25 Texas Administrative Code

§289.229

Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Radiation Therapy Simulation Systems, and Electronic Brachytherapy Devices

(Effective September 30, 2024)

(Shaded text is added or significant changes to the December 2011 rule)

25 TAC §289.229

Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Radiation Therapy Simulation Systems, and Electronic Brachytherapy Devices (continued)

§289.229. Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Radiation Therapy Simulation Systems, and Electronic Brachytherapy Devices.

(a) Purpose. This section establishes the following requirements for using accelerators, therapeutic radiation machines, radiation therapy simulation systems, and electronic brachytherapy (EBT) devices.

(1) Requirements for the registration of a person using radiation machines used in healing arts.

(A) A person must not use radiation machines except as authorized in a certificate of registration issued by the Department of State Health Services (department) as specified in the requirements of this section.

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

(2) Requirements are intended to control receipt, possession, use, and transfer of radiation machines by any person so the total radiation dose to an individual, excluding background radiation, does not exceed the standards for protection against radiation prescribed in this section. This section does not limit actions necessary to protect public health and safety during an emergency.

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

(b) Scope.

(1) This section applies to a person who receives, possesses, uses, acquires, or transfers an accelerator used in industrial operations and research and development, therapeutic radiation machines, radiation therapy simulation systems, and EBT devices used in the healing arts. The registrant is responsible for the administrative control and for directing the use of the accelerators, other therapeutic radiation machines, radiation therapy simulation systems, and EBT devices.

(2) The requirements of this section are in addition to and not in substitution for other applicable requirements of:

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

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

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

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

(E) §289.227 of this chapter (relating to Use of Radiation Machines in the Healing Arts); and

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

(3) Registrants engaged in industrial radiographic operations are subject to the requirements of §289.255 of this chapter (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).

(4) Registrants engaged in veterinary accelerator operations are subject to the requirements of §289.233 of this chapter (relating to Radiation Control Regulations for Radiation Machines Used in Veterinary Medicine).

(5) An entity, defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as a "covered entity" under 45 Code of Federal Regulations (CFR) Parts 160 and 164 may be subject to privacy standards governing how information identifying a patient can be used and disclosed. Failure to follow HIPAA requirements may result in the department referring a potential violation to the United States Department of Health and Human Services.

(c) Prohibitions.

(1) The department prohibits the use of accelerators, therapeutic radiation machines, radiation therapy simulation systems, or EBT devices posing a significant threat or danger to occupational and public health and safety, as specified in §289.205 and §289.231 of this chapter.

(2) An individual must not be exposed to the useful beam of accelerators, therapeutic radiation machines, radiation therapy simulation systems, or EBT devices except for healing arts purposes and unless a physician of the healing arts has authorized such exposure. This provision specifically prohibits the deliberate exposure of an individual for training, demonstration, or other non-healing arts purposes.

(3) Research and development using radiation machines on humans is prohibited unless approved by an Institutional Review Board (IRB) as required by 45 CFR Part 46 and 21 CFR Part 56. The IRB must include at least one physician of the healing arts to direct any use of radiation as specified in §289.231(b) of this chapter.

(4) Remote operation of radiation machines on humans is prohibited.

(5) Use of therapeutic radiation machines in the healing arts without the supervision of a physician of the healing arts is prohibited.

(6) Use of EBT devices in the healing arts without the supervision of a certified physician, as defined in (e)(12), is prohibited.

(d) Exemptions. An individual who is a sole physician, sole operator, and the only occupationally exposed individual is exempt from the following requirements:

(1) §289.203(b) and (c) of this chapter; and

(2) subsection (h)(1)(G) of this section.

(e) Definitions. When used in this section, the following words and terms have the following meaning unless the context indicates otherwise.

(1) Absorbed dose (D)--The mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to the mass dM. The System International (SI) unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is gray (Gy). The previously used special unit of absorbed dose (rad) is replaced by gray.

(2) Absorbed dose rate--Absorbed dose per unit time for machines with timers, or dose monitor unit per unit time for linear accelerators.

(3) Accelerator beam quality--The type and penetrating power of the ionizing radiation produced for certain machine settings.

(4) 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.

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

(6) Beam axis--The axis of rotation of the beam limiting device.

(7) Beam-flattening filter--See definition for field-flattening filter.

(8) Beam-limiting device--A field-defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

(9) Beam monitoring system--A system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

(10) Beam quality--The penetrating power of the x-ray beam identified numerically by the half-value layer and influenced by kilovolt peak (kVp) and filtration.

(11) Central axis of the beam--An imaginary line passing through the center of the useful beam and the center of the plane figure formed by the edge of the first beam-limiting device.

(12) Certified physician--A physician licensed by the Texas Medical Board and certified in radiation oncology or therapeutic radiology.

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

Figure: 25 TAC §289.229(e)(13)

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

Where: s = estimated standard deviation of the population
$\overline{X}$ = mean value of observations in sample
X_i = ith observation in sample
n = number of observations in sample.

(14) Collimator--A device or mechanism by which the x-ray beam is restricted in size.

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

(16) Continuous pressure type switch--A switch that can only power a device when the operator maintains continuous pressure on the switch.

(17) Control panel--The part of the radiation machine where the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors are located. For purposes of this section, console is an equivalent term.

(18) Conventional radiation therapy simulator--A radiation machine with radiographic or fluoroscopic capabilities uniquely designed for the direct purpose of simulating radiation therapy treatment ports.

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

(20) CT radiation therapy simulator--CTs that interface with radiation therapy linear accelerators.

(21) Diaphragm--A device or mechanism by which the x-ray beam is restricted in size.

(22) Dose monitor unit (DMU)--A unit response from the beam monitoring system from which the absorbed dose can be calculated.

(23) Dosimetry system--An ion chamber used as a dosimeter for measurement of clinical photon and electron beams with calibration coefficients determined either in air or in water and traceable to a national primary standards dosimetry laboratory.

(24) Electronic brachytherapy--A method of radiation therapy using electrically generated x-rays to deliver a radiation dose at a distance of up to a few centimeters by intracavitary, intraluminal, or interstitial application, or by applications with the source in contact with the body surface or very close to the body surface.

(25) Electronic brachytherapy (EBT) device--The system used to produce and deliver therapeutic radiation, including the x-ray tube, the control mechanism, the cooling system, and the power source.

(26) External beam radiation therapy--Therapeutic irradiation in which the source of radiation is at a distance from the body.

(27) Field-flattening filter--A filter used to homogenize the absorbed dose rate over the radiation field.

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

(29) 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.

(30) Gantry--The part of the radiation therapy system that supports and allows possible movements of the radiation head about the center of rotation.

(31) Gray (Gy)--The SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is replaced by the gray (1 Gy = 100 rad).

(32) Half-value layer (HVL)--The thickness of a specified material that attenuates x-radiation or gamma radiation to the extent the exposure rate (air kerma rate) or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

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

(34) Image receptor--Any device that transforms incident x-ray photons either into a visible image or into another form made into a visible image by further transformations.

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

(36) Image-Guided Radiation Therapy (IGRT)--Radiation therapy employing advanced imaging to maximize accuracy and precision throughout the entire process of treatment delivery with the goal of optimizing the accuracy and reliability of radiation therapy to the target while minimizing dose to normal tissues.

(37) Intensity-Modulated Radiation Therapy (IMRT)--A technology for delivering highly conformal external beam radiation to a well-defined treatment volume with radiation beams whose intensity varies across the beam.

(38) Interlock--A device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

(39) Interruption of irradiation--The stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(40) Irradiation--The exposure of a living being or matter to ionizing radiation.

(41) Irradiation filter (filter)--Radiation absorbers or beam-modifying devices placed in the useful high-energy beam to shape the beam and optimize the target volume dose distribution in therapeutic radiation machines subject to subsection (h) of this section. Irradiation filter types are defined as follows.

(A) Dynamic or virtual wedge--A wedge produced by computer-controlled movement of one or more collimator jaws. The wedge generates a spatial dose distribution similar to a physical wedge. The wedge-shaped graduated attenuation across the radiation beam can produce symmetric or asymmetric radiation fields.

(B) Multileaf collimator (MLC) wedge filter--A beam-limiting device made of individual "leaves" of a high atomic numbered material, usually tungsten, that can move independently in and out of the path of a radiotherapy beam to shape and vary its intensity.

(C) Physical wedge filter--Physical wedges are made of metallic material and are manually placed in the useful radiation beam. The wedges are shaped in such a way as to produce graduated attenuation across the radiation field.

(D) Stereotactic radiosurgery (SRS) filter--A precise form of target localization delivering radiation through narrow circular cones or circular collimator tubes with lenses or computer leaf-driven systems enabling more precise beam filtering or shaping for complex radiation fields.

(42) Isocenter--The center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

(43) Kilovolt (kV) (kilo electron volt (keV))--The energy given to a particle with one electron charge when passing through a potential difference of one thousand volts in a vacuum. (Note: current convention is to use kV for photons and keV for electrons.)

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

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

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

(47) Leakage technique factors--The technique factors associated with the source assembly used when measuring leakage radiation.

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

(49) Light field--The area illuminated by light, simulating the radiation field.

(50) Medical event--An event meeting the criteria specified in subsection (i) of this section.

(51) Megavolt (MV) (megaelectron volt (MeV))--The energy given to a particle with one electron charge when passing through a potential difference of one million volts in a vacuum.

(52) Mobile EBT device--An EBT device transported from one address to be used at another address.

(53) Moving beam radiation therapy--Radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation, and rotational therapy.

(54) Nominal treatment distance--The following nominal treatment distances apply.

(A) For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam, as specified by the manufacturer.

(B) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam to the isocenter. For non-isocentric equipment, this distance is specified by the manufacturer.

(55) Output--The exposure rate (air kerma rate), dose rate, or a quantity related to these rates from a therapeutic radiation machine.

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

(57) Phantom--An object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

(58) Physician--An individual licensed by the Texas Medical Board to practice medicine under Texas Occupations Code Chapter 155.

(59) Port film--An x-ray exposure made with a radiation therapy system to visualize a patient's treatment area using radiographic film.

(60) Portable shielding--Moveable shielding placed in the primary or secondary beam to reduce radiation exposure to the patient, occupational worker, or a member of the public. The shielding can be easily moved to position using mobility devices or by hand.

(61) Prescribed dose--The total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using clinically acceptable and historically consistent assumptions for the treatment technique and calculations previously used for patients treated with the same clinical technique.

(62) Primary dose monitoring system--A system monitoring the useful beam during irradiation and terminating irradiation when a preselected number of monitor units are delivered.

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

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

(A) Primary protective barrier. A barrier sufficient to attenuate the useful beam to the required degree.

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

(65) Protective glove--A glove made of radiation-absorbing materials used to reduce radiation exposure.

(66) Quality assurance (QA) check--A test or analysis performed at a specified interval to verify the consistent output of radiation equipment.

(67) Radiation detector--A device providing, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(68) Radiation field--See definition for useful beam.

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

(70) Radiation therapy simulation system--An x-ray system intended for localizing and confirming the volume to be irradiated during radiation treatment and confirming the position and size of the therapeutic irradiation field.

(71) Radiation therapy system--A system utilizing machine-produced, prescribed doses of ionizing radiation for treatment.

(72) Radiation treatment head--The structure from which the useful beam emerges.

(73) Scan--The complete process of collecting x-ray transmission data to produce one or more tomograms.

(74) Scan increment--The amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

(75) Scan sequence--A preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

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

(77) Scattered radiation--Secondary radiation occurring when the beam intercepts an object causing the x-rays to be scattered.

(78) Secondary dose monitoring system--A system terminating irradiation in the event of failure of the primary dose monitoring system.

(79) Shutter--A device attached to the tube housing assembly capable of completely intercepting the useful beam and with a lead equivalency greater than or equal to the tube housing assembly.

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

(81) Stationary beam therapy--Radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

(82) Supervision--Delegating the task of applying radiation to a person by a physician. The physician can only delegate tasks to an individual certified under the Medical Radiologic Technologist Act, Texas Occupations Code Chapter 601. The physician assumes full responsibility for these tasks and ensures the tasks are administered correctly.

(83) Target--The part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation.

(84) Termination of irradiation--The stopping of irradiation in a fashion not permitting the continuation of irradiation without resetting operating conditions at the control panel.

(85) Therapeutic radiation machine--X-ray, particle, or electron-producing equipment designed and used for external beam radiation therapy.

(86) Traceable to a national standard--This indicates 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.

(87) Tube housing assembly--The tube housing with tube installed.

(88) Useful beam--Radiation passing through the window, aperture, cone, or other collimating device of the source housing. Also referred to as the primary beam.

(89) Virtual simulation--A process using the import, manipulation, display, and storage of electronic patient images to create linear accelerator treatment ports.

(90) Virtual source--A point from which radiation appears to originate.

(91) Wedge transmission factor--The ratio of doses, with and without the wedge, at a point along the central axis of the useful beam that compensates for the decrease in dose produced by the filter.

(92) Written directive--An order in writing for the administration of radiation to a specific patient as specified in subsection (h)(1)(F)(ii) of this section.

(f) Accelerators used for research and development or industrial operations.

(1) Registration. Each person possessing an accelerator for non-human use must apply for and receive a certificate of registration from the department before beginning use of the accelerator. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registration from the department as specified in §289.226(i)(1) of this chapter.

(2) Facility requirements.

(A) Each accelerator facility must be provided with primary and secondary barriers necessary to assure compliance with §289.231(m) and (o) of this chapter.

(B) A radiation survey must be conducted when the accelerator is registered and capable of producing radiation to determine compliance with §289.231(m) and (o) of this chapter.

(C) The registrant must maintain a copy of the initial and all subsequent vault survey reports for inspection by the department as specified in subsection (l) of this section. Vault surveys must be performed:

(i) on all new and existing facilities not previously surveyed by, or under the direction of, the registrant; and

(ii) upon installation, replacement, or upgrade to a higher energy accelerator.

(D) The registrant must maintain a copy of the initial survey report for inspection by the agency in accordance with subsection (l) of this section. A completed survey report must include:

(i) a diagram of the facility detailing building structures and the position of the accelerator, control panel, and associated equipment;

(ii) a description of the accelerator, including the manufacturer, model and serial number, beam type, and beam energy;

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

(iv) conditions under which radiation measurements were taken;

(v) survey data including:

(I) projected annual total effective dose equivalent (TEDE) in areas adjacent to the accelerator; and

(II) a description of workload, use, and occupancy factors employed in determining the projected annual TEDE; and

(vi) documentation of all instances where the facility violates this chapter's applicable requirements. Any deficiencies detected during the survey must be corrected before using the accelerator.

(3) Safety requirements.

(A) Interlock systems, including inherent, add-on, and aftermarket devices attaching to the accelerator, must comply with the following requirements.

(i) Instrumentation, readouts, and controls in the accelerator console are clearly identified.

(ii) Each entrance into a target room or other high radiation area is provided with a safety interlock terminating the useful beam under conditions of barrier penetration.

(iii) When the production of radiation has been interrupted, it is only possible to resume operation of the accelerator by manually resetting the interlock at the console.

(iv) Each safety interlock is on an electrical circuit allowing the interlock to operate independently of all other safety interlocks.

(v) All safety interlocks are designed so any defect or component failure in the interlock system prevents operating the accelerator.

(vi) A scram button or other emergency power cut-off switch is labeled. The scram button or cut-off switch includes a manual reset so the accelerator cannot be restarted from the accelerator console without resetting the cut-off switch.

(vii) The safety interlock system includes a visible or audible alarm indicating when any interlock has been activated.

(viii) All interlocks and visible or audible alarms are tested for proper operation at intervals meeting or exceeding nationally recognized, published guidelines from a professional body with expertise in accelerator radiation technologies, or manufacturer recommendations.

(ix) If an interlock or alarm is operating improperly, it is immediately labeled as defective and repaired within seven calendar days.

(x) Records of tests and repairs required by this paragraph are made and maintained as specified in subsection (l) of this section for inspection by the department.

(B) Each registrant must develop, implement, and maintain written operating and safety procedures (OSP) as specified in subsection (h)(1)(G) of this section.

(C) The registrant must ensure radiation measurements are performed with a calibrated dosimetry system. The dosimetry system calibration must be traceable to a national standard. Instruments and equipment must be calibrated at an interval not to exceed 24 months. Each accelerator facility must have appropriate portable monitoring equipment available that is operable and calibrated for the radiation produced at the facility.

(D) A radiation protection survey must be performed and the results recorded when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(E) For portable or mobile accelerators, such as neutron generatorsused at temporary job sites where permanent shielding is not available, radiation protection must be provided by temporary shielding or by providing an adequate exclusion area around the accelerator while it is in use.

(F) Records of calibration and survey results made as specified in subparagraphs (C) and (D) of this paragraph must be maintained according to subsection (l) of this section.

(G) The registrant must perform radiation surveys and contamination smears before the transfer or disposal of an accelerator operating at or above 10 MeV. The survey must be documented and maintained by the registrant for inspection by the department as specified in subsection (l) of this section.

(H) The registrant must retain records of receipt, transfer, and disposal of all radiation machines specific to each authorized use location. The records must be maintained by the registrant for inspection by the department as specified in subsection (l) of this section. The records must include the:

(i) date;

(ii) manufacturer name;

(iii) model;

(iv) serial number from the control panel or console of the radiation machine; and

(v) name of the individual making the record.

(4) Training requirements for operators.

(A) An individual must not operate an accelerator unless the individual has received instruction in and demonstrated competence with the following:

(i) OSP as specified in paragraph (3)(B) of this subsection;

(ii) radiation warning and safety devices incorporated into the equipment and in the room;

(iii) identification of radiation hazards associated with the use of the equipment; and

(iv) procedures for reporting a medical event or an actual or suspected exposure to the operator.

(B) Records of the training specified in subparagraph (A) of this paragraph must be made and maintained for department inspection as specified in subsection (l) of this section.

(g) Requirements for an accelerator used in industrial radiography. In addition to the requirements in subsections (f)(1), (f)(2), and (f)(3)(C) – (H) of this section, accelerators used for industrial radiography must meet the applicable requirements of §289.255 of this chapter.

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(h) Requirements for therapeutic radiation machines, radiation therapy simulation systems used in the healing arts, and EBT devices.

(1) General requirements.

(A) Each person possessing a therapeutic radiation machine capable of operating at or above 1 MeV or an EBT device must apply for and receive a certificate of registration from the department before using the accelerator for human use. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registration from the department.

(B) A person possessing a radiation therapy simulation system or a therapeutic radiation machine capable of operating below 1 MeV must apply for a certificate of registration within 30 days after energizing the equipment.

(C) An individual who operates a radiation machine for human use must meet the appropriate credentialing requirements as specified in the Medical Radiologic Technologist Certification Act, Texas Occupations Code Chapter 601. Copies of the credentialing document must be maintained at the location where the individual is working. A copy of the credentialing document must be maintained by the registrant for inspection by the department as specified in subsection (l) of this section.

(D) The EBT registration requires the physician to be:

(i) licensed by the Texas Medical Board; and

(ii) certified in:

(I) radiation oncology or therapeutic radiology by the American Board of Radiology; or

(II) radiation oncology by the American Osteopathic Board of Radiology.

(E) The registrant must ensure an operator of an EBT device completes device-specific training and maintains a record of each individual’s training as specified in subsection (l) of this section. The device-specific training must include:

(i) completing a training program provided by the manufacturer; or

(ii) training substantially equivalent to the manufacturer's training program from a certified physician or a licensed medical physicist trained to use the device.

(F) Each facility must develop a written QA program or an electronic reporting system. The QA program must be implemented to minimize deviations from facility procedures and to document preventative measures taken before serious patient injury or therapeutic misadministration.

(i) The QA program must include the following topics:

(I) treatment planning and patient simulation;

(II) charting and documenting treatment field parameters;

(III) dose calculation and review procedures;

(IV) review of daily treatment records; and

(V) for EBT devices, verification of catheter placement and device exchange procedures.

(ii) A written directive must be prepared before administration of a therapeutic radiation dose except where a delay in providing a written directive would jeopardize the patient's health. If an oral directive must be made, the information contained in the oral directive must be documented immediately in the patient's record. A written directive must be prepared within 24 hours of the oral directive.

(iii) A written directive changing an existing written directive for any therapeutic radiation procedure is only acceptable if the revision is dated and signed by a certified physician before the administration of the therapeutic dose, or the next fractional dose.

(iv) Deviations from the prescribed treatment, from the facility's QA program, or from the OSP must be investigated and brought to the attention of the certified physician or licensed medical physicist, and the radiation safety officer (RSO).

(v) The patient's identity must be verified by more than one method as the individual named in the written directive before administration.

(vi) The discovery of each medical event must be reported as specified in subsections (i) and (j) of this section.

(vii) The review of the QA program must include all the deviations from the prescribed treatment and must be conducted at intervals not to exceed 14 months. A signed record of each dated review must be maintained for inspection by the department as specified in subsection (l) of this section and must include evaluations and findings of the review.

(G) Written OSP must be developed by a licensed medical physicist with a specialty in therapeutic radiological physics and must include any restrictions required for the safe operation of each therapeutic radiation machine. These procedures must be available in the control area of the therapeutic radiation machine, radiation therapy simulation system, or EBT device. The registrant must maintain records of OSP as specified in subsection (l) of this section for inspection by the department. The operator must be able to demonstrate familiarity with these procedures. The OSP must address the following requirements:

(i) therapeutic radiation machines must not be used for irradiation of a patient unless full calibration measurements and QA checks have been completed;

(ii) therapeutic radiation machines must not be used in the administration of radiation therapy if a QA check indicates a significant change in the operating characteristics of a system as specified in the written procedures;

(iii) therapeutic radiation machines must not be left unattended unless secured by a locking device, or computerized password system, preventing unauthorized use;

(iv) mechanical supporting or restraining devices must be used when there is a need to immobilize a patient or port film for radiation therapy;

(v) no individual, other than the patient, is allowed in the treatment room during exposures from therapeutic radiation machines operating above 150 kV;

(vi) at energies less than or equal to 150 kV, any individual in the treatment room, other than the patient, must be protected by a barrier sufficient to meet the requirements of §289.231(m) and (o) of this chapter;

(vii) a technique chart for radiation therapy simulation systems must be used as specified in paragraph (5)(A)(i) of this subsection;

(viii) occupational and public radiation dose must be controlled as specified in §289.231(m) and (o) of this chapter;

(ix) occupational dose must be monitored as specified in §289.231(n) of this chapter;

(x) protective devices must be used for radiation therapy simulation systems as specified in paragraph (5)(A)(iii) of this subsection;

(xi) operators of radiation machines must be credentialled as specified in subparagraph (C) of this paragraph;

(xii) film processing program for conventional radiation therapy simulation systems must be performed as specified in paragraph (5)(E)(i) of this subsection;

(xiii) procedures for restriction and alignment of the beam for conventional radiation therapy simulation systems as specified in paragraph (5)(F)(iii) of this subsection;

(xiv) methods utilized for testing interlocks, entrance controls, and alarm systems;

(xv) notifications and reports must be provided to individuals as specified in §289.203(d) of this chapter; and

(xvi) notices to workers must be posted as specified in §289.203(b) of this chapter.

(H) A registrant with equipment granted variances by the United States Food and Drug Administration (FDA) to 21 CFR Part 1020 must maintain copies of those variances at authorized use locations as specified in subsection (l) of this section.

(I) The registrant must perform radiation surveys and contamination smears before the transfer or disposal of an accelerator operating at or above 10 MeV. Surveys must be documented and maintained by the registrant for inspection by the department as specified in subsection (l) of this section.

(J) Where applicable, the licensed medical physicist must perform acceptance testing on the treatment planning system of therapy-related computer systems as specified in protocols accepted by nationally recognized, published guidelines, from a professional body with expertise in the use of therapeutic radiation technologies. In the absence of such a published protocol, the manufacturer's current protocol must be followed.

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

(A) Equipment requirements.

(i) When the tube is operated at its leakage technique factors, the leakage radiation must not exceed the values specified at the distance stated for the classification of the radiation machine system shown in the following Table I. 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 §289.229(h)(2)(A)(i)

Table I

System	Measurement Location	Leakage Limit
5-50 kV	5 centimeters (cm) from the tube housing assembly	1 milligray (mGy) in 1 hour (hr)
>50 and <500 kV	1 meter (m) from the target	1 cGy in 1 hr
	5 cm from the tube housing assembly	30 cGy in 1 hr

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

(iii) Removable and adjustable beam-limiting devices must meet the following requirements.

(I) Removable beam-limiting devices must, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 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 patient.

(II) Adjustable beam-limiting devices must, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kVp and maximum treatment filter.

(III) Adjustable beam-limiting devices must meet the requirements of subclause (I) of this clause.

(iv) The filter system must be designed so:

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

(II) an interlock system prevents irradiation if the proper filter is not in place;

(III) the air kerma rate escaping from the filter slot must not exceed 1 centigray/hour (cGy/hr) at 1 meter (m) under any operating conditions; and

(IV) each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle must appear on the wedge or wedge tray.

(v) The tube housing assembly must be capable of being immobilized for stationary treatments.

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

(vii) The contact therapy tube housing assembly must have a removable shield of at least 0.5 mm lead equivalency at 100 kVp capable of being positioned over the entire useful beam exit port during periods when the beam is not in use.

(viii) The timer must:

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

(II) activate with the production of radiation and retain its reading after irradiation is interrupted;

(III) be reset to zero after irradiation is terminated and before irradiation can be re-initiated;

(IV) terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(V) permit selection of exposure times as short as 1 second;

(VI) not permit exposure if set at zero;

(VII) not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer factor to compensate for mechanical lag; and

(VIII) be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

(ix) The control panel, in addition to the displays required in clause (viii)(I) of this subparagraph, must have the following:

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

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

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

(IV) means for terminating an exposure at any time;

(V) a locking device preventing unauthorized use of the therapeutic radiation system (a computerized password system also constitutes a locking device);

(VI) a positive display of specific filters in the beam; and

(VII) emergency buttons or switches clearly labeled as to their functions.

(x) There must be a means of initially determining the SSD to within 1 centimeter (cm) and of reproducing this measurement to within 2 mm.

(xi) Unless it is possible to bring the radiation output to the prescribed exposure parameters within 5 seconds, the beam must be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. After the unit is at operating parameters, the shutter must be controlled electrically by the operator from the control panel. An indication of shutter position must appear at the control panel.

(xii) Each therapeutic radiation system equipped with a beryllium or other low-filtration window must be clearly labeled on the tube housing assembly and at the control panel.

(B) Facility requirements for therapeutic radiation systems capable of operating above 50 kVp.

(i) Provision must be made for continuous two-way aural communication between the patient and the operator at the control panel.

(ii) Windows, mirrors, closed-circuit television, or an equivalent system must be provided to permit continuous observation of the patient during irradiation and be located so the operator can observe the patient from the control panel.

(I) If the viewing system described in clause (ii) of this subparagraph fails or is inoperative, treatment must not be performed with the unit until the system is restored.

(II) If a facility has a primary viewing system by electronic means and an alternate viewing system, and both viewing systems described in clause (ii) of this subparagraph fail or are inoperative, treatment must not be performed with the unit until one of the systems is restored.

(C) Additional facility requirements for therapeutic radiation systems capable of operation above 150 kVp.

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

(ii) The control panel must be located outside the treatment room or in an enclosed booth inside the room.

(iii) Interlocks must be provided to ensure all entrance doors are 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 must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel. When any door is opened while the x-ray tube is activated, the exposure at a distance of 1 m from the source must be reduced to less than 1 milligray per hour (mGy/hr) (100 millirad per hour (mrad/hr)).

(D) Surveys, calibrations, and QA checks.

(i) Surveys must be performed as follows.

(I) All new and existing facilities not previously surveyed must have an initial shielding survey made by a licensed medical physicist, as authorized by 22 Texas Administrative Code (TAC) §160.17 (relating to Medical Physicist Scope of Practice), who must provide a written report of the survey to the registrant. Additional surveys must be done after any change in the facility, facility design, or equipment that might cause a significant increase in radiation hazard.

(II) The registrant must maintain a copy of the initial survey report and all subsequent survey reports required by subclause (I) of this clause as specified in subsection (l) of this section for inspection by the department.

(III) The survey report must indicate all instances where the installation violates this chapter's applicable requirements.

(ii) Full calibrations must be performed as follows.

(I) The calibration of a therapeutic radiation system must be performed at intervals not to exceed 12 months and after any change or replacement of components that could cause a change in the radiation output. The calibrations must ensure the dose at a reference point in a water or plastic phantom can be calculated to within an uncertainty of 5 percent.

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

(III) The calibration of the therapeutic radiation system includes:

(-a-) verification the radiation therapy system is operating in compliance with the design specifications;

(-b-) HVL for each kV setting and filter combination used;

(-c-) the exposure rates (air kerma rates) as a function of field size, technique factors, filter, and treatment distance used; and

(-d-) the degree of congruence between the radiation field and the field indicated by the localizing device, if such device is present, which must be within 5 mm for any field edge.

(IV) Calibration measurements of the radiation output of a therapeutic radiation system must be performed with a calibrated dosimetry system. Calibration of the dosimetry system must be performed and completed at intervals not to exceed 24 months and traceable to a national standard.

(V) Records of calibration measurements specified in this clause must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department.

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

(iii) QA checks must be performed on therapeutic radiation systems capable of operation at greater than 150 kVp. Such measurements must meet the following requirements.

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

(II) If a licensed medical physicist does not perform the QA check measurements, the results of the QA check measurements must be reviewed by a licensed medical physicist with a specialty in therapeutic radiological physics within five treatment days and a record made of the review. If the output varies by more than 5 percent from the expected value, a licensed medical physicist with a specialty in therapeutic radiological physics must be notified immediately.

(III) The written QA check procedures must specify the testing or measurement frequency and state that the QA check must be performed during the calibration specified in clause (ii) of this subparagraph. The acceptable tolerance for each parameter measured when compared to the value for that parameter determined in the calibration specified in clause (ii) of this subparagraph must be stated.

(IV) The written QA check procedures must include special operating instructions required to be carried out whenever a parameter in subclause (III) of this clause exceeds an acceptable tolerance.

(V) Whenever a QA check indicates a significant change in the operating characteristics of a system, as specified in the procedures, the system must be recalibrated, as required in clause (ii) of this subparagraph.

(VI) Records of written QA checks and any necessary corrective actions must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department. A copy of the most recent QA check must be available at a designated area within the therapy facility housing the therapeutic radiation system.

(VII) QA checks must be obtained using a system satisfying the requirements of clause (ii)(IV) of this subparagraph.

(iv) All testing reports must meet or exceed nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations.

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

(A) 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) must not exceed 0.1 percent of the maximum absorbed dose in rads (mGy) of the unattenuated useful beam. The absorbed dose for this leakage radiation requirement must be measured 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 nominal treatment distance and outside the maximum useful beam size. The unattenuated useful beam must be measured at the point of intersection of the central axis of the beam and the plane surface.

(I) Measurements excluding those for neutrons must be averaged over an area up to, but not exceeding, 100 square centimeters (cm^2) at the positions specified.

(II) Measurements of the portion of the leakage radiation dose contributed by neutrons must be averaged over an area up to, but not exceeding, 200 cm^2.

(III) For each system, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified for the specified operating conditions.

(IV) Records on leakage radiation measurements must be maintained as specified in subsection (l) of this section for inspection by the department.

(ii) Irradiation filters.

(I) Dynamic or virtual wedge filter.

(-a-) An interlock system must be provided to prevent irradiation if any virtual or dynamic wedge selected in the treatment room does not agree with the virtual or dynamic wedge selection and operation carried out at the treatment console.

(-b-) The dose distribution selected must include:

(-1-) beam energy;

(-2-) field size; and

(-3-) wedge angle.

(-c-) A virtual wedge transmission factor must be established and utilized.

(II) Multileaf collimator (MLC) filter.

(-a-) An interlock system must be provided to prevent irradiation if the spatial dose distribution selected in the treatment room does not agree with the filter selection and operation carried out at the treatment console.

(-b-) The distribution selected must include:

(-1-) beam energy; and

(-2-) MLC selection.

(III) Stereotactic radiosurgery (SRS) filter.

(-a-) An interlock system must be provided to prevent irradiation if the spatial dose distribution selected in the treatment room does not agree with the filter selection and operation carried out at the treatment console.

(-b-) The distribution selected must include:

(-1-) beam energy;

(-2-) SRS cone; or

(-3-) MLC selection.

(-c-) A virtual wedge transmission factor must be established and utilized.

(IV) Physical wedge filter.

(-a-) Each wedge filter removable from the system must be marked with an identification number.

(-b-) Documentation must be available at the console containing a description of the filter.

(-c-) The wedge angle must appear on the wedge or wedge tray (if permanently mounted to the tray).

(-d-) If the wedge or wedge tray is damaged, the wedge must be removed from clinical service.

(-e-) Irradiation must 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.

(-f-) A display must be provided at the treatment console showing the accelerator beam quality in use.

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

(iii) Beam Quality. The registrant must determine data sufficient to assure the following beam quality requirements in tissue equivalent material are met.

(I) 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 must not exceed the values stated in Table II. Linear interpolation must be used for values not stated.

Figure: 25 TAC §289.229(h)(3)(A)(iii)(I)

Table II

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

(II) Compliance with subclause (I) of this clause must be determined using:

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

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

(-c-) 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.

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

Figure: 25 TAC §289.229(h)(3)(A)(iii)(III)

Table III

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

(IV) Compliance with subclause (III) of this clause must be determined by measurements:

(-a-) within a tissue equivalent phantom using an instrument allowing extrapolation to the surface absorbed dose;

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

(-c-) after removal of all beam-modifying devices capable of being removed without the use of tools, except for beam-scattering or beam-flattening filters; and

(-d-) using the largest field size available not exceeding 15 cm by 15 cm.

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

(I) At least two independent radiation detectors must be used. The detectors must be incorporated into two independent dose monitoring systems.

(II) The incorporated detector and monitoring system must meet the following requirements.

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

(-b-) Each detector must 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.

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

(-d-) The design of the dose monitoring systems must assure the malfunctioning of one system does not affect the correct functioning of the secondary system; and failure of any element common to both systems affecting the correct function of both systems must terminate irradiation.

(-e-) Each dose monitoring system must have a legible display at the treatment console. Each display must:

(-1-) maintain a reading until intentionally reset to zero;

(-2-) have only one scale and no scale multiplying factors;

(-3-) utilize a design so increasing dose is displayed by increasing numbers and if there is an overdosage of radiation, the absorbed dose may be accurately determined; and

(-4-) retain the dose monitoring information in at least one system for 15 minutes in the event of a power failure.

(v) For equipment inherently capable of producing useful beams with unintentional asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions must 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 percent of the central axis dose rate, an indication of this condition must be displayed at the console; and if this difference exceeds 10 percent of the central axis dose rate, the irradiation must be terminated.

(vi) Selection and display of dose monitor units must meet the following requirements.

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

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

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

(IV) After termination of irradiation, the preselected dose monitor units must be reset manually before irradiation can be initiated.

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

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

(II) A secondary dose monitoring system must be present. The system must 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.

(III) An indicator on the console must show which dose monitoring system has terminated irradiation.

(viii) A locking device must 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 must be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment console. Following an interruption, it must 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 must be automatically terminated.

(x) It must 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 must meet the following requirements.

(I) A timer with a display is provided at the treatment console. The timer has a preset time selector and an elapsed time indicator.

(II) The timer is a cumulative timer activating with the production of radiation and retaining its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it is necessary to reset the elapsed time indicator to zero.

(III) After termination of irradiation and before irradiation can be reinitiated, the preset time selector is reset manually.

(IV) The timer terminates 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 must meet the following additional requirements.

(I) Irradiation is not possible until a selection of radiation type has been made at the treatment console.

(II) An interlock system is provided to:

(-a-) ensure the equipment can emit only the radiation type selected;

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

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

(III) The radiation type selected is displayed at the treatment console before and during irradiation.

(xiii) Equipment capable of generating radiation beams of different energies must meet the following requirements.

(I) Irradiation is not possible until a selection of energy has been made at the treatment console.

(II) An interlock system is 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.

(III) The nominal energy value selected is displayed at the treatment console before and during irradiation.

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

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

(II) An interlock system is 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.

(III) The selection of stationary or moving beam is displayed at the treatment console. An interlock system must be provided to ensure the equipment can only operate in the selected mode.

(IV) An interlock system is 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.

(V) Moving beam therapy is controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.

(-a-) An interlock system must 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.

(-b-) Where gantry angle terminates the irradiation in arc therapy, the dose monitor units must be within 5 percent from the value calculated from the absorbed dose per unit angle relationship.

(VI) Where the dose monitor system terminates the irradiation in moving beam therapy, the termination of irradiation must meet the requirements of clause (vii) of this subparagraph.

(xv) A system must 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 clause (iv) of this subparagraph may form part of this system. In addition, the dose monitor unit rate must be displayed at the treatment console. If the equipment can deliver, under any conditions, an absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device must be provided to terminate irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated must be in a record maintained by the registrant as specified in subsection (l) of this section for department inspection.

(xvi) The registrant must determine, or obtain from the manufacturer, the location with reference to an accessible point on the gantry, 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 must be provided so all radiation safety interlocks can be checked for correct operation.

(B) Facility and shielding requirements.

(i) Each installation must be provided with primary and secondary barriers as are necessary to assure compliance with §289.231(m) and (o) of this chapter.

(ii) All protective barriers must be fixed except for entrance doors or beam interceptors.

(iii) The console must be located outside the treatment room and all emergency buttons or switches must be clearly labeled as to their functions.

(iv) Windows, mirrors, closed-circuit television, or an equivalent system must be provided to permit continuous observation of the patient following positioning and during irradiation and must be located so the operator can see the patient from the console.

(I) If the viewing system described in clause (iv) of this subparagraph fails or is inoperable, treatment must not be performed with the unit until the system is restored.

(II) In a facility with a primary viewing system by electronic means and an alternate viewing system, if both viewing systems described in clause (iv) of this subparagraph fail or are inoperative, treatment must not be performed with the unit until one of the systems is restored.

(v) Provision must be made for continuous two-way aural communication between the patient and the operator at the console independent of the accelerator. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication must be used. When this is the case, a description of the alternate method must be submitted to and approved by the department.

(vi) Treatment room entrances must 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."

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

(C) Surveys, dose calibrations, QA checks, and operational requirements.

(i) Surveys must be performed as follows.

(I) All new and existing facilities not previously surveyed must have an initial shielding survey made by a licensed medical physicist as authorized by 22 TAC §160.17 who must provide a written report of the survey to the registrant. The physicist who performs the survey must be an individual who:

(-a-) did not consult in the design of the therapeutic radiation machine installation and;

(-b-) is not employed by or within any corporation or partnership with the person who consulted in the design of the installation.

(II) The survey report must include:

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

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

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

(-d-) conditions under which radiation measurements were taken; and

(-e-) survey data including:

(-1-) projected annual TEDE in areas adjacent to the therapy room; and

(-2-) a description of workload, use, and occupancy factors employed in determining the projected annual TEDE.

(III) The registrant must maintain a copy of the survey report, and a copy of the survey report must be provided to the department within 30 days of completion of the survey. Records of the survey report must be maintained as specified in subsection (l) of this section for inspection by the department.

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

(V) In addition, such surveys must be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

(ii) Dose calibrations. Records of calibration measurements specified in subclause (I) of this clause and dosimetry system calibrations specified in subclause (III) of this clause must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department. A copy of the latest calibrated absorbed dose rate measured as specified in subclause (I) of this clause must be available at a designated area within the facility housing the radiation therapy system. Calibrations of therapeutic systems must be performed as follows.

(I) The calibration of systems subject to this subsection are performed as specified in an established calibration protocol before the system is first used for irradiation of a patient and then at intervals not exceeding 12 months and after any change significantly altering the calibration, spatial distribution, or other characteristics of the therapy beam.

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

(-b-) Acceptance testing, commissioning, and dose calibration must be performed as specified in current published recommendations from a nationally recognized professional association with expertise in the use of therapeutic radiation technologies. In the absence of a protocol published by a national professional association, the manufacturer's protocol, or equivalent quality, safety, and security protocols, must be followed.

(-c-) At a minimum, the calibration protocol must include all items in subclauses (III) - (V) of this clause.

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

(III) Calibration radiation measurements required by subclause (I) of this clause are performed using a dosimetry system:

(-a-) having a calibration factor for cobalt-60 gamma rays traceable to a national standard;

(-b-) traceable to a national standard and at an interval not to exceed 24 months;

(-c-) calibrated to the extent an uncertainty can be stated for the radiation quantities monitored by the system; and

(-d-) having constancy checks performed as specified by the licensed medical physicist with a specialty in therapeutic radiological physics.

(IV) Calibrations must be in sufficient detail to ensure the dose at a reference point in a tissue equivalent phantom can be calculated to within an uncertainty of 5 percent.

(V) The calibration of the therapy unit must include the following determinations.

(-a-) Verification that the equipment is operating in compliance with the design specifications concerning the light field, patient 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.

(-b-) Verification of the accuracy of the absorbed dose rate at various depths in a tissue equivalent phantom for the range of field sizes and effective energies used in all therapy procedures.

(-c-) Uniformity of the radiation field to include symmetry, flatness, and dependence on the gantry angle.

(-d-) Verification that existing isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

(-e-) Verification of transmission factors for all accessories such as wedges, block trays, and universal and custom-made beam modifying devices.

(VI) Calibration of therapeutic systems containing asymmetric jaws, multileaf collimation, or dynamic or virtual wedges must be performed with an established protocol. The procedures must be developed by a licensed medical physicist with a specialty in therapeutic radiological physics and must be in writing or documented in an electronic reporting system.

(iii) QA checks must be performed on systems subject to this paragraph during calibrations and then at weekly intervals with the period between QA checks not to exceed five treatment days. Such radiation output measurements must meet the following requirements.

(I) The QA check procedures must be performed as specified in established protocol, be in writing or documented in an electronic reporting system, and be developed by a licensed medical physicist with a specialty in therapeutic radiological physics. The protocol must meet or exceed nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations. At a minimum, the QA check protocol must include all items in subclauses (III) - (VI) of this clause.

(II) If a licensed medical physicist does not perform the QA check measurements, the results of the QA check measurements must be reviewed by a licensed medical physicist at a frequency not to exceed five treatment days and a record kept of the review. If the output varies by more than 3 percent from the expected value, a licensed medical physicist must be notified immediately.

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

(IV) Where a system has built-in devices providing a measurement of any parameter during irradiation, such measurement must not be utilized as a QA check measurement.

(V) A parameter exceeding a tolerance set by a licensed medical physicist must be corrected before the system is used for patient irradiation.

(VI) Whenever a QA check indicates a significant change in the operating characteristics of a system, as specified in a licensed medical physicist's written procedures, the system must be recalibrated.

(VII) Records of QA check measurements and any necessary corrective actions must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department.

(VIII) QA checks must be completed using a system satisfying the requirements of clause (ii)(III) of this subparagraph.

(iv) Facilities with therapeutic radiation machines with energies of 1 MeV and above must procure the services of a licensed medical physicist with a specialty in therapeutic radiological physics.

(I) The physicist must be responsible for:

(-a-) dose calibration of radiation machines;

(-b-) supervision and review of beam and clinical dosimetry;

(-c-) measurement, analysis, and tabulation of beam data;

(-d-) establishment of QA procedures and performance of QA check review; and

(-e-) review of absorbed doses delivered to patients.

(II) The licensed medical physicist described in subclause (I) of this clause must also be available and responsive to immediate problems or emergencies.

(4) Requirements for EBT devices. In addition to the requirements in paragraph (1) of this subsection, EBT devices must meet the requirements in this paragraph.

(A) Technical requirements for EBT devices.

(i) The timer must:

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

(II) activate with the production of radiation and retain its reading after irradiation is interrupted;

(III) be reset to zero after irradiation is terminated and before irradiation can be re-initiated;

(IV) terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(V) permit selection of exposure times as short as 1 second;

(VI) not permit an exposure if set at zero; and

(VII) be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

(ii) The control panel, in addition to the displays required in subparagraph (A)(i) of this paragraph, must have:

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

(II) means for indicating x-rays are being produced;

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

(IV) means for terminating an exposure at any time.

(iii) All emergency buttons or switches must be clearly labeled as to their functions.

(B) Surveys, calibrations, and QA checks.

(i) Survey procedures.

(I) All new and existing facilities with an EBT device must have an initial shielding survey made by a licensed medical physicist, as authorized by 22 TAC §160.17, who must provide a written survey report to the registrant. Additional surveys must be done when:

(-a-) making any change in the portable shielding; and

(-b-) relocating the electronic therapy device.

(II) The registrant must maintain a copy of the initial survey report and all subsequent survey reports as specified in subsection (l) of this section for inspection by the department.

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

(ii) Calibrations procedures. Records of calibration measurements must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department. A copy of the latest calibrated absorbed dose rate measured on the EBT device must be available at a designated area within the therapy facility housing the EBT device.

(I) Calibration procedures must be in writing, or documented in an electronic reporting system, and must have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics.

(II) The registrant must make calibration measurements required by this section as specified in any current recommendations from a recognized national professional association (such as the American Association of Physicists in Medicine Report Number 152) for an EBT device, when available. Equivalent alternative methods are acceptable. In the absence of a protocol by a national professional association, a published protocol included in the device manufacturer operator's manual must be followed.

(III) The calibration of the EBT device must be performed after changing the x-ray tube or replacing components that could cause a change in the radiation output. The calibration must ensure the dose at a reference point in a water or plastic phantom can be calculated to within an uncertainty of 5 percent.

(IV) The calibration of the radiation output of the EBT device must be performed by a licensed medical physicist with a specialty in therapeutic radiological physics who is physically present at the facility during such calibration.

(V) The calibration of the therapeutic EBT device must include verification that the EBT device is operating in compliance with the design specifications.

(VI) Calibration of the radiation output of the EBT device must be performed with a calibrated dosimetry system. The dosimetry calibration must be traceable to a national standard. The calibration interval must not exceed 24 months.

(iii) QA check. Records of the written QA checks and any necessary corrective actions must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department. A copy of the most recent QA check must be available at a designated area within the therapy facility housing the therapeutic radiation system.

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

(II) If a licensed medical physicist does not perform the QA check measurements, the results of the QA check measurements must be reviewed by a licensed medical physicist with a specialty in therapeutic radiological physics within two treatment days, and a record made of the review.

(III) The written QA check procedures must specify the operating instructions required to be carried out whenever a parameter exceeds an acceptable tolerance as established by the licensed medical physicist.

(IV) The certified physician or licensed medical physicist must prevent the clinical use of a malfunctioning device until the malfunction identified in the QA check has been evaluated and corrected or, if necessary, the equipment repaired.

(V) QA checks must be completed using a dosimetry system satisfying the requirements of clause (ii)(VI) of this subparagraph.

(5) Radiation therapy simulation systems.

(A) General requirements. In addition to the requirements in paragraph (1)(B), (C), (F), and (H) of this subsection, radiation therapy simulation systems must comply with the following:

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

(ii) Operating and safety procedures. Each registrant develops, implements, and maintains written OSP as specified in paragraph (1)(G) of this subsection and §289.227(i)(2)(A) of this chapter.

(iii) Protective devices. When utilized, protective devices meet the following requirements.

(I) Protective devices must be made of no less than 0.25 mm lead equivalent material.

(II) Protective devices, including aprons, gloves, and shields, are checked annually for defects, such as holes, cracks, and tears. The registrant must perform these checks by visual, tactile, or x-ray imaging. If a defect is found, equipment must be replaced or removed from service until repaired. A record of this test is made and maintained by the registrant as specified in subsection (l) of this section for inspection by the department.

(iv) Viewing system. Windows, mirrors, closed circuit television, or an equivalent system is provided to permit the operator to continuously observe the patient during irradiation. The operator is able to maintain continuous verbal, visual, and aural contact with the patient.

(v) Operator position. The operator's position during the exposure ensures the operator's exposure is as low as reasonably achievable (ALARA). The operator is a minimum of 6 feet from the source of radiation or protected by an apron, gloves, or other shielding having a minimum of 0.25 mm lead equivalent material.

(vi) Holding of the tube. An individual does not hold the tube or tube housing assembly supports during any radiographic exposure.

(vii) No individuals other than the patient and the operator are allowed in the treatment room during the operation of the simulator.

(B) Facility design requirements.

(i) Provision must be made for two-way aural communication between the patient and the operator at the control panel.

(ii) Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous patient observation during irradiation and be located so the operator can see the patient from the console. If the viewing system described in this clause fails or is inoperable, the unit must not be used until the system is restored.

(iii) In a facility with a primary viewing system by electronic means and an alternate viewing system, and both viewing systems described in this clause fail or are inoperative, the unit must not be used until one of the systems is restored.

(C) Requirements for radiation therapy simulation systems utilizing standard CT systems.

(i) Equipment requirements.

(I) Tomographic systems must meet the following requirements.

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

(-b-) For any multiple tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

(-c-) If a device using a light source is used to satisfy the requirements of item (-a-) or (-b-) of this subclause, the light source must 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.

(II) The CT system must be designed so the CT conditions of operation to be used during a scan or a scan sequence are indicated before the initiation of a scan or a scan sequence. For equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions must be visible from any position from which scan initiation is possible.

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

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

(V) All emergency buttons or switches must be clearly labeled as to their functions.

(VI) Termination of exposure must meet the following requirements.

(-a-) Means must 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 equipment failure affecting data collection. Such termination must occur within an interval limiting the total scan time to no more than 110 percent of its preset value using either a backup timer or a device that monitors equipment function.

(-b-) A signal visible to the operator must indicate when the x-ray exposure has been terminated through the means required by item (-a-) of this subclause.

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

(VII) CT systems containing a gantry must meet the following requirements.

(-a-) The total error in the indicated location of the tomographic plane or reference plane must not exceed 5 mm.

(-b-) If the x-ray production period is less than 0.5 seconds, the indication of x-ray production must be actuated for at least 0.5 seconds. Indicators at or near the gantry must be discernible from any point external to the patient opening, where insertion of any part of the human body into the primary beam is possible.

(-c-) The deviation of indicated scan increment versus actual increment must not exceed plus or minus 1 mm with any mass from 0 to 100 kilograms (kg) resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented distance or 30 cm, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

(ii) Additional requirements for CT systems integrated with virtual simulation features and linear accelerator capabilities (e.g., 3-D cone beam or modulation).

(I) QA procedures for the CT simulation system must be performed with an established protocol meeting or exceeding nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations.

(II) QA procedures for the CT simulation system must be in writing, or documented in an electronic reporting system, by a licensed medical physicist with a specialty in therapeutic radiological physics.

(III) The electronic transfer of the treatment delivery parameters to the delivery system must be verified at the treatment location. The CT simulation treatment planning and the linear accelerator must interface accurately.

(iii) QA for CT simulation software.

(I) QA procedures for CT simulation software systems must be in writing, or documented in an electronic reporting system, by a licensed medical physicist with a specialty in therapeutic radiological physics.

(II) The protocol established must meet or exceed nationally recognized, published guidelines from a professional body with expertise in the use of therapeutic radiation technologies or manufacturer recommendations.

(III) The CT QA procedures must include:

(-a-) spatial/geometry accuracy tests;

(-b-) evaluation of digitally reconstructed radiographs; and

(-c-) periodic QA testing.

(IV) The electronic transfer of the treatment delivery parameters to the delivery system must be verified at the treatment location. The software for the CT simulation treatment planning computer and the linear accelerator must interface accurately.

(iv) Dose measurements of the radiation output of the CT system.

(I) Dose measurements must be completed as specified in §289.227(n)(3) of this chapter.

(II) Equipment performance evaluations (EPEs) must be completed as specified in §289.227(o) of this chapter.

(III) Records of dose measurements and EPEs specified in subclause (I) and (II) of this clause must be maintained by the registrant as specified in subsection (l) of this section for inspection by the department.

(D) A maintenance schedule must be developed as specified by the manufacturer. The schedule must include:

(i) dose measurements required by subparagraph (C)(iv) of this paragraph; and

(ii) acquisition of images obtained with phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by subparagraph (F) of this paragraph. The registrant must maintain either of the following as specified in subsection (l) of this section for inspection by the department:

(I) copies of the images obtained from the image display device; or

(II) images stored in digital form.

(E) Conventional radiation therapy simulation systems designed with x-ray or fluoroscopic capabilities.

(i) Film processing.

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

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

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

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

(V) Corrections or repairs of the light leaks or other deficiencies in subclauses (II), (III), and (IV) of this clause must 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 department. Records of the correction or repairs must include the date and initials of the individual performing these functions and must be maintained as specified in subsection (l) of this section for inspection by the department.

(VI) Documentation of the items in subclauses (II), (III), and (V) of this clause must be maintained at the site where performed and must include the date and initials of the individual completing these items. These records must be kept as specified in subsection (l) of this section for inspection by the department.

(ii) Alternative processing systems. Users of daylight processing systems, laser processors, self-processing film units, or other alternative processing systems must follow the manufacturer's recommendations for image processing. Documentation that the registrant is following the manufacturer's recommendations must include the date and initials of the individual completing the document and must be maintained at the site where performed as specified in subsection (l) of this section for inspection by the department.

(iii) Digital imaging acquisition systems. Users of digital imaging acquisition systems must follow the QA protocol for image processing established by the manufacturer or, if no manufacturer's protocol is available, by the registrant. The registrant must include the protocol, whether established by the registrant or the manufacturer, in its OSP. The registrant must document the frequency at which the QA protocol is performed. Documentation must include the date and initials of the individual completing the document and must be maintained at the site where performed as specified in subsection (l) of this section for inspection by the department.

(F) Additional requirements for conventional radiation therapy simulation systems used in the general radiographic mode of operation for radiation therapy port documentation.

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

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§289.229(h)(5)(F)(i)

Figure: 25 TAC §289.229(h)(5)(F)(i)

TABLE IV
HALF-VALUE LAYER FOR SELECTED kVp

	X-ray tube voltage (kilovolt peak)	Minimum HVL (mm of aluminum)	Minimum HVL (mm of aluminum)
Designed Operating Range	Measured Operating Potential	X-ray Systems Manufactured before June 10, 2006 (Except Dental)	X-ray Systems Manufactured On or After June 10, 2006 (Except Dental)
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) Technique and exposure indicators.

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

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

(iii) Beam limitation.

(I) The beam limiting device (collimator) must restrict the useful beam to the area of clinical interest.

(II) A method must be provided to visually define the center (cross-hair centering) of the x-ray field to within a 2 mm diameter.

(III) A method must be provided to accurately indicate the distance to within 2 mm.

(IV) The delineator wires must be accurate with the indicated setting within 2 mm.

(V) The x-ray field must be congruent with the light field within 2 mm.

(iv) Timers. Means must 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 must not be possible to make an exposure when the timer is set to a "zero" or "off" position and a visual and audible signal must indicate when an exposure has been terminated.

(v) Automatic exposure control (AEC). When an AEC is provided, an indication must be made on the control panel when this mode of operation is selected.

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

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

(viii) Linearity.

Figure: 25 TAC §289.229(h)(5)(F)(viii)

The average ratios of exposure mR to the indicated mAs product obtained at any two consecutive mA or mAs settings must not differ by more than 0.10 times their sum, where X_1 and X_2 are the average mR/mAs values obtained at each of two consecutive tube current settings:

$$|\bar{x}_1 - \bar{x}_2| \leq 0.10(\bar{x}_1 + \bar{x}_2)$$

(G) Additional requirements for radiation therapy simulation systems utilizing fluoroscopic capabilities.

(i) X-ray production in the fluoroscopic mode must be controlled by a device requiring continuous pressure by the fluoroscopist for the entire time of the exposure (continuous pressure type switch).

(ii) During fluoroscopy and cinefluorography, the kV and the Milliampere (mA) must be continuously indicated at the control panel and the fluoroscopist's position.

(iii) The SSD must not be less than 20 cm for image-intensified fluoroscopes used for examinations as specified in the registrant's OSP. The written OSP must provide precautionary measures to be adhered to during the use of this device. The procedures must provide information on the means to restore the unit to a 30 cm SSD when the unit is returned to general service.

(iv) Fluoroscopic timers must meet the following requirements.

(I) Means must be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device must not exceed five minutes without resetting.

(II) A signal audible to the fluoroscopist must indicate the completion of any preset cumulative on-time. The signal must continue to sound while x-rays are produced until the timing device is reset. In lieu of such a signal, the timer must terminate the beam after the preset cumulative on-time is completed.

(v) The exposure foot switch must be permanently mounted in the control booth to ensure the operator cannot enter the simulator room while the fluoroscope is activated.

(vi) Radiation therapy simulation systems must duplicate the geometric conditions of the radiation therapy equipment plan, and therefore measurements regarding geometric conditions must be performed as specified in subsection (h)(3)(C)(iii)(I) of this section.

(vii) If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment-delivery parameters to the treatment-delivery unit must be verified at the treatment location.

(i) Medical events.

(1) Medical events involving equipment operating at energies below 1 MeV and EBT devices must be reported when:

(A) the event involves the wrong individual, or the wrong treatment site;

(B) the treatment consists of three or fewer fractions, and the calculated total administered dose differs from the total prescribed dose by more than 10 percent; or

(C) the calculated total administered dose differs from the total prescribed dose by more than 20 percent.

(2) Medical events involving equipment operating with energies of 1 MeV and above must be reported when:

(A) the event involves the wrong individual, wrong type of radiation, wrong energy, or wrong treatment site;

(B) the treatment consists of three or fewer fractions, and the calculated total administered dose differs from the total prescribed dose by more than 10 percent;

(C) the calculated total administered dose differs from the total prescribed dose by more than 20 percent; or

(D) the combination of external beam radiation therapy and radioactive material therapy causes over-radiation of a patient resulting in physical injury or death.

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(j) Reports of medical events.

(1) For a medical event, a registrant must do the following:

(A) notify the department by telephone no later than 24 hours after the discovery of the event;

(B) notify the referring physician and the patient of the event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant that either the referring physician will inform the patient or that based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant must notify the patient as soon as possible. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the event, because of any delay in notification;

(C) submit a written report to the department within 15 days after the discovery of the event. The report must not include the patient's name or other information that could lead to the identification of the patient. The written report must include the following:

(i) registrant's name and certificate of registration number;

(ii) prescribing physician's name;

(iii) a brief description of the event;

(iv) why the event occurred;

(v) the effect on the patient;

(vi) what improvements are needed to prevent recurrence;

(vii) actions taken to prevent recurrence;

(viii) whether the registrant notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient"); and if not, why not; and

(ix) if the patient was notified, what information was provided to the patient; and

(D) furnish the following to the patient within 15 days after discovery of the event if the patient was notified:

(i) a copy of the report that was submitted to the department; or

(ii) a brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the department can be obtained from the registrant.

(2) Each registrant must retain a record of each event as specified in subsection (l) of this section for inspection by the department. The record must contain the following:

(A) the names of all involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician);

(B) the patient's identification number;

(C) a brief description of the event;

(D) why it occurred;

(E) the effect on the patient;

(F) what improvements are needed to prevent recurrence; and

(G) the actions taken to prevent a recurrence.

(3) Aside from the notification requirement, nothing in subsection (i) of this section and paragraphs (1) and (2) of this subsection affects any rights or duties of registrants, and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

(k) Emerging and future technologies.

(1) Each registrant must develop, implement, and maintain a dedicated quality management program to control the process of administering therapeutic radiation with newly acquired FDA-cleared emerging technologies or previously unused features of a future technology system.

(2) Implementation and ongoing clinical use of the technology dated before the technology arrives at the facility or the new features are used must include:

(A) an explicit strategy to ensure the quality of processes and patient safety; and

(B) an approval from facility management and the radiation oncology safety team before the technology arrives or new features are used.

(3) The radiation oncology safety team must develop the quality management program.

(4) The quality management program must address, at a minimum:

(A) education and training about the new technology and features;

(B) a system and timeline for ongoing competency assessment;

(C) a system for real-time recording of ongoing issues related to the technology and clinical use of the new technology or features;

(D) a strategy for timely investigation and adjudication of accidents and process deviations that may be captured in the system developed in paragraph (2) of this subsection;

(E) a strategy for routine review at intervals not to exceed 12 months of the clinical use of the new technology and features, which includes an assessment of the current use compared to paragraph (2) of this subsection and plan to either update the clinical use plan or steps to bring the clinical use back into alignment with paragraph (2) of this subsection;

(F) a strategy to ensure the quality of equipment functions; and

(G) an explicit strategy for ensuring quality after hardware and software updates and after equipment repair.

(5) The quality management program must follow current published recommendations from a recognized national professional association with expertise in therapeutic radiation technologies. In the absence of a protocol published by a national professional association, the manufacturer's protocol or equivalent quality, safety, and security protocol must be followed.

(6) New technology issues must be reported to the manufacturer and the department, and be reviewed and addressed via the registrant’s reporting system.

(l) Records for department inspection. The registrant must maintain the following records at the time intervals specified, for inspection by the department. The records may be maintained in electronic format.

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Figure: 25 TAC §289.229(l)

	Name of Record	Rule Cross-Reference	Time Interval Required for Record Keeping
Accelerators used for research and developments and Industrial Operations			
(A)	Initial surveys	(f)(2)(C)	Until termination of registration
(B)	Tests and repairs	(f)(3)(A)(x)	5 years
(C)	Calibration, surveys	(f)(3)(F)	5 years
(D)	Contamination smear for units operating greater than 10 MeV	(f)(3)(G)	Until termination of registration
(E)	Receipt, transfers, and disposal	(f)(3)(H)	Until termination of registration
(F)	Training for operators	(f)(4)(B)	Until 2 years after the individual terminates employment
Therapeutic radiation machines, radiation therapy simulation systems, and EBT devices			
(G)	Credentials of operators EBT device operators	(h)(1)(C) (h)(1)(E)	Until 2 years after the individual terminates employment
(H)	Review of quality assurance program	(h)(1)(F)(vii)	5 years
(I)	Written OSP	(h)(1)(G)	Until transfer of machine or termination of registration
(J)	FDA variances	(h)(1)(H)	Until transfer of machine or termination of registration

(K)	Initial and Subsequent Surveys Therapy (below 1 MeV) Therapy (1 MeV and above) EBT device	 (h)(2)(D)(i)(II) (h)(3)(C)(i)(III) (h)(4)(B)(i)(II)	Until termination of registration
(L)	Calibration Therapy (below 1 MeV) Therapy (1 MeV and above) EBT device	 (h)(2)(D)(ii)(V) (h)(3)(C)(ii) (h)(4)(B)(ii)	5 years
(M)	Contamination Smears for units operating greater than 10 MeV	(h)(1)(I)	Until termination of registration
(N)	QA checks and corrective actions Therapy (below 1 MeV) Therapy (1 MeV and above) EBT device	 (h)(2)(D)(iii)(VI) (h)(3)(C)(iii)(VII) (h)(4)(B)(iii)	5 years after the QA checks
(O)	Leakage measurements Therapy (1 MeV and above)	 (h)(3)(A)(i)	5 years
(P)	Protective devices for radiation therapy simulation systems	(h)(5)(A)(iii)(II)	3 years
(Q)	Film processing records for simulators	(h)(5)(E)(i)(V), (VI) and (ii)	3 years
(R)	Digital imaging acquisition systems	(h)(5)(E)(iii)	3 years
(S)	CT dose measurements	(h)(5)(C)(iv)(III)	5 years

(T)	CT films resulting from quality control tests	(h)(5)(D)(ii)	1 year or until a new phantom image is performed
(U)	Reports of medical events	(j)(2)	Until termination of registration