

25 TEXAS ADMINISTRATIVE CODE

§289.233

Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine

Texas Regulations for Control of Radiation

(New Rule Effective April 26, 2021)

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

§289.233. Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine.

(a) Purpose. This section establishes the following requirements for radiation machines used in veterinary medicine.

(1) Fees for certificates of registration for veterinary facilities and provisions for payment will be processed in accordance with §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), as amended.

(2) Requirements for the registration of persons using radiation machines used in veterinary medicine.

(3) Requirements that are 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 radiation machines 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 public health and safety during an emergency.

(4) Requirements for the use of radiation machines including that the registrant shall ensure the requirements of this section are met in the operation of such radiation machines and only persons who have received proper instructions in the safe use of radiation machines shall be permitted to operate the radiation machines.

(5) Requirements for specific record keeping and general provisions for records and reports.

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

(7) In accordance with the Act, Texas Health and Safety Code, Chapter 401; the Administrative Procedure Act, Texas Government Code, Chapter 2001; 1 TAC Chapter 155; and §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures) governing of:

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(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 requirements of this section, an order, or a condition of certificate of registration;

(C) assessing administrative penalties; and

(D) determining propriety of other agency orders.

(b) Scope.

(1) Except as specifically provided in other sections of this chapter, this section applies to persons who receive, possess, use, or transfer radiation machines used in veterinary medicine.

(A) The dose limits in this section do not apply to doses received from background radiation or voluntary participation in medical research programs.

(B) Facilities conducting animal research must register under §289.228 of this title (relating to Radiation Safety Requirements for Industrial Radiation Machines).

(C) No radiation may be deliberately applied to animals except by or under the supervision of a veterinarian authorized by the Texas Board of Veterinary Medical Examiners to engage in veterinary medicine.

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

(3) Registrants who are also registered by the agency to receive, possess, acquire, transfer, or use Class IIIb and Class IV lasers in veterinary medicine shall also comply with the requirements of §289.301 of this title (relating to Registration and Radiation Safety Requirements for Lasers and Intense-Pulsed Light Devices).

(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 section as it deems appropriate or necessary to minimize danger to public health and safety, property, or the environment.

(5) Registrants who are also specifically licensed by the agency to receive, possess, use, and transfer radioactive materials must also comply with the applicable requirements of:

(A) §289.201 of this title (relating to General Provisions for Radioactive Material);

(B) §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Materials)

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(C) §289.252 of this title (relating to Licensing of Radioactive Material);

(D) §289.256 of this title (relating to Medical and Veterinary Use of Radioactive Material); and

(E) §289.257 of this title (relating to Packaging and Transportation of Radioactive Material).

(6) In addition to this section, the veterinary registrant must meet the requirements in:

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

(B) §289.204 of this title;

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

(D) §289.226 of this title (relating to Registration of Machine Use and Services); and

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

(c) Prohibitions.

(1) The agency may prohibit use of radiation machines that pose significant threat or endanger occupational and public health and safety, in accordance with this subsection and subsections (a), (b), and (d) - (g) of this section.

(2) Individuals shall not be exposed to the useful beam.

(3) In no case shall an individual hold the tube or tube housing assembly support during any radiographic exposure. Hand-held radiation machines shall be held only in the manner specified by the manufacturer.

(d) 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, Texas Health and Safety Code, Chapter 401.

(4) Adult--An individual who is 18 years or older.

(5) Agency--The Department of State Health Services.

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(6) Agreement state--Any state with which the United States Nuclear Regulatory Commission (NRC) has entered into an effective agreement under Section 274b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

(7) Air kerma--The kinetic energy released in air by ionizing radiation. Kerma is the quotient of dE by dM , where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM . The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is Gy. For purposes of this section, when exposure in air measured in roentgen (R) is to be converted to dose in air measured in Gy, a nationally recognized standard air conversion factor shall be used.

(8) Applicant--A person seeking a certificate of registration issued in accordance with the provisions of the Act and the requirements in this section.

(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) Attenuate--To reduce the air kerma rate upon passage of radiation through matter.

(11) Attenuation block--A block or stack, having dimensions 20 centimeters (cm) by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation. The nominal chemical composition of type 1100 aluminum alloy is 99 percent minimum aluminum, 0.12 percent copper.

(12) 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).

(13) 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 radiation machines regulated by the agency.

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

(15) Beam axis--A line from the source through the centers of the x-ray fields.

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

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(17) 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.

(18) Central axis of the beam--A line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

(19) 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 Act and this chapter.

(20) 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.

(21) Commissioner--The Commissioner of the Department of State Health Services.

(22) Committed Effective Dose Equivalent ($H_{E,50}$)--The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum W_T H_{T,50}$).

(23) Computed tomography (CT)--The production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(24) 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.

(25) CT conditions of operation--All selectable parameters governing the operation of a CT system including, nominal tomographic section thickness, filtration, and the technique factors as defined in this subsection.

(26) CT gantry--The tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames that hold these components.

(27) 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.

(28) Deep dose equivalent (H_d) that applies to external whole-body exposure--The dose equivalent at a tissue depth of 1 cm (1,000 milligrams per square centimeter (mg/cm^2)).

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

(30) Dose--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

(31) Dose equivalent (H_t)--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.

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

(33) Effective dose equivalent (H_E)--The sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).

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

(35) Entrance exposure (Entrance air kerma)--The exposure in air expressed in roentgens (R) or the dose in air (air kerma) expressed in Gy, measured at the point where the center of the useful beam enters the animal.

(36) Equipment performance evaluations (EPE)--Required testing performed by a registered service provider at a specified interval to ensure radiation machines operate in compliance with this chapter.

(37) 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 SI unit of exposure is the coulomb per kilogram (C/kg). The roentgen is the special unit of exposure. For purposes of this section, this term is used as a noun.

(38) Exposure rate (air kerma rate)--The exposure per unit of time. For purposes of this section "air kerma rate" is an equivalent term.

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

(40) 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.

(41) 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.

(42) Field size--The dimensions along the major axes of an area in a plane perpendicular to the central axis of the beam at the normal treatment or examination source to image distance and defined by the intersection of the major axes and the 50 percent isodose line.

(43) Filter--Material placed in the useful beam to preferentially absorb selected radiation.

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(44) Fluoroscopic imaging assembly--A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptors, such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(45) Focal spot--The area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

(46) Gray (Gy)--The SI unit of absorbed dose. One Gy is equal to an absorbed dose of 1 joule per kilogram (J/kg) or 100 rad.

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

(48) High radiation area--An area, accessible to individuals, in which radiation levels external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 millisievert (mSv)) in one hour at 30 cm from any source of radiation or from any surface that the radiation penetrates.

(49) Image intensifier--A device, installed in its housing, that instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

(50) Image receptor--Any device, such as a fluorescent screen, radiographic film, or digital sensor 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.

(51) Individual--A human being.

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

(A) individual monitoring devices; or

(B) survey data.

(53) 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," "dosimeter," and "personnel monitoring equipment" are equivalent terms. Examples of individual monitoring devices include film badges, thermoluminescence dosimeters, optically stimulated luminescence dosimeters, pocket ionization chambers (pocket dosimeters), and electronic personal dosimeters.

(54) Inspection--An examination or observation, including records, tests, surveys, and monitoring to determine compliance with the Act and requirements of this section, orders, and conditions of the agency.

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(55) 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.

(56) Irradiation--The exposure of matter to ionizing radiation.

(57) kV--Kilovolt.

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

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

(60) Lens dose equivalent--The external dose equivalent to the lens of the eye at a tissue depth of 0.3 cm (300 mg/cm²).

(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.

(62) mA--Milliampere.

(63) mAs--Milliampere-second.

(64) Medical research--The investigation of various health risks and diseases as it pertains to veterinary practices.

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

(66) Minor--An individual who is under 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 section, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(69) Occupational dose--The dose received by an individual during the course of employment in which the individual's assigned duties involve exposure to sources of 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 section,

from voluntary participation in medical research programs, or as a member of the public.

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

(71) 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 NRC and other federal government agencies licensed or exempted by the NRC.

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

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

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

(75) Protective apron--An apron made of radiation absorbing materials used to reduce radiation exposure.

(76) 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, which is a barrier sufficient to attenuate the useful beam to the required degree; or

(B) secondary protective barrier, which is a barrier sufficient to attenuate the stray radiation to the required degree.

(77) 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 section, or from voluntary participation in medical research programs, or as a member of the public.

(78) Rad--The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram (erg/g) or 0.01 J/kg (0.01 Gy).

(79) Radiation (ionizing radiation)--Any alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

(80) 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 mSv) in 1 hour at 30 cm from the radiation machine or from any surface that the radiation penetrates.

(81) Radiation machine--An x-ray system, subsystem, or component capable of producing ionizing radiation except those devices with radioactive material as the only source of radiation. For purposes of this section, "radiation machine," "x-ray equipment," "x-ray system," and "x-ray unit" are equivalent terms. Types of radiation machines include:

(A) A stationary radiation machine, which is a radiation machine that is installed in a fixed location.

(B) A hand-held radiation machine, which is a radiation machine that is designed to be hand-held during operation.

(C) A portable radiation machine, which is a radiation machine that is mounted on a permanent base with wheels or casters for moving while completely assembled, including a hand-carried radiation machine that is designed to be mounted on a support while operating.

(D) A mobile radiation machine, which is a radiation machine that is transported in a vehicle to be used at various temporary locations.

(82) Radiation safety officer (RSO)--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.

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

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

(85) Regulation--See definition for rule.

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

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

(88) 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

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purposes, including the experimental production and testing of models, devices, radiation machines, equipment, materials, and processes.

(89) 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.

(90) Roentgen (R)--The special unit of exposure. One R equals 2.58×10^{-4} C/kg of air (See definition for exposure).

(91) 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."

(92) Scan--The complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

(93) Scan time--The period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

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

(95) Secondary protective barrier--See definition for protective barrier.

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

(97) Shutter--A device attached to the tube housing assembly that can totally intercept the useful beam and that has a lead equivalency not less than that of the tube housing assembly.

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

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

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

(101) Source-to-skin distance (SSD)--The distance from the source to the skin of the animal.

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

(103) Spot film--A radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

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

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

(106) Survey--An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, disposal, and presence of radiation machines. When appropriate, such survey includes, tests, physical examination of location of radiation machines, measurements of levels of radiation present, and evaluation of administrative and engineered controls.

(107) Technique chart--A chart that provides technical factors, anatomical examination, and animal size for examination being performed needed to make clinical radiographs when the radiation machine is in manual mode.

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

(A) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

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

(C) for CT systems designed for pulsed operations, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(D) for CT systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds or the product of tube current and exposure time in mAs when the scan time and exposure time are equivalent; and

(E) for all other x-ray systems, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

(109) 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.

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(110) Texas Regulations for Control of Radiation--All sections of Chapter 289 of this title.

(111) Total effective dose equivalent--The sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(112) 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.

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

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

(115) Unrestricted 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.

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

(117) Veterinarian--An individual licensed by the Texas Board of Veterinary Medical Examiners.

(118) Veterinary medicine--The term when used in this chapter has the same meaning as found in Texas Occupations Code, Chapter 801.

(119) Very high radiation area--An area, accessible to individuals, in which radiation levels from radiation machines external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at 1 meter from a radiation machine or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, Gy and rad, are appropriate, rather than units of dose equivalent, Sv and rem.

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

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

(122) 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.

(123) X-ray control panel--A device that controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment, such as timers,

phototimers, automatic brightness stabilizers, and similar devices that control the technique factors of an x-ray exposure.

(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 air kerma rate is one-fourth of the maximum in the intersection.

(125) 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.

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

(127) 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.

(e) Exemptions.

(1) The agency may, upon application 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 law does not prohibit the exemption and it will not result in a significant risk to public health or safety or the environment. 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.

(2) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this section, if the dose equivalent rate averaged over an area of 10 square cm does not exceed 0.5 millirem (5 microsieverts) per hour at 5 cm 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.

(4) Facilities that have placed all radiation machines in storage, including on-site storage secured from unauthorized use or removal, and have notified the agency in

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writing, are exempt from the requirements of this section. This exemption is void if any radiation machine is energized resulting in the production of radiation. Before resuming use of the radiation machine, the radiation machine shall meet all requirements of this section.

(5) 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.

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

(7) Portable radiation machines designed to be hand-held are exempt from the requirements of subsection (i)(5)(I) of this section. The portable radiation machines shall be held according to manufacturer's specifications.

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

(A) operating and safety procedures specified in subsection (j)(2) of this section;

(B) instructions to workers specified in subsection (j)(3)(G) of this section; and

(C) posting of notices to workers specified in subsection (j)(4)(B) of this section.

(f) Communications.

(1) Except where otherwise specified, all communications and reports concerning this chapter and applications filed under the communications and reports should be faxed, emailed, or mailed by postal service to Radiation Control, Department of State Health Services, P.O. Box 149347, MC 2003, Austin, Texas, 78714-9347. Communications, reports, and applications may be delivered in person to the agency's office located at 8407 Wall Street, Austin, Texas, 78754.

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

(g) 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.

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(h) Fees for certificates of registration for veterinary facilities.

(1) Payment of fees.

(A) Each application for a certificate of registration for radiation machines used in veterinary medicine shall be accompanied by a nonrefundable fee specified in §289.204 of this title, as amended. No application will be accepted for filing or processed before payment of the full amount specified.

(B) A nonrefundable fee specified in §289.204 of this title, as amended, shall be paid for each certificate of registration for radiation machines in veterinary medicine.

(C) Each application for reciprocal recognition of an out-of-state registration shall be accompanied by the nonrefundable fee specified in §289.204 of this title, as amended, provided that no such fee has been submitted within 24 months of the date of commencement of the proposed activity.

(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 §289.204 of this title, as amended, the agency will not process that application until such fee is paid.

(B) In any case where the agency finds that a registrant has failed to pay a fee prescribed in §289.204 of this title, as amended, by the due date, the agency may implement compliance procedures as provided in §289.205 of this title, as amended.

(3) Electronic fee payments. Renewal payments may be processed through www.texas.gov or another electronic payment system specified by the agency. For all types of electronic fee payments, the agency will collect additional fees, in amounts determined by www.texas.gov to recover costs associated with electronic payment processing.

(i) Registration of radiation machine use.

(1) Requirements for application for registration of radiation machines used for veterinary medicine.

(A) 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. For initial registrations with multiple radiation machine use locations, a separate application shall be completed for each radiation machine location under the registration.

(B) Each person having a radiation machine used in veterinary medicine 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.

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(C) If the application is incomplete 60 days after submission, the agency may abandon the application and return the original application. The applicant shall cease use of all radiation machines once the application has been abandoned.

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

(E) An RSO shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application. The RSO shall meet the applicable qualifications of clause (i) of this subparagraph and carry out the duties specified in clause (iv) of this subparagraph.

(i) The RSO shall have the following qualifications:

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

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

(III) experience in the use and familiarity of the type of radiation machine used.

(ii) In addition to the qualifications in clause (i) of this subparagraph, documentation of the following shall be submitted to the agency:

(I) for a veterinarian RSO, the veterinary license board number;

(II) for a non-veterinarian RSO, at least two years of supervised experience in the use of veterinary radiation machines under the supervision of a licensed veterinarian.

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

(iv) Specific duties of the RSO include the following:

(I) establishing and overseeing operating and safety procedures that maintain radiation exposures ALARA, and reviewing the procedures at intervals not to exceed 12 months to ensure that the procedures are current and conform with this section;

(II) ensuring that individual monitoring devices:

(-a-) are properly used by occupationally exposed personnel;

(-b-) that records are kept of the monitoring results; and

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(-c-) that timely notifications are made as required by subsections (j)(4)(B) and (C) and (k)(3)(B)-(D) of this section;

(III) investigating and reporting to the agency:

(-a-) each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this section; and

(-b-) each theft or loss of radiation machines, determining the cause, and taking steps to prevent its recurrence;

(IV) having a thorough knowledge of management policies and administrative procedures of the registrant and keeping management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable.

(V) assuming control and having the authority to institute corrective actions, including shutdown of operations when necessary in emergency situations or unsafe conditions;

(VI) making and maintaining records as required by this section; and

(VII) ensuring that personnel are adequately trained, complying with this section, the conditions of the certificate of registration, the operating and safety procedures of the registrant, and records maintained in accordance with subsection (k)(2) of this section.

(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 or radiation machine use locations. If an application includes a request for an additional authorization other than use of a veterinary radiation machine, compliance with other applicable sections of this chapter will be required.

(H) Each application for a certificate of registration shall be accompanied by the fee specified in §289.204 of this title, as amended. No application will be accepted for filing or processed before payment of the full amount specified.

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

(i) be authorized to conduct business in the State of Texas as listed on the Texas Secretary of State (SOS) website; and

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(ii) file an assumed name certificate with the Texas SOS if using an assumed name in their application.

(J) An application for use of radiation machines for veterinary medicine shall be signed by a licensed veterinarian. The application shall also be signed by the RSO if the RSO is someone other than the veterinarian.

(K) 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 §289.231(aa) of this title.

(L) 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.

(M) Each person possessing a therapeutic radiation machine capable of operating at or above 1 million electron volts (1 MeV) shall apply for and receive a certificate of registration from the agency before using the accelerator for veterinary use. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registration from the agency.

(N) Each person possessing a simulator or a therapeutic radiation machine capable of operating below 1 MeV shall apply for a certificate of registration within 30 days after energizing the radiation machine.

(2) Application for registration of mobile service operation used in veterinary medicine. In addition to the requirements of paragraph (1) of this subsection, each applicant shall apply for and receive authorization from the agency for mobile service operation before beginning mobile service operation. The following shall be submitted:

(A) An established main location where the radiation machines and related compliance documents and records 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 position during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's position.

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

(3) Issuance of certificate of registration.

(A) A certificate of registration will be approved if the agency determines that an application meets the requirements of the Act and the requirements of this

chapter. The certificate of registration authorizes proposed activities and contains the 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, additional requirements and conditions concerning the registrant's possession, use, and transfer of radiation machines subject to this chapter as it deems appropriate or necessary in order to:

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

(C) The agency may request, and the registrant shall provide, additional information after the certificate of registration has been issued to enable the agency to determine whether the certificate of registration should be modified in accordance with paragraph (7) of this subsection.

(4) 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 Act, now or hereafter in effect, and to the applicable requirements of this chapter and orders of the agency.

(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) 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.

(5) Responsibilities of the registrant.

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

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(B) The registrant shall designate an individual qualified in accordance with subsection (i)(1)(E) of this section as the RSO and shall ensure the individual continually performs the responsibilities of the RSO as identified in subsection (i)(1)(E)(iv) of this section.

(C) Persons using radiation machines in accordance with subsection (i)(2) of this section, concerning application for mobile services, shall have a valid certificate of registration issued by the agency before initiation of the mobile services.

(D) No person shall use a radiation machine unless the person has applied for registration within 30 days after beginning use of the radiation machine in accordance with subsection (i)(1)(A) of this section.

(E) No registrant shall engage any person for services described in §289.226(b)(11) of this title until such person provides to the registrant evidence of registration with the agency.

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

(i) the initial installation of the first radiation machine for a new certificate of registration; or

(ii) the registrant authorized for demonstration and sale may demonstrate a radiation machine in accordance with subparagraph (K) of this paragraph.

(G) The registrant shall notify the agency in writing of any changes that would render the information contained in the application for registration or the certificate of registration inaccurate. The notification shall be in writing and signed by an authorized representative. Notification is required within 30 days of the following changes:

(i) name of business;

(ii) mailing address;

(iii) street address where radiation machine will be used;

(iv) additional radiation machine site/location;

(v) RSO;

(vi) name and registration number of the entity contracted for "provider of equipment," registered in accordance with §289.226 of this title; or

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

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

- (i) the bankruptcy court in which the petition for bankruptcy was filed;
and
- (ii) the case name, number, and date of filing the petition.

(I) The registrant shall inventory all radiation machines in the registrant's possession at an interval not to exceed 12 months.

(i) The inventory shall include:

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

(ii) Records of the inventory shall be made and maintained in accordance with subsection (k)(2) of this section for inspection by the agency.

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

(i) The records shall include the following:

- (I) manufacturer's name, model, and serial number from the control panel;
- (II) date of the receipt, transfer, and disposal;
- (III) name and address of person the radiation machine received from, transferred to, or disposed of; and
- (IV) name of the individual recording the information.

(ii) Records of receipt, transfer, and disposal of radiation machines shall be made and maintained in accordance with subsection (k)(2) of this section for inspection by the agency.

(K) The following criteria applies to loaner or demonstration radiation machines.

(i) For persons having a valid certificate of registration, radiation machines used for loaner or demonstration radiation machines may be used for up to 30 days. After 30 days, the registrant shall:

(I) notify the agency of an increase in the number of radiation machine authorized by the certificate of registration in any radiation machine type or type of use category; and

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(II) perform an equipment performance evaluation on the radiation machine in accordance with subsection (j)(5)(N) of this section.

(ii) For persons who do not hold a valid certificate of registration, a loaner radiation machine may be used up to 30 days, by or under the direction of a veterinarian licensed by the Texas Board of Veterinary Medical Examiners in accordance with this section.

(6) 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 do the following:

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

(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 §289.204 of this title, as amended.

(7) The agency shall take actions for modification, suspension, and revocation of certificates of registration, shall be taken in accordance with §289.205 of this title.

(j) Use of radiation machines for veterinary medicine.

(1) ALARA. Persons 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 ALARA.

(2) 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 radiation machine.

(A) The registrant shall document that each individual operating a radiation machine has read the operating and safety procedures annually not to exceed 12 months. This documentation shall be maintained in accordance with subsection (k)(2) of this section for inspection by the agency. 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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(B) The operating and safety procedures shall include the following procedures as applicable:

(i) posting notices to workers in accordance with paragraph (4)(B) of this subsection;

(ii) instructions to workers in accordance with paragraph (3)(G) of this subsection;

(iii) notifications and reports to individuals in accordance with paragraph (4)(B) and (C) of this subsection and subsection (k)(3)(B)-(D) of this section;

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

(v) occupational dose requirements in accordance with paragraph (3)(A) of this subsection;

(vi) personnel monitoring requirements in accordance with paragraphs (3)(B), (D), and (E) of this subsection;

(vii) controlling a radiation area in accordance with paragraph (4)(C) and (D) of this subsection;

(viii) use of a technique chart in accordance with paragraph (5)(A) of this subsection;

(ix) use of protective devices in accordance with paragraph (3)(H) of this subsection;

(x) exposure of individuals in accordance with paragraph (3)(I) of this subsection;

(xi) holding of animals or image receptors in accordance with the following:

(I) 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 animal or image receptor;

(xii) control of scattered radiation in accordance with paragraph (6)(C) of this subsection; and

(xiii) film processing program or digital image processing in accordance with paragraphs (10)-(12) of this subsection.

(3) Personnel requirements.

(A) Occupational dose limits. Except as otherwise exempted, all individuals who are associated with the operation of a radiation machine are subject to the

§289.233(j)(3)(A)(i)

occupational dose limits of this subparagraph regarding dose limits to individuals, and the personnel monitoring requirements of subparagraph (B) of this paragraph.

(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 (TEDE) being equal to 5 rems (0.05 Sv).

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

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

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

(III) The annual limits for a minor shall be 10 percent 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 mSv). 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.

(-a-) The registrant shall make efforts to avoid substantial variation above a uniform monthly air kerma 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.

(-b-) If by the time the woman declares pregnancy to the registrant, the dose equivalent to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the registrant shall be deemed to be in compliance with clause (i) of this subparagraph, if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

(-c-) The dose equivalent to an embryo/fetus shall be taken as the dose equivalent that is most representative of the dose equivalent to the embryo/fetus from external radiation, that is, in the mother's lower torso region.

(-d-) If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device that is most representative of the dose equivalent to the embryo/fetus shall be the dose equivalent to the embryo/fetus. Assignment of the highest dose equivalent for the declared pregnant woman to the embryo/fetus is

not required unless that dose is also the most representative dose equivalent for the region of the embryo/fetus.

(-e-) If multiple measurements have not been made, assignment of the highest dose equivalent for the declared pregnant woman shall be the to the embryo/fetus.

(ii) The assigned 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 skin receiving the highest exposure.

(iii) When a protective apron is worn while working with fluoroscopic radiation machines used for clinical diagnostic or research purposes, the effective dose equivalent for external radiation shall be determined as follows:

(I) when only one individual monitoring device is used, and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent (EDE) for external radiation; or

(II) when only one individual monitoring device is used, and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in clause (i) of this subparagraph, the reported deep dose equivalent value multiplied by 0.3 shall be the EDE for external radiation; or

(III) when individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck (collar), the EDE for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck (collar) outside the protective apron multiplied by 0.04.

(iv) 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, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(v) 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. See subparagraph (F)(iv) of this paragraph.

(B) Conditions requiring individual monitoring of occupational dose. Each registrant shall monitor exposures from radiation machines at levels sufficient to demonstrate compliance with the occupational dose limits of this section. As a minimum, each registrant shall monitor occupational exposure to radiation from radiation machines and shall supply and require the use of individual monitoring devices by:

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(i) adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in subparagraph (A)(i) of this paragraph;

(ii) minors likely to receive, in one year from radiation machines external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin of the whole body or to the skin of any extremities in excess of 0.5 rem (5 mSv);

(iii) declared pregnant women likely to receive during the entire pregnancy, from radiation machines external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and

(iv) individuals entering a high or very high radiation area.

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

(i) Each registrant shall conduct operations so that:

(I) the TEDE to individual members of the public from exposure to radiation from radiation machines does not exceed 0.5 rem (5 mSv) in a year, exclusive of the dose contribution from background radiation, exposure of animals 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 registered external sources does not exceed 0.002 rem (0.02 mSv) 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.

(iv) The registrant shall ensure that in facilities utilizing both radiation producing machines and radioactive materials, the TEDE to an individual member of the public shall not exceed 0.1 rem (1 mSv) in one year.

(D) Compliance with dose limits for individual members of the public.

(i) The registrant shall make or cause to be made surveys of radiation levels in unrestricted areas to demonstrate compliance with the dose limits for individual members of the public as required in subparagraph (C) of this paragraph.

(ii) A registrant shall show compliance with the annual dose limit in subparagraph (C) of this paragraph by demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit.

(iii) Registrants exempt from individual monitoring requirements in accordance with subparagraph (B) of this paragraph are exempt from the requirements of clauses (i) and (ii) of this subparagraph.

(E) Location and use of individual monitoring devices.

(i) Each registrant shall ensure that individuals who are required to monitor occupational doses in accordance with subparagraph (B) of this paragraph wear and use individual monitoring devices as follows.

(I) An individual monitoring device shall be assigned to and worn by only one individual.

(II) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device shall be worn outside of the protective apron.

(III) If an additional individual monitoring device is used for monitoring the dose to an embryo/fetus of a declared pregnant woman, in accordance with subparagraph (B)(iii) of this paragraph, it shall be located at the waist under any protective apron being worn by the woman.

(IV) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with subparagraph (A)(i)(II)(-a-) of this paragraph, shall be located at the neck (collar) or at a location closer to the eye, outside any protective apron being worn by the monitored individual.

(V) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subparagraph (A)(i)(II)(-b-) of this paragraph, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device, to the extent practicable, shall be oriented to measure the highest dose to the extremity being monitored.

(ii) Each registrant shall ensure that individual monitoring devices are returned to the dosimetry processor for proper processing.

(iii) Each registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

(F) Determination of occupational dose for the current year.

(i) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring in accordance with subparagraph (B) of this paragraph, the registrant shall determine the occupational radiation dose received during the current year. Occupational dose includes doses received from exposure to registered/licensed or unregistered/unlicensed sources of radiation as defined in subsection (d) of this section.

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(ii) In complying with the requirements of clause (i) of this subparagraph, a registrant may:

(I) accept, as a record of the occupational dose that the individual received during the current year RC Form 233-1 (Occupational Exposure Record for a Monitoring Period) from prior or other current employers, or other clear and legible record, of all information required on that form and indicating any periods of time for which data are not available;

(II) accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's prior or other current employers for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; or

(III) obtain reports of the individual's dose equivalent from prior or other current employers for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, telegram, fax, letter, or email. The registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(iii) The registrant shall record the exposure data for the current year, as required by clause (i) of this subparagraph, on RC Form 233-1, or other clear and legible record, of all the information required on RC Form 233-1.

(iv) If the registrant is unable to obtain a complete record of an individual's current occupational dose while employed by any other registrant or licensee, the registrant shall assume in establishing administrative controls in accordance with subsection (j)(3)(A)(iv) of this section for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter; or 416 millirems (mrem) (4.16 mSv) for each month for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(v) If an individual has incomplete (for example, a lost or damaged personnel monitoring device) current occupational dose data for the current year and that individual is employed solely by the registrant during the current year, the registrant shall:

(I) assume that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter;

(II) assume that the allowable dose limit for the individual is reduced by 416 mrem (4.16 mSv) for each month; or

(III) assess an occupational dose for the individual during the period of missing data using surveys, radiation measurements, or other comparable data for the purpose of demonstrating compliance with the occupational dose limits.

(vi) Administrative controls established in accordance with clause (iv) of this subparagraph shall be documented and maintained for inspection by the agency. Occupational dose assessments made in accordance with clause (v) of this subparagraph and records of data used to make the assessment shall be made and maintained for inspection by the agency. The registrant shall retain the records in accordance with subsection (k)(2) of this section.

(G) Instructions to workers.

(i) All individuals likely to receive in a year an occupational dose in excess of 100 millirem (1 mSv) shall be:

(I) kept informed of the storage, transfer, or use of sources of radiation in the licensee's or registrant's workplace;

(II) instructed in the health protection problems associated with exposure to sources of radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(III) instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of agency requirements and certificates of registration, for the protection of personnel from exposures to sources of radiation occurring in such areas;

(IV) instructed of their 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 sources of radiation;

(V) instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to sources of radiation; and

(VI) advised as to the radiation exposure reports that workers may request in accordance with subsection (k)(3)(D)(i) and (ii) of this section.

(ii) The extent of these instructions shall be commensurate with potential radiological health protection problems associated with the sources of radiation in the workplace.

(H) Protective devices. Protective devices shall be utilized when required, as in subparagraphs (J)(i) and (ii) and (K) of this paragraph and paragraph (6)(C) of this subsection.

(i) Protective devices shall be of no less than 0.25 millimeter (mm) lead equivalent material except as specified in paragraph (6)(C)(ii)(I) of this subsection.

(ii) Protective devices, including aprons, gloves, and shields shall be checked annually for defects, such as holes, cracks, and tears. These checks may

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be performed by the registrant by visual or tactile means, or x-ray imaging. If a defect is found, protective devices shall be replaced or removed from service until repaired. A record of this test shall be made and maintained by the registrant in accordance with subsection (k)(2) of this section for inspection by the agency.

(I) Exposure of individuals. No individual other than the animal, operator, and ancillary personnel shall be in the x-ray room or area while exposures are being made unless such individual's assistance is required.

(J) Holding of animal or image receptor.

(i) When an animal or image receptor must be held in position during an exposure, mechanical supporting or restraining devices shall be used when the exam permits.

(ii) If an animal or image receptor must be held by an individual during an exposure, that individual shall be protected with appropriate shielding devices described in subparagraph (H) of this paragraph.

(iii) The registrant's written operating and safety procedures required by paragraph (2) of this subsection shall include the following:

(I) 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 animal or image receptor.

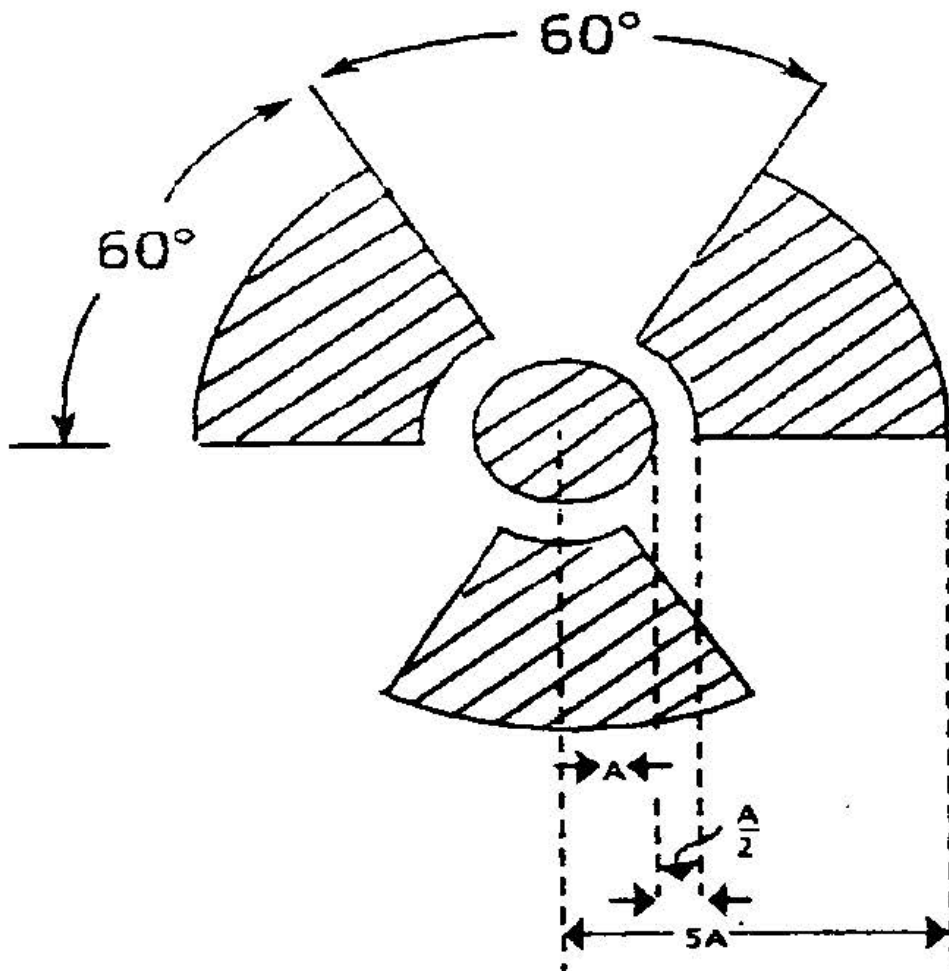
(K) Operator position. The operator position during the exposure shall be such that the operator's exposure is ALARA and the operator is a minimum of six feet from the radiation machine or protected by an apron, gloves, or other shielding having a minimum of 0.25 mm lead equivalent material.

(L) Holding of tube. In no case shall an individual hold the tube or tube housing assembly support during any radiographic exposure. Hand-held radiation machines shall be held only in the manner specified by the manufacturer.

(4) Facility requirements.

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

Figure: 25 TAC §289.233(j)(4)(A)



(i) the cross-hatched area of the symbol is to be magenta, 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, §289.233;

(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

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(IV) any notice of violation, if applicable, involving radiological working conditions, or order issued in accordance with subsection (a) of this section and §289.205 of this title, and documentation of the corrections of any violations.

(ii) RC Form 233-2 Notice to Employees, or an equivalent document containing at least the same wording as RC Form 233-2.

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

(iv) Documents, notices, or forms posted in accordance with this section 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) be conspicuous; and

(III) be replaced if defaced or altered.

Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

NOTICE TO EMPLOYEES

TEXAS REGULATIONS FOR CONTROL OF RADIATION

The Department of State Health Services has established standards for your protection against radiation hazards, in accordance with the Texas Radiation Control Act, Health and Safety Code, Chapter 401.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to-

1. Apply these rules to work involving sources of radiation.
2. Post or otherwise make available to you a copy of the Department of State Health Services rules, certificates of registration, notices of violations, and operating procedures that apply to your work, and explain their provisions to you.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the rules and the operating procedures that apply to your work. You should observe the rules for your own protection and protection of your co-workers.

WHAT IS COVERED BY THESE RULES

1. Limits on exposure to sources of radiation in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Individual monitoring devices, surveys, and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports;
6. Options for workers regarding agency inspections; and
7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The rules require that your employer give you a written report if you receive an exposure in excess of any applicable limit set forth in the rules or in the certificate of registration. The basic limits for exposure to employees are set forth in 25 Texas Administrative Code (TAC) §289.233(j)(4)(A) - (C) of this title (relating to Radiation Control Regulations for Veterinary Radiation Machines.) This subsection specifies limits on exposure to radiation.

2. If you work where individual monitoring devices are provided in accordance with 25 TAC §289.231 of this title (relating to General Provisions and Standards for Protection Against Machine-Produced Radiation):

- (a) your employer shall furnish to you an annual written report of your exposure to radiation if
 - (1) the individual's occupational dose exceeds 100 mrem (1 mSv) total effective dose equivalent or 100 mrem (1 mSv) to any individual organ or tissue; or
 - (2) the individual requests his or her annual dose report in writing.
- (b) your employer shall give you a written report, upon termination of your employment, of your radiation exposures if you request the information on your radiation exposure in writing.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Department of State Health Services. In addition, any worker or representative of the workers, who believes that there is a violation of the Texas Radiation Control Act, the rules issued thereunder, or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Department of State Health Services. The request shall state the specific grounds for the notice, and shall be signed by the worker or the representative of the workers. During inspections, agency inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition that the individual believes contributed to or caused any violations as described above.

POSTING REQUIREMENTS

Copies of this notice shall be posted in a sufficient number of places in every establishment where employees are employed in activities registered, in accordance with 25 TAC §289.233 (relating to Radiation Control Regulations for Veterinary Radiation Machines), to permit employees to observe a copy on the way to or from their place of employment.

Applicable section of 25 TAC Chapter 289 may be viewed online, at www.dshs.texas.gov/radiation. Our license and/or certificate of registration and any associated documents, our operation procedures, and any "Notice of Violation" or order issued by the agency may be viewed at the following location: _____

(C) Posting requirements.

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

(ii) The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(iii) The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

(D) Exceptions to posting requirements. A registrant is not required to post caution signs in areas or rooms containing radiation machines for periods of less than eight hours, if each of the following conditions is met:

(i) the radiation machines are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation in excess of the limits established in this section; and

(ii) the area or room is subject to the registrant's control.

(E) General surveys and monitoring.

(i) Each registrant shall make, or cause to be made, surveys that:

(I) are necessary for the registrant to comply with this section; and

(II) are necessary under the circumstances to evaluate:

(-a-) the magnitude and extent of radiation levels; and

(-b-) the potential radiological hazards.

(ii) The registrant shall ensure that instruments and equipment used for qualitative and quantitative radiation measurements, for example, dose rate, are operable and calibrated:

(I) by a person licensed or registered by the agency, another agreement state, a licensing state, or the United States Nuclear Regulatory Commission to perform such service;

(II) at intervals not to exceed 24 months unless a different time interval is specified in another section of this chapter;

(III) after each instrument or equipment repair;

(IV) for the types of radiation used and at energies appropriate for use; and

(V) at an accuracy within 20 percent of the true radiation level.

(iii) Record of the dosimetry system calibration shall include:

(I) manufacturer's name, model and serial number of each calibrated instrument;

(II) date of the calibration; and

(III) name of the individual recording the information.

(iv) All individual monitoring devices, except for direct and indirect reading pocket dosimeters, electronic personal dosimeters, and those individual monitoring devices used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with paragraph (3)(A) of this subsection, with other applicable provisions of this chapter, shall be processed and evaluated by a dosimetry processor:

(I) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(II) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(F) Control of access to high radiation areas.

(i) The registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(I) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in one hour at 30 cm from the source of radiation from any surface that the radiation penetrates;

(II) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(III) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(ii) In place of the controls required by clause (i) of this subparagraph for a high radiation area, the registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(iii) The registrant may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

(iv) The registrant shall establish the controls required by clauses (i) and (iii) of this subparagraph in a way that does not prevent individuals from leaving a high radiation area.

(G) Control of access to very high radiation areas.

(i) In addition to the requirements in subparagraph (F) of this paragraph, the registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in one hour at 1 m from a radiation machine or any surface through which the radiation penetrates at this level.

(ii) The entry control devices required by clause (i) of this subparagraph shall be established in such a way that no individual will be prevented from leaving the area.

(H) Security and control of radiation machines.

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

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

(iii) Any person using hand-held veterinary radiation machines shall ensure proper storage of the unit to include:

(I) securing the unit against theft or unauthorized use; and

(II) storing the unit in locked cabinets, storage rooms or work areas when not under immediate supervision of authorized users.

(5) Radiation machine requirements.

(A) Technique chart.

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

(ii) Technique and exposure indicators.

(I) 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 before the exposure shall be indicated.

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

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(III) The x-ray control shall provide visual or audible indication of the production of x-rays observable at or from the operator's protected position whenever x-rays are produced.

(IV) The indicated technique factors shall be accurate to meet manufacturer's specifications. If these specifications are not available from the manufacturer, the factors shall be accurate to within plus or minus 10 percent 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 control unit.

(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 radiation machine.

(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.

(I) 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.

Figure: 25 TAC §289.233(j)(5)(E)(i)(I)

TABLE I - HALF-VALUE LAYER FOR SELECTED kVp

| X-ray Tube Voltage (kilovolt peak) | | Minimum HVL (mm of aluminum) | |
|---------------------------------------|------------------------------------|--|---|
| Designed operating range | Measured operating potential | X-ray systems manufactured before June 10, 2006 | X-ray systems manufactured on or after June 10, 2006 |
| Below 51 | 30 | 0.3 | 0.3 |
| | 40 | 0.4 | 0.4 |
| | 50 | 0.5 | 0.5 |
| 51 to 70 | 51 | 1.2 | 1.3 |
| | 60 | 1.3 | 1.5 |
| | 70 | 1.5 | 1.8 |
| Above 70 | 71 | 2.1 | 2.5 |
| | 80 | 2.3 | 2.9 |
| | 90 | 2.5 | 3.2 |
| | 100 | 2.7 | 3.6 |
| | 110 | 3.0 | 3.9 |
| | 120 | 3.2 | 4.3 |
| | 130 | 3.5 | 4.7 |
| | 140 | 3.8 | 5.0 |
| | 150 | 4.1 | 5.4 |

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

(ii) Filtration controls.

(I) For radiation machines that have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filters and shall prevent an exposure unless the minimum amount of filtration required by subparagraph (A) of this paragraph is in the useful beam for the given kVp that has been selected.

(II) Any other radiation machine having removable filters shall be required to have the minimum amount of filtration as required by subparagraph (E)(i)(I) of this paragraph 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 before 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) Beam limiting devices.

(i) The beam-limiting device shall provide the same degree of protection as is required of the housing.

(ii) The numerical SID indicator shall be present and shall be accurate to within 2.0 percent of the SID for the beam-limiting device.

(iii) The center of the x-ray field, when perpendicular to the image receptor, shall be accurate to within plus or minus 2.0 percent of the SID with respect to the center of the image receptor.

(iv) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor.

(v) Indication of field size dimensions and SIDs shall be specified in inches or centimeters.

(vi) The field size indicated on the beam-limiting device shall not exceed 2.0 percent of the SID along the width and length, separately, of the actual x-ray field size.

(H) Portable x-ray systems. Portable x-ray systems shall comply with the requirements in subparagraph (G) of this paragraph, as applicable, based on manufacturer's design.

(I) 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 an exposure of 0.5 seconds or less or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

(J) Stationary or portable radiation machines. All stationary or portable radiation machines used for veterinary x-rays shall be provided with the following:

(i) a continuous pressure type exposure switch; and

(ii) either a six and one-half foot high protective barrier for operator protection during exposures; or

(iii) a means for the operator to be at least six feet from the tube housing assembly.

(K) Hand-held portable radiation machines. Operators using portable radiation machines designed to be hand-held are exempt from the requirements of paragraph (3)(K) of this subsection. The hand-held portable radiation machine shall be held only in the manner specified by the manufacturer. The operator shall wear protective devices in accordance with paragraph (3)(H) of this subsection.

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(L) Portable radiation machines. Portable radiation machines shall comply with the requirements in subparagraph (H) of this paragraph, as applicable, based on manufacturer's design.

(M) Radiation machines needing correction or repair.

(i) The correction or repair shall begin within 30 days following the failure and shall be performed according to a plan designated by the registrant.

(ii) Correction or repair shall be completed no longer than 90 days from discovery unless authorized in writing by the agency.

(iii) The registrant shall maintain records of corrections or repairs and any tests, measurements or numerical readings listed in subsection (j)(5) of this section in accordance with subsection (k)(2) of this section for inspection by the agency.

(N) Equipment performance evaluations (EPE).

(i) For all radiation machines used in veterinary medicine, the registrant shall perform, or cause to be performed, EPE tests for each item specified in clauses (iii) through (vii) of this subparagraph as follows:

(I) within 30 days after initial installation of radiation machines:

(II) within 30 days after reinstallation of a radiation machine;

(III) within 30 days after repair of a radiation machine component that would affect the radiation output that includes the timer, tube, and power supply; and

(IV) after initial installation, the EPE tests shall be performed every 5 years.

(ii) Records of the EPE results shall include the following:

(I) measurements and numerical readings;

(II) indication of pass or fail for each test; and

(III) maintenance by the registrant in accordance with subsection (k)(2) of this section for inspection by the agency.

(iii) Timer.

(I) The accuracy of the timer shall meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer accuracy shall be plus or minus 10 percent 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.

(iv) Kilovolt peak (kVp). The accuracy of the kVp setting shall meet manufacturer's specifications. If the registrant does not possess documentation of the appropriate manufacturer's kVp specifications, the indicated kVp shall be accurate to within plus or minus 10 percent of the indicated setting(s). For radiation machines with fewer than three fixed kVp settings, the radiation machine shall be checked at those settings.

(v) 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 within manufacturer's specifications.

(vi) Collimation. Field limitation shall meet the requirements for beam-limiting devices of subparagraph (G) of this paragraph.

(vii) Measurements of the radiation output for a radiographic x-ray, fluoroscopic, CT, therapeutic machine, simulator, and electronic brachytherapy device. Measurements for the radiation output of a radiographic x-ray shall be performed by a registered service provider. Measurements for the radiation output for a fluoroscopic, CT, and therapeutic, simulators and electronic brachytherapy devices shall be performed by licensed medical physicist with a calibrated dosimetry system in accordance with the following.

(I) The dosimetry system calibration shall be traceable to a national standard.

(II) Dosimetry systems shall be calibrated within 24 months from the date of the prior calibration.

(III) Measurements of radiation output shall be performed with a dosimetry system that has been calibrated within the 24 months preceding the date of the measurement.

(IV) Record of the dosimetry system calibration shall include:

(-a-) manufacturer's name, model and serial number of each calibrated instrument;

(-b-) date of the calibration; and

(-c-) name of the individual recording the information.

(viii) Record of dosimetry system calibration. The registrant shall record the dosimetry system calibration information specified in clause (vii)(I) - (IV) of this subparagraph and maintain that record in accordance with subsection (k)(2) of this section for inspection by the agency.

(6) Additional requirements for fluoroscopic radiation machines.

(A) Limitation of the useful beam. Limitation of the useful beam shall be as follows.

(i) Primary barrier.

(I) The fluoroscopic imaging assembly shall be provided with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID.

(II) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the useful beam and the imaging device is in place and operable.

(III) The air kerma rate due to transmission through the barrier with the attenuation block in the useful beam, combined with radiation through the image intensifier if provided, shall not exceed 3.34×10^{-3} percent of the entrance air kerma rate at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor.

(ii) Measuring compliance of barrier transmission.

(I) The air kerma rate due to transmission through the primary protective barrier combined with radiation through the image intensifier shall be determined by measurements averaged over an area of 100 cm² with no linear dimension greater than 20 cm.

(II) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop.

(III) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm.

(IV) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(V) The attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance air kerma rate and between this point and the input surface of the fluoroscopic imaging assembly.

(VI) The collimator shall be fully open when the measurement is made.

(iii) X-ray field.

(I) Compliance with subclauses (II)-(VII) of this clause shall be determined with the beam axis perpendicular to the plane of the image receptor.

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(II) Fluoroscopic radiation machine with a fixed SID and the capability of a visible area of no greater than 300 cm² shall be provided with either stepless adjustment of the x-ray field or a means to further limit the x-ray field at the image receptor to 125 cm² or less. If the fluoroscopic radiation machine is provided with stepless adjustment, the minimum x-ray field size at the maximum SID shall be less than or equal to 5 cm by 5 cm at the image receptor.

(III) Fluoroscopic radiation machines with a variable SID or a fixed SID with the capability of a visible area of greater than 300 cm² shall be provided with stepless adjustment of the field size. The minimum x-ray field size at the maximum SID shall be less than or equal to 5 cm by 5 cm at the image receptor.

(IV) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3.0 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4.0 percent of the SID.

(V) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor.

(VI) For fluoroscopic radiation machines with only a manual mode of collimation, the x-ray field produced shall be limited to the area of the spot-film cassette at 16 inches above tabletop. Additionally, during fluoroscopy, the beam shall be restricted to the area of the input phosphor.

(VII) Spot-film devices shall meet the following additional requirements.

(-a-) Means shall be provided between the source and the animal for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot-film selector.

(-1-) Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.

(-2-) The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor shall not exceed 3.0 percent of the SID when adjusted for full coverage of the selected portion of the image receptor.

(-3-) The sum, without regard to sign of the misalignment along any two orthogonal dimensions, shall not exceed 4.0 percent of the SID.

(-b-) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2.0 percent of the SID.

§289.233(j)(6)(B)

(B) Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the fluoroscopist for the entire time of the exposure (continuous pressure type switch). When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposures at any time but means may be provided to permit completion of any single exposure of the series in process.

(C) Control of scattered radiation.

(i) Fluoroscopic configuration, including fluoroscopic table designs, shall not permit any portion of any individual's body, except the head, neck, and extremities, to be exposed to scattered radiation emanating from above or below the tabletop unless the radiation has passed through not less than a total of 0.25 mm lead equivalent material. The material may be drapes, self-supporting curtains, or viewing shields, in addition to any lead equivalency provided by a protective apron.

(ii) Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met.

(I) All persons in the room where fluoroscopy is performed shall wear protective aprons that provide a shielding equivalent of 0.35 mm of lead.

(II) The fluoroscopic field size shall be reduced to the absolute minimum required for the procedure being performed (area of clinical interest).

(III) Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use or nonuse of the protective drapes.

(iii) For image-intensified fluoroscopic radiation machines with only a manual mode of collimation, the x-ray field produced shall be limited to the area of the spot-film cassette at 40cm above tabletop. Additionally, during fluoroscopy, the beam shall be restricted to the area of the input phosphor.

(7) Additional requirements for CT radiation machines.

(A) Warning Label. 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 control unit.

(B) Indicated technique factors. The indicated technique factors shall be accurate to meet manufacturer's specifications. If these specifications are not available from the manufacturer, the factors shall be accurate to within plus or minus 10 percent of the indicated setting.

(C) Tomographic plane indication and alignment.

§289.233(j)(7)(C)(i)

(i) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(ii) For any multiple slice tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

(iii) If a device using a light source is used to satisfy the requirements of clause (i) or (ii) of this subparagraph, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(D) Initiation of operation.

(i) The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

(ii) Means shall be provided to require operator initiation of each individual scan or series of scans.

(iii) All emergency buttons/switches shall be clearly labeled as to their functions.

(E) Termination of exposure.

(i) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of radiation machine failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices that monitor radiation machine function.

(ii) A signal visible to the operator shall indicate when the x-ray exposure has been terminated through the means required by clause (i) of this subparagraph.

(iii) The operator shall be able to terminate the x-ray exposure at any time during a scan or series of scans under CT radiation machines control of greater than 0.5 seconds duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation before initiation of another scan.

(8) Additional requirements for therapeutic radiation machines, simulators and electronic brachytherapy devices.

(A) General requirements.

(i) Each veterinarian possessing a therapeutic radiation machine, a simulator, or an electronic brachytherapy device shall apply for and receive a certificate of registration from the agency before using the device for veterinary

§289.233(j)(8)(A)(ii)

use. A person may energize the device for purposes of installation and acceptance testing before receiving a certificate of registration from the agency.

(ii) The registrant for veterinary use of a therapeutic radiation machine, a simulator, or an electronic brachytherapy device shall be a veterinarian licensed by the Texas Board of Veterinary Medical Examiners.

(iii) Operators of the therapeutic radiation machine, simulator, or electronic brachytherapy device shall:

(I) complete device-specific training with a training program provided by the manufacturer; or

(II) complete training received that is substantially equivalent to the manufacturer's training program from a licensed medical physicist who is trained to use the device; and

(III) retain a record of each individual's device specific training by the registrant in accordance with subsection (k) of this section for inspection by the agency.

(iv) Each facility shall develop a quality assurance program in writing or in an electronic reporting system. The quality assurance program shall be implemented as a method of minimizing deviations from facility procedures.

(I) The quality assurance program shall include the following topics:

(-a-) Occupational and public radiation safety during simulation;
and

(-b-) Occupational and public radiation safety during treatment.

(II) Deviations from the operating and safety procedures shall be investigated and brought to the attention of the veterinarian and the RSO.

(III) The review of the quality assurance program shall be conducted at intervals not to exceed 14 months.

(v) Written operating and safety procedures shall be developed by a licensed medical physicist with a specialty in therapeutic radiological physics and shall include any restrictions required for the safe operation of the particular therapeutic radiation device. These procedures shall be available in the control area of the therapeutic radiation device. The operators shall be able to demonstrate familiarity with these procedures. These procedures shall include the following:

(I) therapeutic radiation machines shall not be left unattended unless secured by a locking device which will prevent unauthorized use (A computerized password system would also constitute a locking device);

(II) when there is a need to immobilize an animal or port film for radiation therapy, mechanical supporting or restraining devices shall be used;

§289.233(j)(8)(A)(v)(III)

(III) no individual, other than the animal, shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV;

(IV) at energies less than or equal to 150 kV, any individual in the treatment room shall be protected by a barrier sufficient to meet the requirements of §289.231(m) of this title;

(V) radiation dose requirements in accordance with §289.231(m) of this title;

(VI) personnel monitoring requirements in accordance with §289.231(m) of this title;

(VII) use of protective devices for simulators in accordance with paragraph (3)(H) of this subsection;

(VIII) procedures for restriction and alignment of beam for simulators in accordance with paragraph (5)(G) of this subsection.

(vi) The registrant shall perform radiation surveys and contamination smears before the transfer or disposal of an accelerator operating at or above 10 MeV. Such surveys shall be documented and maintained by the registrant for inspection by the agency in accordance with subsection (k)(2) of this section.

(B) Therapeutic radiation machines capable of operating at energies below 1 MeV.

(i) Equipment requirements.

(I) When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the values specified at the distance stated for the classification of that radiation machine system shown in the following Table II. The leakage technique factors are the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Figure: 25 TAC §289.233(j)(8)(B)(i)(I)

| TABLE II | | |
|--|------------------------|-------------------------|
| System | Leakage Limit | Measurement Location |
| 0-150 kVp (manufactured or installed prior to March 1, 1989) | 1 R (10 mGy) in 1 hr | 1 meter (m) from source |
| 0-150 kVp (manufactured or installed after March 1, 1989) | 100 mR (1 mGy) in 1 hr | 1 m from source |
| 151 – 499 kVp | 1 R (10 mGy) in 1 hr | 1 m from source |

(II) Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

(III) Removable and adjustable beam-limiting devices shall meet the following requirements.

(-a-) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1.0 percent of the useful beam at the maximum kVp and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the x-ray field to shape the useful beam to the individual animal.

(-b-) Adjustable beam-limiting devices installed before March 1, 1989, shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5.0 percent of the useful beam at the maximum kVp and maximum treatment filter.

(-c-) Adjustable beam-limiting devices installed after March 1, 1989, shall meet the requirements of subclause (I) of this clause.

(IV) The filter system shall be so designed that:

(-a-) the filters cannot be accidentally displaced at any possible tube orientation;

(-b-) for equipment installed after March 1, 1989, an interlock system prevents irradiation if the proper filter is not in place;

(-c-) the radiation at 5 cm from the filter insertion slot opening does not exceed 30 roentgens per hour (R/hr) (300 mGy/hr) under any operating conditions; and

(V) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters (mm), and such marking shall be readily accessible for use during calibration procedures.

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(VI) Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 mm lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(VII) The timer shall:

(-a-) have a display provided at the treatment control panel and a pre-set time selector; and

(-b-) not permit an exposure if set at zero;

(VIII) The control panel, in addition to the displays required in subclause (VII)(-a-) of this clause, shall have the following:

(-a-) an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

(-b-) an indication of whether x-rays are being produced;

(-c-) means for indicating x-ray tube potential and current;

(-d-) means for terminating an exposure at any time;

(-e-) a locking device that will prevent unauthorized use of the therapeutic radiation system (a computerized password system would also constitute a locking device); and

(-f-) emergency buttons/switches that shall be clearly labeled as to their functions.

(IX) There shall be means of determining initially the SSD to within 1 cm.

(X) An indication of shutter position, if applicable, shall appear at the control panel.

(ii) Facility Requirements

(I) Each installation shall be provided with primary and secondary barriers as are necessary to assure compliance with §289.231(m) of this title. All protective barriers shall be fixed except for entrance doors or beam interceptors.

(II) For therapeutic radiation systems capable of operation above 150 kVp.

(-a-) The control panel shall be located outside the treatment room or in an enclosed booth inside the room.

(-b-) Interlocks shall be provided such that all entrance doors shall be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not

be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

(iii) Surveys, Calibrations and Spot Checks.

(I) Surveys shall be performed as follows.

(-a-) All new and existing facilities not previously surveyed shall have an initial survey made by a licensed medical physicist with a specialty in therapeutic radiological physics, who shall provide a written report of the survey to the registrant. Additional surveys shall be done after any change in the facility, facility design, or equipment that might cause a significant increase in radiation hazard.

(-b-) The registrant shall maintain a copy of the initial survey report and all subsequent survey reports required by this subclause in accordance with subsection (k)(2) of this section for inspection by the agency.

(-c-) The survey report shall indicate all instances where the installation is in violation of applicable requirements of this chapter.

(II) Calibrations shall be performed as follows.

(-a-) The calibration of a therapeutic radiation system shall be performed at intervals not to exceed one year and after any change or replacement of components that could cause a change in the radiation output.

(-b-) The calibration of the radiation output of the therapeutic radiation system shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics who is physically present at the facility during such calibration.

(-c-) The calibration of the therapeutic radiation system shall include verification that the radiation therapy system is operating in compliance with the design specifications.

(-d-) Calibration of the radiation output of a therapeutic radiation system shall be performed with a calibrated dosimetry system. The dosimetry system calibration shall be traceable to a national standard. The calibration interval for the dosimetry system shall not exceed 24 months.

(-e-) Records of calibration measurements specified in clause (ii) of this subparagraph shall be maintained by the registrant in accordance with subsection (k)(2) of this section for inspection by the agency.

(-f-) A copy of the latest calibrated absorbed dose rate measured on a particular therapeutic radiation system shall be available at a designated area within the therapy facility housing that therapeutic radiation system.

(III) Spot checks shall be performed on therapeutic radiation systems capable of operation at greater than 150 kVp.

§289.233(j)(8)(B)(iii)(III)(-a-)

(-a-) The spot check procedures shall be in writing, or documented in an electronic reporting system, and shall have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(-b-) Records of written spot checks and any necessary corrective actions shall be maintained by the registrant in accordance with subsection (k)(2) of this section for inspection by the agency. A copy of the most recent spot check shall be available at a designated area within the therapy facility housing that therapeutic radiation system.

(C) Therapeutic radiation machines capable of operating at energies of 1 MeV and above.

(i) Equipment requirements.

(I) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (mGy) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 m radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (mGy) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters (cm²) at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 cm². For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified for the specified operating conditions. Records on leakage radiation measurements shall be maintained in accordance with subsection (k)(2) of this section for inspection by the agency.

(II) Each wedge filter that is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. The wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge tray is damaged, the wedge transmission factor shall be re-determined. Equipment manufactured after March 1, 1989, shall meet the following requirements.

(-a-) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment console, either manually or automatically.

(-b-) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

(-c-) A display shall be provided at the treatment console showing the beam quality in use.

§289.233(j)(8)(C)(i)(II)(-d-)

(-d-) An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment console.

(III) The registrant shall determine data sufficient to assure that the following beam quality requirements in tissue equivalent material are met.

(-a-) The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 cm greater than the practical range of the electrons shall not exceed the values stated in the following Table III. Linear interpolation shall be used for values not stated.

Figure: 25 TAC §289.233(j)(8)(C)(i)(III)(-a-)

Table III

| Maximum Energy of Electron Beam in MeV | X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose |
|---|---|
| 1 | 0.03 |
| 15 | 0.05 |
| 35 | 0.10 |
| 50 | 0.20 |

(-b-) Compliance with subclause (I) of this clause shall be determined using:

(-1-) a measurement within a tissue equivalent phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

(-2-) a field size of 10 cm by 10 cm; and

(-3-) a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 cm and whose depth is sufficient to perform the required measurement.

(-c-) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in the following Table IV. Linear interpolation shall be used for values not stated.

Figure: 25 TAC §289.233(j)(8)(C)(i)(III)(-c-)

Table IV

| Maximum Photon Energy in MeV | Absorbed Dose at Surface as a Fraction of Maximum Absorbed Dose |
|-------------------------------------|--|
| 0.5 | 0.90 |
| 1 | 0.80 |
| 2 | 0.70 |
| 5 | 0.60 |
| 15 | 0.50 |
| 35 | 0.40 |
| 50 | 0.20 |

(-d-) Compliance with subclause (III) of this clause shall be determined by measurements made as follows:

(-1-) within a tissue equivalent phantom using an instrument that will allow extrapolation to the surface absorbed dose;

(-2-) using a phantom whose size and placement meet the requirements of subclause (II) of this clause;

(-3-) after removal of all beam modifying devices that can be removed without the use of tools, except for beam scattering or beam-flattening filters; and

(-4-) using the largest field size available that does not exceed 15 cm by 15 cm.

(IV) All therapeutic radiation systems shall be provided with radiation detectors in the radiation head. These shall include the following, as appropriate.

(-a-) Equipment manufactured after March 1, 1989, shall be provided with at least two independent radiation detectors. The detectors shall be incorporated into two independent dose monitoring systems.

(-b-) Equipment manufactured on or before March 1, 1989, shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

(-c-) The detector and the system into which that detector is incorporated shall meet the following requirements.

(-1-) Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

(-2-) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

(-3-) Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

(-4-) For equipment manufactured after March 1, 1989, the design of the dose monitoring systems shall assure that the malfunctioning of one system shall not affect the correct functioning of the secondary system, and failure of any element common to both systems that could affect the correct function of both systems shall terminate irradiation.

(-5-) Each dose monitoring system shall have a legible display at the treatment console. For equipment manufactured after March 1, 1989, each display shall maintain a reading until intentionally reset to zero; have only one scale and no scale multiplying factors; utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and each display shall retain the dose monitoring information in at least one system for a 15-minute period of time in the event of a power failure.

(V) In equipment manufactured after March 1, 1989, inherently capable of producing useful beams with unintentional asymmetry exceeding 5.0 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam-limiting device. If the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5.0 percent of the central axis dose rate, indication of this condition shall be at the console; and if this difference exceeds 10 percent of the central axis dose rate, the irradiation shall be terminated.

(VI) Selection and display of dose monitor units shall meet the following requirements.

(-a-) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment console.

(-b-) The preselected number of dose monitor units shall be displayed at the treatment console until reset manually for the next irradiation.

(-c-) After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.

(-d-) For equipment manufactured after March 1, 1989, after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

(VII) Termination of irradiation by the dose monitoring system or systems during stationary beam therapy shall meet the following requirements.

§289.233(j)(8)(C)(i)(VII)(-a-)

(-a-) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(-b-) If original design of the equipment includes a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the console has been detected by the secondary dose monitoring system.

(-c-) For equipment manufactured after March 1, 1989, a secondary dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units, whichever is smaller, above the preselected number of dose monitor units set at the console has been detected by the secondary dose monitoring system.

(-d-) For equipment manufactured after March 1, 1989, an indicator on the console shall show which dose monitoring system has terminated irradiation.

(VIII) A locking device shall be provided in the system to prevent unauthorized use of the x-ray system. A computerized password system would also constitute a locking device.

(IX) It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment console. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

(X) It shall be possible to terminate irradiation and equipment movements or go from an interruption condition to termination conditions at any time from the operator's position at the treatment console.

(XI) Timers shall meet the following requirements.

(-a-) A timer that has a display shall be provided at the treatment console. The timer shall have a preset time selector and an elapsed time indicator.

(-b-) The timer shall be a cumulative timer that activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(-c-) For equipment manufactured after March 1, 1989, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

§289.233(j)(8)(C)(i)(XI)(-d-)

(-d-) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

(XII) Equipment capable of producing more than one radiation type shall meet the following additional requirements.

(-a-) Irradiation shall not be possible until a selection of radiation type has been made at the treatment console.

(-b-) An interlock system shall be provided to:

(-1-) ensure that the equipment can emit only the radiation type that has been selected;

(-2-) prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment console;

(-3-) prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted; and

(-4-) prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

(-c-) The radiation type selected shall be displayed at the treatment console before and during irradiation.

(XIII) Equipment capable of generating radiation beams of different energies shall meet the following requirements.

(-a-) Irradiation shall not be possible until a selection of energy has been made at the treatment console.

(-b-) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment console.

(-c-) The nominal energy value selected shall be displayed at the treatment console before and during irradiation.

(XIV) Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements.

(-a-) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment console.

(-b-) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment console.

§289.233(j)(8)(C)(i)(XIV)(-c-)

(-c-) The selection of stationary or moving beam shall be displayed at the treatment console. An interlock system shall be provided to ensure that the equipment can only operate in the mode that has been selected.

(-d-) For equipment manufactured after March 1, 1989, an interlock system shall be provided to terminate irradiation if movement of the gantry occurs during stationary beam therapy or stops during moving beam therapy unless such stoppage is a preplanned function.

(-e-) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(-1-) For equipment manufactured after March 1, 1989, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.

(-2-) For equipment manufactured after March 1, 1989, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5.0 percent from the value calculated from the absorbed dose per unit angle relationship.

(-f-) Where the dose monitor system terminates the irradiation in moving beam therapy, the termination of irradiation shall be as required by subclause (VII) of this clause.

(XV) For equipment manufactured after March 1, 1989, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in subclause (IV) of this clause may form part of this system. In addition, the dose monitor unit rate shall be displayed at the treatment console. If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided that terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be in a record maintained by the registrant in accordance with subsection (k)(2) of this section for agency inspection.

(XVI) The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of the x-ray target or the virtual source of x-rays and the electron window or the virtual source of electrons if the system has electron beam capabilities.

(XVII) Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation.

(ii) Facility and shielding requirements.

§289.233(j)(8)(C)(ii)(I)

(I) Each installation shall be provided with primary and secondary barriers as are necessary to assure compliance with §289.231(m) of this title.

(II) All protective barriers shall be fixed except for entrance doors or beam interceptors.

(III) The console shall be located outside the treatment room and all emergency buttons/switches shall be clearly labeled as to their functions.

(IV) Treatment room entrances shall be provided with a warning light in a readily observable position near the outside of all access doors to indicate when the useful beam is "on."

(V) Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the console.

(iii) Surveys, calibrations, spot checks, and operational requirements.

(I) Surveys shall be performed as follows.

(-a-) All new and existing facilities not previously surveyed shall have an initial survey made by a licensed medical physicist with a specialty in therapeutic radiological physics, who shall provide a written report of the survey to the registrant. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

(-b-) The survey report shall include the following:

(-1-) a diagram of the facility that details building structures and the position of the console, therapeutic radiation machine, and associated equipment;

(-2-) a description of the therapeutic radiation system, including the manufacturer, model and serial number, beam type, and beam energy;

(-3-) a description of the instrumentation used to determine radiation measurements, including the date and source of the most recent calibration for each instrument used;

(-4-) conditions under which radiation measurements were taken;

(-5-) projected annual TEDE in areas adjacent to the therapy room; and

(-6-) a description of workload, use, and occupancy factors employed in determining the projected annual TEDE.

§289.233(j)(8)(C)(iii)(I)(-c-)

(-c-) The registrant shall maintain a copy of the survey report and a copy of the survey report shall be provided to the agency within 30 days of completion of the survey. Records of the survey report shall be maintained in accordance with subsection (k)(2) of this section for inspection by the agency.

(-d-) The survey report shall include documentation of all instances where the installation is in violation of applicable regulations. Any deficiencies detected during the survey shall be corrected before using the machine.

(II) Calibrations of therapeutic systems shall be performed as follows.

(-a-) The calibration of systems subject to this subsection shall be performed in accordance with an established calibration protocol before the system is first used for irradiation of an animal and thereafter at time intervals that do not exceed 12 months and after any change that might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The calibration procedures shall be in writing, or documented in an electronic reporting system, and shall have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(-b-) The calibration shall be performed by a licensed medical physicist with a specialty in therapeutic radiological physics who is physically present at the facility during the calibration.

(-c-) The calibration shall include verification that the equipment is operating in compliance with the design specifications concerning the light field, animal positioning lasers, and back-pointer lights with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and collimator system, and beam flatness and symmetry at the specified depth.

(-d-) Records of calibration measurements shall be maintained according to subsection (k)(2) of this section for inspection by the agency.

(III) The spot check procedures shall be performed in accordance with established protocol, shall be in writing, or documented in an electronic reporting system, and shall have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(-a-) The written spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

(-b-) Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant in accordance with subsection (k) of this section for inspection by the agency.

(D) General requirements for simulators in radiation therapy.

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(i) A technique chart relevant to the particular radiation machine shall be provided or electronically displayed in the vicinity of the console and used by all operators.

(ii) Each registrant shall have and implement written operating and safety procedures in accordance with paragraph (2) of this subsection.

(iii) When utilized, protective devices shall follow the requirements of paragraph (3)(H) of this subsection.

(iv) The operator's position during the exposure shall follow the requirements of paragraph (3)(K) of this subsection.

(v) No individuals other than the animal and the operators shall be in the treatment room during operation of the simulator.

(9) Educational facilities. Facilities conducting training using live animals are held to the requirements of this section except for paragraphs (10) - (12) of this subsection concerning film processing.

(10) Automatic and manual film processing for veterinary facilities and mobile veterinary 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 processing area. 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.

(C) Darkroom light leak tests shall be performed 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.

(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 made and maintained in accordance with subsection (k)(2) of this section for inspection by the agency.

(11) Alternative processing systems. Users of daylight processing systems, laser processors, self-processing film units, 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)(2) of this section for inspection by the agency.

(12) Digital imaging acquisition systems.

(A) Users of digital imaging acquisition systems shall follow quality assurance/quality control (QA/QC) protocol for digital imaging established by the manufacturer.

(i) The registrant shall include the protocols established in subparagraph (B) of this paragraph in its operating and safety procedures.

(ii) The registrant shall document the frequency at which the QA/QC protocol is performed. Documentation shall:

(I) include the date and initials of the individual completing the document and the images acquired; and

(II) be maintained and available at the authorized use location where performed in accordance with subsection (k)(2) of this section for inspection by the agency.

(B) If a protocol cannot be established by the manufacturer, it shall be developed and implemented by the registrant.

(i) The QA/QC protocol, as developed and implemented by the registrant, shall include image quality testing for spatial resolution, noise, artifacts and contrast by using a commercially purchased testing tool or an inanimate object of at least three varying densities.

(I) Images shall be acquired with each x-ray image receptor at an interval not to exceed three months.

(II) Test images shall be compared to previous test images to assess degradation of image quality.

(III) If a radiation machine or components of the digital imaging acquisition system require correction or repair following a quality test, the correction or repair shall begin within 30 days following the failure and the registrant shall perform or cause to be performed the correction or repair according to a designated plan. Correction or repair shall be completed no longer than 90 days from discovery unless authorized in writing by the agency.

(ii) The registrant shall include the protocols established in this paragraph in its operating and safety procedures.

(iii) The registrant shall document the frequency at which the QA/QC protocol is performed. Documentation shall:

(I) include the date and initials of the individual completing the document and the images acquired; and

(II) be maintained and available at the authorized use location where performed in accordance with subsection (k)(2) of this section for inspection by the agency.

(k) Records and reports.

(1) General provisions for records and reports.

(A) Each registrant shall maintain records at each site including sites authorized by certificate of registration condition and records sites for mobile services. The records shall include those specified in paragraph (2) of this subsection and shall be maintained at the time interval indicated for inspection by the agency. These records may be maintained in electronic format. These records shall be accessible to radiation machine operators during working hours.

(B) All records required by this chapter shall be accurate and factual.

(C) 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.

(D) Each registrant shall use the SI units Gy, Sv, 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 chapter.

(E) 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, or deep dose equivalent.

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

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

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

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

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(J) Copies of records required in subsections (i)(5)(I) and (J), and (j)(10)(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 site specified on a certificate of registration in accordance with paragraph (2) of this subsection.

(K) Records of surveys.

(i) Each registrant shall make and maintain records showing the results of surveys required by subsection (j)(4)(E) of this section for inspection by the agency. The registrant shall retain these records in accordance with paragraph (2) of this subsection.

(ii) The registrant shall retain the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents in accordance with paragraph (2) of this subsection.

(L) Records of individual monitoring results.

(i) Each registrant shall make or cause to be made and maintain records in accordance with subsection (j)(3)(F) of this section of the doses received by all individuals for whom monitoring was required in accordance with subsection (j)(3)(F) of this section, and records of doses received during accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:

(I) the deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin of the whole body, and shallow dose equivalent to the skin of any extremities; and

(II) the data used to make occupational dose assessments in accordance with subsection (j)(3)(F)(v) of this section.

(ii) The registrant shall make entries of the records specified in clause (i) of this subparagraph at intervals not to exceed one year and within 90 days of the end of the year.

(iii) The registrant shall make or cause to be made and maintain the records specified in clause (i) of this subparagraph on RC Form 233-1 in accordance with the instructions for RC Form 233-1, or in clear and legible records containing all the information required by RC Form 233-1.

(iv) The registrant shall make or cause to be made and maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

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(v) The registrant shall retain each required form or record required by this subsection in accordance with paragraph (2) of this subsection for inspection by the agency. The registrant shall retain records used in preparing RC Form 233-1 or equivalent in accordance with paragraph (2) of this subsection.

(M) Records of dose to individual members of the public.

(i) Each registrant shall make and maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public for inspection by the agency. See subsection (j)(3)(C) and (D) of this section.

(ii) The registrant shall retain the records required by clause (i) of this subparagraph in accordance with paragraph (2) of this subsection.

(2) Record or document requirements. Each registrant shall maintain the following records at each site, including authorized records sites for mobile services, at the time intervals specified and make available to the agency for inspection.

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Figure: 25 TAC §289.233(k)(2)

| | Name of Records/Documents | Specific Rule Subsection | Time Interval for Keeping Records/Documents |
|-----|--|--|--|
| (A) | Current 25 TAC, §289.233 of this title | As listed on certificate of registration | Until termination of registration |
| (B) | Inventory of all radiation machines possessed | (i)(5)(I)(ii) | Until next routine on-site inspection |
| (C) | Receipt, transfer, and disposal of each radiation machine possessed | (i)(5)(J)(ii) | Until termination of registration |
| (D) | Current operating and safety procedures Documentation that all staff who operate the radiation machine(s) have read this document | (j)(2)(A) | Until termination of registration Until next routine on-site inspection |
| (E) | Surveys (public dose evaluation) | (j)(3)(D) | Until termination of registration |
| (F) | Occupational dose assessment and administrative control records | (j)(3)(F)(iii) | Until termination of registration |
| (G) | Protective devices annual check | (j)(3)(H)(ii) | 5 years |
| (H) | Current certificate of registration | (j)(4)(B)(i)(II) | Until termination of registration |
| (I) | Notice of violation from last inspection, and documentation of corrections, if applicable | (j)(4)(B)(i)(IV) | Until next routine on-site inspection |

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| | | | |
|-----|---|--------------------------|---|
| (J) | Records of machine corrections or repairs | (j)(5)(M)(iii) | 6 years |
| | Name of Records/Documents | Specific Rule Subsection | Time Interval for Keeping Records/Documents |
| (K) | Equipment performance evaluations | (j)(5)(N)(ii)(III) | 6 years |
| (L) | Records of dosimetry system calibrations | (j)(5)(N)(viii) | 5 years |
| (M) | Film processing records and corrections | (j)(10)(E) | Until next routine on-site inspection |
| (N) | Records of chemicals and light leak tests | (j)(10)(F) | Until next routine on-site inspection |
| (O) | Alternate processing systems records | (j)(11) | Until next routine on-site inspection |
| (P) | Digital imaging acquisition systems records | (j)(12)(A)(ii)(II) | Until next routine on-site inspection |
| (Q) | Records at Additional Authorized Sites | (k)(1)(A) | While site is authorized on registration |
| (R) | Individual Monitoring Records | (k)(1)(L) | Until termination of Registration |
| (S) | Occupational Dose Results, RC Form 233-1 | (k)(1)(L)(i)-(iii) | Update annually; Maintain until termination of registration |
| (T) | Embryo/Fetus Dose | (k)(1)(L)(iv) | Until termination of registration |
| (U) | Records Used to Prepare RC Form 233-1 | (k)(1)(L)(v) | 5 years |
| (V) | Dose to Individual Members of the Public | (k)(1)(M) | Until termination of registration |
| (W) | Surveys, Measurements, Calibrations Used for Dose Determination | (k)(1)(M)(ii) | Until termination of registration |

(3) 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:

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

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

(III) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible TEDE to persons in unrestricted areas;

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

(V) 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.

(i) 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 Sv) or more;

(II) a lens dose equivalent of 75 rems (0.75 Sv) 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

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by the registrant that may have caused, or threatens to cause an individual to receive, in a period of 24 hours:

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

(II) lens dose equivalent exceeding 15 rems (0.15 Sv); 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 Sv).

(iii) Registrants shall make the initial notification reports required by clauses (i) and (ii) of this subparagraph by telephone to the agency shall confirm the initial notification report within 24 hours by facsimile or other electronic media 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 radiation are stated in a separate and detachable portion of the report.

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

(i) 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 (j)(3)(A)(i)(I) of this section;

(-b-) the occupational dose limits for a minor in subsection (j)(3)(A)(i)(III) of this section;

(-c-) the limits for an embryo/fetus of a declared pregnant woman in subsection (j)(3)(A)(i)(IV) of this section;

(-d-) the limits for an individual member of the public in subsection (j)(3)(C) of this section; or

(-e-) any applicable limit in the certificate of 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 registration, whether or not involving exposure of any individual in excess of the limits in subsection (j)(3)(C) of this section

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(ii) Each report required by clause (i) of this subparagraph 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

(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 clause (i) of this subparagraph for each individual exposed shall include the name, a unique identification number, and date of birth. With respect to the limit for the embryo/fetus in subsection (j)(3)(A)(i)(IV) 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 clause (i) of this subparagraph shall submit the report in writing to the agency.

(D) Reports to individuals of exposures.

(i) Radiation exposure data for an individual shall be reported annually to the individual as specified in this section. The information reported shall include data and results obtained in accordance with requirements of this section, 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;

(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 §289.233. You should preserve this report for further reference."

(ii) Each registrant shall provide an annual written report to advise each worker of the worker's dose, received in that monitoring year, as shown in records made and maintained by the registrant in accordance with paragraph (1)(M) of this subsection, if:

(I) the individual's occupational dose exceeds 0.1 rem (1 mSv) total effective dose equivalent or 0.1 rem (1 mSv) to any individual organ or tissue; or

(II) the individual requests the individual's annual dose report in writing.

(iii) At the written request of a worker formerly engaged in activities controlled by the registrant, each registrant shall furnish a written report of the worker's exposure to radiation machines. The report shall include the dose record for each year the worker was required to be monitored in accordance with subsection (j)(3)(B) of this section. Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to radiation machines and the dates and work sites under the certificate of registration in which the worker participated during this period.

(iv) When a registrant is required, in accordance with subparagraphs (B) and (C) of this paragraph, to report to the agency any exposure of an individual 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.

(v) At the written request of a worker who is terminating employment with the registrant in work involving exposure to radiation machines during the current year, each registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate. When the final individual monitoring results are available, those written results shall be provided to the worker or the worker's designee.

(vi) When a registrant is required in accordance with paragraph (3)(C) of this subsection 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 a copy of the report submitted to the agency, to the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency and shall comply with the provisions of paragraph (3)(D) of this subsection.