

(J) a description of the radiation machine involved, including, the manufacturer name, model and serial number;

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If your x-ray machine is lost or stolen, you must tell the agency immediately by telephone.

Within 30 days from your telephone call, send the agency a written report that includes these details:

- **manufacturer's name, model and serial number**
- **how the machine was lost or stolen**
- **what happened to the machine**
- **what you have done to prevent it from happening again**

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§289.232(j)(2)(A)(ii)(II)

(II) a description of the circumstances under which the loss or theft occurred;

(III) a statement of disposition, or probable disposition, of the radiation machine involved;

(IV) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(V) actions that have been taken, or will be taken, to recover the radiation machine; and

(VI) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of radiation machines.

(iii) Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

(iv) The registrant shall prepare any report filed with the agency in accordance with this subsection so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(B) Reports of incidents.

§289.232(j)(2)(B)(i)

(j) Notwithstanding other requirements for notification, each registrant shall immediately report each event involving a radiation machine possessed by the registrant that may have caused or threatens to cause an individual to receive:

(I) a total effective dose equivalent of 25 rems (0.25 sievert) or more;

(II) a lens dose equivalent of 75 rems (0.75 sievert) or more; or

(III) a shallow dose equivalent to the skin of the whole body or to the skin of any extremities of 250 rads (2.5 grays) or more.

(ii) Each registrant shall, within 24 hours of discovery of the event, report to the agency each event involving loss of control of a radiation machine possessed by the registrant that may have caused, or threatens to cause an individual to receive, in a period of 24 hours:

(I) a total effective dose equivalent exceeding 5 rems (0.05 sievert);

(II) a lens dose equivalent exceeding 15 rems (0.15 sievert); or

(III) a shallow dose equivalent to the skin of the whole body or to the skin of any extremities exceeding 50 rems (0.5 sievert).

§289.232(j)(2)(B)(iii)

(iii) Registrants shall make the initial notification reports required by clauses (i) and (ii) of this subparagraph by telephone to the agency and shall confirm the initial notification report within 24 hours by telegram, mailgram, or facsimile to the agency.

(iv) The registrant shall prepare each report filed with the agency in accordance with this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(C) Reports of exposures and radiation levels exceeding the limits.

(j) In addition to the notification required by subparagraph (B) of this paragraph, each registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(I) incidents for which notification is required by subparagraph (B) of this paragraph;

(II) doses in excess of any of the following:

(-a-) the occupational dose limits for adults in subsection (i)(4)(A)(j) of this section;

(-b-) the occupational dose limits for a minor in subsection (i)(4)(A)(j)(III) of this section;

§289.232(j)(2)(C)(i)(II)(-c-)

(-c-) the limits for an embryo/fetus of a declared pregnant woman in subsection (i)(4)(A)(i)(IV) and (V) of this section;

(-d-) the limits for an individual member of the public in subsection (i)(4)(B) of this section; or

(-e-) any applicable limit in the registration;

(III) levels of radiation in:

(-a-) a restricted area in excess of applicable limits in the certificate of registration; or

(-b-) an unrestricted area in excess of 10 times the applicable limit set forth in this section or in the certificate of registration conditions, whether or not involving exposure of any individual in excess of the limits in subsection (i)(4)(B) of this section.

(ii) Each report required by subparagraph (C)(i) of this paragraph shall describe the extent of exposure of individuals to radiation, including, as appropriate:

(I) estimates of each individual's dose;

(II) the levels of radiation involved;

(III) the cause of the elevated exposures, dose rates; and

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§289.232(j)(2)(C)(i)(IV)

(IV) corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, and associated registration conditions.

(iii) Each report filed in accordance with subparagraph (C)(i) of this paragraph shall include for each individual exposed: the name, social security number, and date of birth. With respect to the limit for the embryo/fetus in subsection (i)(4)(A)(i)(IV) and (V) of this section, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(iv) All registrants who make reports in accordance with subparagraph (C)(i) of this paragraph shall submit the report in writing to the agency.

(D) Reports to individuals of exposures.

(i) If applicable, radiation exposure data for an individual shall be reported to the individual as specified in this paragraph. The information reported shall include data and results obtained in accordance with agency requirements, orders, certificate of registration conditions, as shown in records made and maintained by the registrant in accordance with this subsection. Each notification and report shall:

(I) be in writing;

(II) include appropriate identifying data such as the name of the registrant, the name of the individual, and the individual's identification number;

§289.232(j)(2)(D)(i)(III)

(III) include the individual's exposure information; and

(IV) contain the following statement:
"This report is furnished to you under the provisions of the Texas Regulations for Control of Radiation, 25 Texas Administrative Code §289.232(i)(4)(A)-(C). You should preserve this report for further reference."

(ii) If applicable, each registrant shall advise each worker annually of the worker's estimated dose as shown in records made and maintained by the registrant in accordance with subparagraph (C) of this paragraph.

(iii) When a registrant is required in accordance with subparagraphs (B) and (C) of this paragraph to report to the agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation, the registrant shall also notify the individual and provide the individual with a copy of the report submitted to the agency, including the information required by clause (i) of this subparagraph. Such reports shall be transmitted at a time not later than the transmittal to the agency.

(k) Compliance and hearing procedures.

(1) Inspections.

§289.232(k)(1)(A)

(A) The agency may enter public or private property at reasonable times to determine whether, in a matter under the agency's jurisdiction, there is compliance with the Texas Radiation Control Act, the agency's rules, certificate of registration conditions, and orders issued by the agency.

(B) Each registrant shall afford to the agency at all reasonable times opportunity to inspect machines, activities, facilities, premises, and records in accordance with this section.

(C) During an inspection, agency inspectors may consult privately with workers as specified in subparagraphs (I)-(R) of this paragraph. The registrant may accompany agency inspectors during other phases of an inspection.

(D) If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(E) Each workers' representative shall be routinely engaged in work under control of the registrant and shall have received instructions as specified in subsection (i)(4)(D) of this section.

(F) Different representatives of registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

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The agency may conduct an inspection of your office at any reasonable time.

The inspector may talk with your employees.

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§289.232(k)(1)(G)

(G) With the approval of the registrant and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.

(H) Notwithstanding the other provisions of this section, agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the registrant to enter that area.

(I) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of agency regulations and certificates of registration to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(J) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which that individual has reason to believe may have contributed to or caused any violation of the Texas Radiation Control Act, the requirements in this section, certificate of registration conditions, or any unnecessary exposure of an individual to radiation from any radiation machine under the registrant's control. Any such notice in writing shall comply with the requirements of subparagraph (L) of this paragraph.

§289.232(k)(1)(K)

(K) The provisions of subparagraph (J) of this paragraph shall not be interpreted as authorization to disregard instructions in accordance with subsection (i)(4)(D) of this section.

(L) Any worker or representative of workers who believes that a violation of the Texas Radiation Control Act, the requirements of this section, or certificate of registration conditions exists or has occurred in work under a certificate of registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the registrant by the agency no later than at the time of inspection except that, upon the request of the worker giving such notice, the worker's name and the name(s) of individual(s) referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

(M) If, upon receipt of such notice, the agency determines that the request meets the requirements set forth in subparagraph (L) of this paragraph, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections in accordance with this section need not be limited to matters referred in the request.

(N) No registrant, contractor or subcontractor of a registrant shall discharge or in any manner discriminate against any worker because of the following:

Your employees may request an inspection by the agency if they believe these rules are not being followed.

You may not discriminate against any employee who has requested an inspection.

§289.232(k)(1)(N)(j)

(j) such worker has filed any request or instituted or caused to be instituted any proceeding under this section;

(ii) such worker has testified or is about to testify in any such proceeding; or

(iii) because of the exercise by such worker on behalf of that individual or others of any option afforded by this section.

(O) If the agency determines, with respect to a request under subparagraphs (L)-(N) of this paragraph, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the agency shall notify the requestor in writing of such determination. The requestor may obtain review of such determination in accordance with the provisions of the Texas Radiation Control Act and the Government Code, Chapters 2001 and 2002.

(P) If the agency determines that an inspection is not warranted because the requirements of subparagraph (L) of this paragraph have not been met, the agency shall notify the requestor in writing of such determination. Such determination shall be without prejudice to the filing of a new request meeting the requirements of subparagraph (L) of this paragraph.

§289.232(k)(1)(Q)

(Q) The routine inspection interval for dental facilities is four years. On-site inspections and remote inspections may be alternated. The inspection interval specified is based upon the average number of health-related violations per inspection, as determined from compliance history data. This interval will be reviewed at least every two years, and appropriate adjustments will be made. Registrant's having certificates of registration authorizing multiple uses will be inspected on-site at the most frequent interval specified for the uses authorized.

(R) Notwithstanding the inspection interval specified in subparagraph (Q) of this paragraph, the agency may inspect registrants more frequently due to:

(i) the persistence or severity of violations found during an inspection;

(ii) investigation of an incident or complaint concerning the facility;

(iii) a request for an inspection by a worker(s) in accordance with subparagraphs (L)-(N) of this paragraph;

(iv) any change in a facility or radiation machine that might cause a significant increase in radiation output or hazard;
or

(v) a mutual agreement between the agency and registrant.

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The agency will perform an inspection every 4 years. An inspector will perform an initial on-site inspection at your facility. The next inspection will be a remote inspection. For a remote inspection, you must complete a form that will be sent to you by the agency. You must return it and your equipment performance evaluation record to the agency. Inspections will alternate between on-site and remote.

The agency may inspect more often for these reasons:

- **severe violations of these rules**
- **investigation of incidents or complaints**
- **a request by your employees**
- **a request by you**

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§289.232(k)(1)(S)

(S) The agency will conduct inspections of dental radiation machines in a manner designed to cause as little disruption of a dental practice as is practicable.

(T) For remote inspection of radiation machines, each registrant shall:

(i) respond to a request from the agency for a remote inspection;

(ii) complete the remote inspection forms in accordance with the instructions included with the forms; and

(iii) return to the agency the completed remote inspection forms including documentation of the most recent equipment performance evaluation performed in accordance with subsection (i)(7) of this section and an inventory in accordance with subsection (h)(5)(D) of this section by the deadline indicated on the forms.

(U) Each registrant shall perform, upon instructions from the agency, or shall permit the agency to perform such reasonable surveys as the agency deems appropriate or necessary including, but not limited to, surveys of:

(i) radiation machines;

(ii) facilities where radiation machines are used; and

(iii) other equipment and devices used in connection with utilization or storage of radiation machines.

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The agency will try not to disrupt your practice while performing an on-site inspection.

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§289.232(k)(1)(V)

(V) A person who performs on-site inspection of dental radiation machines will have training in the design and uses of the products as specified in subparagraph (W) of this paragraph.

(W) Training for agency inspectors of dental radiation machines.

(j) Objectives. Training of agency individuals who perform inspections of radiation machines will be conducted by the agency. Upon completion of training, the inspector will be able to:

(I) select and operate the necessary testing equipment used to perform an inspection of radiation machines;

(II) utilize radiation protection principles;

(III) operate radiation detection instruments;

(IV) define basic regulatory terminology;

(V) apply this section regarding radiation machines;

(VI) perform routine agency inspections of radiation machines;

(VII) complete agency inspection documentation;

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Agency inspectors who inspect your facility will be trained in the design and use of x-ray machines.

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§289.232(k)(1)(W)(i)(VIII)

(VIII) demonstrate knowledge of agency ethics, professional, and technical policies; and

(IX) successfully achieve the objectives in this clause.

(ii) Initial training program.

(I) Initial training will be conducted during a six-month period.

(II) All training evaluation instruments will be developed by the agency.

(III) Instruments to be used in determining a proficiency level are as follows:

(-a-) evaluation of each inspector's training needs prior to initial training;

(-b-) evaluation of knowledge obtained and verification of tasks performed by each inspector subsequent to training received by the agency; and

(-c-) evaluation of each inspector's task performance by the agency.

(iii) Continuing education.

§289.232(k)(1)(W)(iii)(I)

(J) The agency inspector of radiation machines will accumulate 24 hours of continuing education regarding radiation machines, at intervals not to exceed 24 months. These hours of continuing education may be acquired as follows:

(-a-) documented continuing education earned in an agency-accepted training format; and

(-b-) agency staff meetings.

(II) Failure to obtain 24 hours of continuing education within each 24 month interval may result in a reassessment by the agency of an agency inspector's proficiency level.

(III) After the initial training period, each inspector of radiation machines will be evaluated by the agency, at intervals not to exceed 12 months.

(iv) Agency proficiency standards. The agency proficiency standards for agency inspectors of radiation machines are as follows.

(J) Level I. The agency inspector has not successfully achieved the objectives in clause (i) of this subparagraph after the initial training period. Additional training is required. Unsupervised inspections will not be performed.

§289.232(k)(1)(W)(iv)(II)

(II) Level II. The agency inspector has partially achieved the objectives in clause (i) of this subparagraph, but has not achieved the objective in clause (j)(IX) of this subparagraph after the initial training period. Additional training is required. Unsupervised inspections are not permitted for the type of radiation machines for which the objectives of clause (j)(IX) of this subparagraph have not been achieved. Unsupervised inspections may be performed for the type of radiation machines for which the objectives in clause (j)(IX) of this subparagraph have been successfully achieved.

(III) Level III. The agency inspector has successfully achieved the objectives in clause (i) of this subparagraph. Supervision is not required for routine inspections.

(X) **Time requirement for record keeping.**

(i) Each registrant shall maintain the following records/documents at each location and make available to the agency for inspection.

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**Keep the records listed in the
recordkeeping chart on pages 232-91
and 92 to show the agency inspector.**

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§289.232(k)(1)(X)(j)

Name of Record/Document	Specific Rule Subsection	Time Interval for Keeping Records/Documents
(I) Inventory of all Radiation Machines Possessed	(h)(5)(D)	4 years
(II) Receipt, Transfer, and Disposal of Each Radiation Machine Possessed	(h)(5)(E)	Until termination of registration
(III) Current Operating and Safety Procedures Documentation that all staff who operate the radiation machine(s) have read this document	(i)(3)	Until termination of registration Until next on-site inspection
(IV) Current §289.232	(i)(5)(B)(j)(I)	Until termination of registration
(V) Current Certificate of Registration	(i)(5)(B)(j)(II)	Until termination of registration
(VI) Notice of Violation From Last Inspection, (if applicable)	(i)(5)(B)(j)(IV)	Until next on-site inspection

The first column lists the record/documents you need to have ready when the agency inspector visits your facility for an inspection.

The second column states where in the rule text you are required to make/document these records/documents.

The third column tells you how long you have to keep the record/document.

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§289.232(k)(1)(X)(j)

Name of Record/Document	Specific Rule Subsection	Time Interval for Keeping Records/Documents
(VII) Documentation of Correction of any Violations	(i)(5)(B)(j)(IV)	Until next on-site inspection
(VIII) Equipment Performance Evaluation Tests	(i)(7)	4 years
(IX) United States Food and Drug Administration Variances	(i)(10)	Until transfer of machines or termination of registration
(X) Records at Additional Authorized Use Locations	(j)(1)(H)	While location is authorized on registration
(XI) Automatic and Manual Film Processing Records	(i)(14)(F)	1 year
(XII) Alternative Film Processing Records	(i)(15)	1 year
(XIII) Digital Imaging Acquisition System Records	(i)(16)	1 year

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(ii) For radiation machines authorized for mobile service, copies of the records specified in clause (j)(III)-(V) of this subparagraph shall be maintained with the radiation machine in accordance with clause (j) of this subparagraph for inspection by the agency. If on-board processors are utilized, film processing records shall also be made on board in accordance with subsection (i)(14)(F) and (15) of this section and maintained in accordance with clause (j) of this subparagraph for inspection by the agency.

(iii) For authorized records locations for mobile services, copies of the records specified in clause (j)(II) and (VI)-(XII) of this subparagraph shall be maintained in accordance with clause (j) of this subparagraph for inspection by the agency.

(2) Hearing and enforcement procedures.

(A) Violations. A court injunction or agency order may be issued prohibiting any violation of any provision of the Texas Radiation Control Act, Health and Safety Code, Chapter 401, or any rule or order issued thereunder. Any person who violates any provision of the Texas Radiation Control Act, Health and Safety Code, Chapter 401, or any rule or order issued thereunder may be subject to civil and/or administrative penalties. Such person may also be guilty of a misdemeanor.

(B) Denial of an application for a certificate of registration.

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If you use x-ray machines outside your office at temporary locations, you must keep records (III)-(V) listed in the recordkeeping chart on page 232-91.

The agency may issue injunctions or orders.

The agency may deny your application for registration. You may request a hearing before it's denied.

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§289.232(k)(2)(B)(i)

(i) When the agency contemplates denial of an application for a certificate of registration, the registrant shall be afforded the opportunity for a hearing. Notice of the denial shall be delivered to the registrant by personal service or certified mail, addressed to the last known address.

(ii) Any applicant or registrant against whom the agency contemplates denial of an application may request a hearing by writing the director within 30 days of service or date of mailing.

(J) The written request for a hearing shall contain the following:

hearing; and
(-a-) statement requesting a

applicant or registrant;
(-b-) name and address of the

(II) Failure to submit a written request for a hearing within 30 days will render the agency action final.

(C) Compliance procedures for registrants and other persons.

(j) A registrant or other person who commits a violation(s) will be issued a notice of violation.

When violations are found at your facility, you will be sent a notice of violation by the agency.

§289.232(k)(2)(C)(ii)

(ii) The terms and conditions of all certificates of registration shall be subject to amendment or modification. A certificate of registration may be modified, suspended, or revoked by reason of amendments to the Texas Radiation Control Act, or for violation of the Texas Radiation Control Act, the requirements of this section, a condition of the certificate of registration, or an order of the agency.

(iii) Any certificate of registration may be modified, suspended, or revoked in whole or in part, for any of the following:

(I) any material false statement in the application or any statement of fact required in accordance with provisions of the Texas Radiation Control Act;

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

(III) violation of, or failure to observe any of the terms and conditions of the Texas Radiation Control Act, Health and Safety Code, Chapter 401, this section, or of the certificate of registration, or order of the agency; or

(IV) existing conditions that constitute a substantial threat to the public health or safety of the environment.

Your certificate of registration may be suspended or revoked for these reasons:

- **giving the agency false information**
- **violations of these rules**

§289.232(k)(2)(C)(iv)

(iv) If another state or federal entity takes an action such as modification, revocation, or suspension of the certificate of registration, the agency may take a similar action against the registrant.

(v) When the agency determines that the action provided for in clause (viii) of this subparagraph or subparagraph (D) of this paragraph is not to be taken immediately, the agency may offer the registrant an opportunity to attend an enforcement conference.

(vi) Notice of any enforcement conference shall be delivered by personal service, or certified mail, addressed to the last known address. An enforcement conference is not a prerequisite for the action to be taken under clause (viii) of this subparagraph or subparagraph (D) of this paragraph.

(vii) Except in cases in which the occupational and public health or safety requires otherwise, no certificate of registration shall be suspended or revoked unless, 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 afforded an opportunity to demonstrate compliance with all lawful requirements.

(viii) When the agency contemplates modification, suspension, or revocation of the certificate of registration, the registrant shall be afforded the opportunity for a hearing. Notice of the contemplated action, along with a complaint, shall be given to the registrant by personal service or certified mail, addressed to the last known address.

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Before suspending or revoking your registration, the agency may offer you the chance to attend an enforcement conference.

You have the right to a hearing if the agency considers suspending or revoking your registration.

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§289.232(k)(2)(C)(ix)

(ix) Any applicant or registrant against whom the agency contemplates an action described in clause (viii) of this subparagraph may request a hearing by submitting a written request to the director within 30 days of service of the notice.

(J) The written request for a hearing shall contain the following:

(-a-) statement requesting a hearing;

(-b-) name, address, and identification number of the registrant against whom the action is being taken.

(II) Failure to submit a written request for a hearing within 30 days will render the agency action final.

(D) Assessment of Administrative Penalties.

(j) When the agency determines that monetary penalties are appropriate, proposals for assessment of and hearings on administrative penalties shall be made in accordance with the Texas Radiation Control Act, Health and Safety Code, §401.384, Title 1, Texas Administrative Code, Chapter 155, and applicable sections of the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title.

The agency can assess monetary penalties for violations of these rules.

§289.232(k)(2)(D)(ii)

(ii) Assessment of administrative penalties shall be based on the following criteria:

(I) the seriousness of the violation(s);

(II) previous compliance history;

(III) the amount necessary to deter future violations;

(IV) efforts to correct the violation; and

(V) any other mitigating or enhancing factors.

(iii) Application of administrative penalties. The agency may impose differing levels of penalties for different severity level violations and different classes of users as follows.

(I) Administrative penalties may be imposed for severity level I and II violations. Administrative penalties may be imposed for severity level III, IV, and V violations when they are combined with those of higher severity level(s) or for repeated violations.

(II) The following Tables IIA and IIB show the base administrative penalties.

TABLE II
BASE ADMINISTRATIVE PENALTIES

Table IIA – Base Amounts

Type of User	Amount
All registrants	\$5,000
Other persons not registered	\$10,000

Table IIB – Percentage of Base Amounts Based on Severity Level of Violation

Severity Level	Percent of Amount Listed in Table IIA
I	100
II	80
III	50
IV	15
V	5

(III) Adjustments to the severity levels and percentages in Table IIB may be made for the presence or absence of the following factors:

§289.232(k)(2)(D)(iii)(III)(-a-)

- reporting;
 - prevent recurrence;
 - event;
 - or increased adverse effects.
- (-a-) prompt identification and
 - (-b-) corrective action to
 - (-c-) compliance history;
 - (-d-) prior notice of similar
 - (-e-) multiple occurrences; and
 - (-f-) negligence that resulted in

(IV) The penalty may be in an amount not to exceed \$10,000 a day for a person who violates the Texas Radiation Control Act or a rule, order, or certificate of registration issued under the Texas Radiation Control Act. Each day a violation continues may be considered a separate violation for purposes of penalty assessment.

(iv) The agency may conduct settlement negotiations.

(E) Severity levels of violations for registrants or other persons.

(i) Violations for registrants or other persons shall be categorized by one of the following severity levels.

Agency violations are divided into levels based on the severity of their impact on health and safety.

§289.232(k)(2)(E)(i)(I)

(I) Severity level I are violations that are most significant and may have a significant negative impact on occupational and/or public health and safety or on the environment.

(II) Severity level II are violations that are very significant and may have a negative impact on occupational and/or public health and safety or on the environment.

(III) Severity level III are violations that are significant and which, if not corrected, could threaten occupational and/or public health and safety or the environment.

(IV) Severity level IV are violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances.

(V) Severity level V are violations that are of minor safety or environmental significance.

(ii) Criteria to elevate or reduce severity levels.

(I) Violations may be elevated to a higher severity level for the following reasons:

(-a-) more than one violation resulted from the same underlying cause;

(-b-) a violation contributed to or was the consequence of the underlying cause, such as a management breakdown or breakdown in the control of registered activities;

§289.232(k)(2)(E)(ii)(I)(-c-)

(-c-) a violation occurred multiple times between inspections;

(-d-) a violation was willful. This means the violation was the result of careless regard for requirements, deception, or other indications of willfulness by the registrant or employees of the registrant; or

(-e-) compliance history.

(II) Violations may be reduced to a lower level for the following reasons:

(-a-) the registrant identified and corrected the violation prior to the agency inspection; or

(-b-) the registrant's actions corrected the violation and prevented recurrence.

(iii) Examples of severity levels. Examples of severity levels are available upon request to the agency.

(F) Impoundment of radiation machines. Radiation machines shall be subject to impounding in accordance with the **Texas Radiation Control Act, Health and Safety Code**, §401.068 and this paragraph.

The agency may impound your x-ray machine for violation of these rules.

§289.232(k)(2)(F)(i)

(i) In the event of an emergency, the agency shall have the authority to impound or order the impounding of radiation machines possessed by any person not equipped to observe or failing to observe the provisions of the Texas Radiation Control Act, or any rules, certificate of registration conditions, or orders issued by the agency. The agency shall submit notice of the action to be published in the *Texas Register* no later than 30 days following the end of the month in which the action was taken.

(ii) At the agency's discretion, the impounded radiation machines may be disposed of by:

(I) returning the radiation machine to a properly registered owner, upon proof of ownership, who did not cause the emergency;

(II) releasing the radiation machine as evidence to police or courts;

(III) returning the radiation machine to a registrant after the emergency is over and settlement of any compliance action; or

(IV) sale, destruction or other disposition within the agency's discretion.

§289.232(k)(2)(F)(iii)

(iii) If agency action is necessary to protect the public health and safety, no prior notice need be given the owner or possessor. If agency action is not necessary to protect the public health and safety, the agency will give written notice to the owner and/or the possessor of the impounded radiation machine of the intention to dispose of the radiation machine. Notice shall be the same as provided in subparagraph (C)(viii) of this paragraph. The owner or possessor shall have 30 days from the date of personal service or mailing to request a hearing under Title 1, Texas Administrative Code, Chapter 155, and the Formal Hearing Procedures, §§1.21, 1.23, 1.25, and 1.27 of this title, and in accordance with subparagraph (C)(ix) of this paragraph, concerning the intention of the agency. If no hearing is requested within that period of time, the agency may take the contemplated action, and such action is final.

(iv) Upon agency disposition of a source of radiation, the agency may notify the owner and/or possessor of any expense the agency may have incurred during the impoundment and/or disposition and request reimbursement. If the amount is not paid within 60 days from the date of notice, the agency may request the Attorney General to file suit against the owner/possessor for the amount requested.

(v) If the agency determines from the facts available to the agency that an impounded radiation machine is abandoned, with no reasonable evidence showing its owner or possessor, the agency may make such disposition of the radiation machine as it sees fit.

(G) Emergency orders.

§289.232(k)(2)(G)(j)

(j) When an emergency exists requiring immediate action to protect the public health or safety or the environment, the agency may, without notice or hearing, issue an order citing the existence of such emergency and require that certain actions be taken as it shall direct to meet the emergency. The agency shall, no later than 30 days following the end of the month in which the action was taken, submit notice of the action for publication in the *Texas Register*. The action taken will remain in full force and effect unless and until modified by subsequent action of the agency.

(ii) An emergency order takes effect immediately upon service.

(iii) Any person receiving an emergency order shall comply immediately.

(iv) The person shall be afforded the opportunity for a hearing on an emergency order. Notice of the action, along with a complaint, shall be given to the person by personal service or certified mail, addressed to the last known address. A hearing shall be held on an emergency order if the person receiving the order submits a written request to the director within 30 days of the date of the order.

(J) The hearing shall be held not less than 10 days nor more than 20 days after receipt of the written application for hearing.

The agency may issue an emergency order to stop using your x-ray machine in order to protect public health and safety. You must follow that order immediately.

You have the right to a hearing on an emergency order.

§289.232(k)(2)(G)(iv)(II)

(II) At the conclusion of the hearing and after the proposal for decision is made as provided in the Texas Administrative Procedure Act, Texas Government Code, Chapter 2001, the commissioner shall take one of the following actions:

- (-a-) determine that no further action is warranted;
- (-b-) amend the certificate of registration;
- (-c-) revoke or suspend the certificate of registration;
- (-d-) rescind the emergency order; or
- (-e-) issue such other order as is appropriate.

(III) The application and hearing shall not delay compliance with the emergency order.

(H) Miscellaneous provisions.

§289.232(k)(2)(H)(j)

(j) Computation of time. A time period established by the requirements of this section shall begin on the first day after the event that invokes the time period. When the last day of the period falls on a Saturday, Sunday, or state or federal holiday, the period shall end on the next day that is not a Saturday, Sunday, or state or federal holiday. The time period shall expire at 5:00 p.m. of the last day of the computed period.

(ii) Hearing location. Hearings will be held at the offices of the State Office of Administrative Hearings in Austin unless the ALJ specifies another location.

(iii) Non-party witness and mileage fees.

(J) A witness or deponent who is not a party (or an employee, agent, or representative of a party) and who is subpoenaed or otherwise compelled to attend an agency hearing or a proceeding to give a deposition, or to produce books, records, papers, accounts, documents, or other objects necessary and proper for the purposes of the hearing or proceeding may receive reimbursement for transportation and other costs at rates established by the current Appropriations Act for state employees.

(II) The person requesting the attendance of the witness or deponent shall deposit with the agency the funds to accrue in accordance with subclause (J) of this clause when filing a motion for the issuance of a subpoena or a commission to take a deposition.

§289.232(k)(2)(H)(iv)

(iv) Service. A return of service by the person who performed personal service, postal return receipt, or proof of mailing to the last known address shall be conclusive evidence of service.

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