



25 TEXAS ADMINISTRATIVE CODE

§289.229

**Radiation Safety Requirements for Accelerators,
Therapeutic Radiation Machines, and Simulators**

(effective October 1, 2000)

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TEXAS REGISTER FORMAT EXPLANATION

The following example is the outline format used for all agency rules. This explanation will help you locate the different references stated throughout the rule:

§289.xxx = sections are the titles	289.252 Licensing of Radioactive Material.
(a) = subsections are the lowercase letters in parenthesis	(a) Appendices.
(1) = paragraphs are the numbers in parenthesis	(1) Criteria relating to use of financial tests and parent company...
(A) = subparagraphs are the UPPERCASE letters in parenthesis	(A) Financial test.
(i) = clauses are the <i>italicized</i> lowercase roman numerals in parenthesis	(i) To pass the financial test, the parent company...
(I) = subclauses are the <i>italicized</i> UPPERCASE roman numerals in parenthesis	(I) The parent company shall have:
(-a-) = items are the lowercase letters with hyphens in parenthesis	(-a-) two of the following...:
(-1-) = subitems are the numbers with hyphens in parenthesis	(-1-) a ratio of total liabilities to...;

FOR EXAMPLE:

When the rule states “paragraph (1) of this subsection”, the rule is referring to paragraph “(1)” within subsection “(a).”

When the rule states “subsection (d) of this section”, the rule is referring to subsection “(d)” within the section, for example, §289.252.

**WHERE CAN THE FORMS REFERENCED
WITHIN THE RULE BE FOUND?**

Forms that are referenced in this rule can be downloaded from
the Bureau of Radiation Control web site at:

www.tdh.state.tx.us/ech/rad/pages/brc.htm

Or call (512) 834-6688 to request a copy of the forms

25 TEXAS ADMINISTRATIVE CODE

§289.229 Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, and Simulators.

(a) Purpose. This section establishes radiation safety requirements for the use of accelerators, therapeutic radiation machines, and radiation therapy simulation systems (simulators). No person shall possess, use, transfer, or acquire an accelerator, a therapeutic radiation machine, or a radiation therapy simulation system (simulator) except as authorized in a certificate of registration issued in accordance with §289.226 of this title (relating to Registration of Radiation Machine Use and Services) or as otherwise provided for in this chapter.

(b) Scope.

(1) This section applies to persons who receive, possess, use or transfer accelerators used in industrial operations and research and development, and therapeutic radiation machines and radiation therapy simulation systems (simulators) used in the healing arts and veterinary medicine. Use of therapeutic radiation machines in the healing arts or veterinary medicine under this section shall be made by or under the supervision of a practitioner of the healing arts or a veterinarian. The registrant shall be responsible for the administrative control and for directing the use of the accelerators, other therapeutic radiation machines, or simulators.

(2) The requirements of this section are in addition to and not in substitution for other applicable requirements of §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.226 of this title, and §289.231 of this title (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 title (relating to Radiation Safety Requirements and Licensing and Registration Procedures for Industrial Radiography).

(c) Prohibitions.

(1) The agency may prohibit use of accelerators, therapeutic radiation machines, and simulators that pose significant threat or endanger occupational and public health and safety, in accordance with §289.205 of this title and §289.231 of this title.

§289.229(c)(2)

(2) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing arts purposes.

(3) No research and/or development using radiation machines on humans shall be conducted unless approved by an Institutional Review Board (IRB) as required by Title 45, Code of Federal Regulations (CFR) Part 46 and Title 21, CFR Part 56. The IRB shall include at least one practitioner of the healing arts to direct any use of radiation in accordance with §289.231(b) of this title.

(d) Exemptions.

(1) Veterinary facilities are exempt from the aural communication requirements for radiation therapy systems and radiation therapy simulators in subsection (h)(2)(B)(i), (h)(3)(B)(v), or (h)(4)(A)(iv) of this section.

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

(A) §289.203(b) and (c) of this title; and

(B) subsection (h)(1)(D) of this section.

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

(1) Aluminum equivalent - The thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question. The nominal chemical composition of type 1100 aluminum alloy is 99% minimum aluminum, 0.12% copper.

(2) Attenuate - To reduce the exposure rate upon passage of radiation through matter.

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

(4) Automatic exposure rate control (AERC) - A device that automatically controls one or more technique factors in order to obtain a required quantity of radiation per unit time at preselected locations.

§289.229(e)(5)

- (5) Barrier (See definition for protective barrier).
- (6) Beam axis - A line from the source through the centers of the x-ray field.
- (7) Beam-flattening filter - A filter used to provide dose uniformity over the area of a useful x-ray beam at a specified depth.
- (8) Beam-limiting device - A device that provides a means to restrict the dimensions of the x-ray field.
- (9) Beam quality - A term that describes the penetrating power of the x-ray beam. This is identified numerically by half-value layer and is influenced by kilovolt peak (kVp) and filtration.
- (10) Beam quality (accelerator) - A term that describes the type and penetrating power of the ionizing radiation produced for certain machine settings.
- (11) Beam monitoring system - A dosimetry system designed to detect and measure the radiation present in the useful beam.
- (12) Beam scattering foil - A foil used to scatter a beam of electrons.
- (13) Calibration of machines - The measurement and specification of absorbed dose to a medium, or exposure in air, at a defined point in a radiation beam.
- (14) 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.
- (15) Coefficient of variation or C - The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

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

where: s ' estimated standard deviation of the population
 \bar{X} ' mean value of observations in sample
 X_i ' i th observation in sample
 n ' number of observations in sample

§289.229(e)(16)

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

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

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

(19) 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.

(20) CT conditions of operation - All selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in this subsection.

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

(22) Diagnostic x-ray system - An x-ray system designed for irradiation of any part of the human body or any animal for the purpose of diagnosis or visualization.

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

(24) Dose monitoring system - A system of devices for the detection, measurement, and display of quantities of radiation.

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

(26) Existing equipment - Therapy systems subject to subsections (h)(2) and (h)(3) of this section that were manufactured on or before March 1, 1989.

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

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

§289.229(e)(29)

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

(30) Gantry - That part of the system supporting and allowing possible movement of the radiation source.

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

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

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

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

(35) Inherent filtration - The filtration of the useful beam provided by the permanently installed components of the x-ray tube housing assembly.

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

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

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

(39) Isocenter - A fixed point in space located at the center of the smallest sphere through which the central axis of the beam passes in all conditions.

(40) Kilovolt - kV (See definition for peak tube potential).

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

§289.229(e)(42)

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

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

(44) Leakage technique factors - The technique factors associated with the source assembly that is used in measuring leakage radiation.

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

(46) Medical research - The investigation of various health risks and diseases using radiation machines as part of the evaluation process.

(47) Moving beam radiation therapy - Radiation therapy with any planned displacement of radiation field or with any planned change of absorbed dose distribution.

(48) New equipment - Systems subject to subsections (h)(2) and (h)(3) of this section that were manufactured after March 1, 1989.

(49) Nominal treatment distance - The following treatment distances shall apply.

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

(B) For x-ray irradiation, the distance from the target along the central axis of the useful beam to the isocenter. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

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

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

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

§289.229(e)(52)

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

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

(55) Primary dose monitoring system - A system that will monitor the useful beam during irradiation and that will terminate irradiation when a preselected number of dose monitor units have been acquired.

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

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

(58) 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 stray radiation to the required degree.

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

(60) Radiation oncologist - A practitioner with a specialty in radiation therapy.

(61) Radiation therapy simulation system (simulator) - 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.

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

§289.229(e)(63)

(63) 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.

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

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

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

(67) Secondary dose monitoring system - A system that will terminate irradiation in the event of failure of the primary system.

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

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

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

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

(72) Spot check - Those tests and analyses performed at specified intervals for the purpose of verifying the consistent output of radiation equipment.

(73) Stationary beam therapy - Radiation therapy without relative displacement of the useful beam.

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

§289.229(e)(75)

(75) Termination of irradiation - The stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(76) Therapy system - An x-ray system that utilizes prescribed doses of ionizing radiation for treatment.

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

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

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

(80) Wedge filter - An added filter effecting continuous progressive attenuation on all or part of the useful beam.

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

(1) Registration. Each person possessing an accelerator shall apply for and receive a certificate of registration in accordance with §289.226(k) of this title before activation of the accelerator, including acceptance testing.

(2) Facility requirements.

(A) Each accelerator facility shall be provided with primary and/or secondary barriers as are necessary to assure compliance with §289.231(m) and (o) of this title.

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

(C) Initial surveys shall be performed as follows.

(i) All new and existing facilities not previously surveyed shall have a survey made by, or under the direction of, the registrant.

§289.229(f)(2)(C)(ii)

(ii) A survey report shall be made and shall include, but not be limited to, the following:

(I) a diagram of the facility that details 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; and

(V) survey data including:

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

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

(iii) The registrant shall maintain a copy of the survey report for inspection by the agency in accordance with subsection (k) of this section.

(iv) The survey report shall include documentation of all instances where the facility is in violation of applicable requirements of this chapter. Any deficiencies detected during the survey shall be corrected prior to using the accelerator.

(3) Safety requirements.

(A) Interlock systems shall comply with the following requirements.

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

(ii) Each entrance into a target room or other high radiation area shall be provided with a safety interlock that shuts down the machine under conditions of barrier penetration.

§289.229(f)(3)(A)(iii)

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

(iv) Each safety interlock shall be on an electrical circuit that allows the interlock to operate independently of all other safety interlocks.

(v) All safety interlocks shall be designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

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

(vii) The safety interlock system shall have a visible or audible alarm that will indicate when any interlock has been activated.

(viii) All interlocks and visible or audible alarms shall be tested for proper operation at intervals not to exceed three months.

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

(x) Records of tests and repairs required by this paragraph shall be made and maintained in accordance with subsection (k) of this section for inspection by the agency.

(B) Each registrant shall develop and implement written operating and safety procedures. The procedures shall include, but may not be limited to, the following:

(i) methods used to secure the accelerator from unauthorized use;

(ii) methods of testing and training operators in accordance with paragraph (4) of this subsection;

(iii) procedures for notifying the proper personnel in the event of an accident;

(iv) posting requirements;

(v) procedures for testing interlocks, entrance controls, and alarm systems;

§289.229(f)(3)(B)(vi)

- (vi) personnel monitoring;
- (vii) maintenance of records; and
- (viii) procedures for necessary area surveys and time intervals.

(C) There shall be available at each accelerator facility, appropriate portable monitoring equipment that is operable and has been calibrated for the appropriate radiations being produced at the facility. The equipment shall be calibrated in accordance with §289.231(s)(2) of this title.

(D) A radiation protection survey shall 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 generators that are used at temporary job sites where permanent shielding is not available, radiation protection shall 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 in accordance with subparagraphs (C) and (D) of this paragraph shall be maintained in accordance with subsection (k) of this section.

(4) Training requirements for operators.

(A) No person shall be permitted to operate an accelerator unless such person has received instruction in and demonstrated competence with the following:

- (i) operating and safety procedures in accordance with 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 an actual or suspected exposure.

§289.229(f)(4)(B)

(B) Records of the training specified in subparagraph (A) of this paragraph shall be made and maintained for agency inspection in accordance with subsection (k) of this section.

(5) Records/documents.

(A) The registrant shall maintain copies of the following records/documents at authorized use locations in accordance with subsection (k) of this section:

(i) current applicable sections of this chapter as listed on the certificate of registration;

(ii) current certificate of registration;

(iii) surveys of radiation levels in unrestricted areas in accordance with paragraph (2)(B) of this subsection;

(iv) personnel monitoring records of occupationally exposed individuals in accordance with §289.231(r) of this title, as applicable;

(v) current operating and safety procedures in accordance with paragraph (3)(B) of this subsection or §289.255 of this title, as applicable;

(vi) operator training in accordance with paragraph (4)(B) of this subsection;

(vii) notice of violation from last inspection, if applicable, and documentation of corrections of violations;

(viii) receipt, transfer, and disposal of accelerators including the date, manufacturer name, model and serial number from the control panel or console of the radiation machine, and identification of the person making the record;

(ix) latest calibrations for each survey instrument in use at the authorized use location in accordance with paragraph (3)(F) of this subsection;

(x) interlock and alarm tests in accordance with paragraph (3)(A)(x) of this subsection; and

(xi) latest radiation survey records in accordance with paragraphs (2)(C)(iii) or (3)(F) of this subsection.

§289.229(f)(5)(B)

(B) Records specified in subparagraph (A) of this paragraph may be maintained in electronic format.

(g) Requirements for accelerator(s) used in industrial radiography. In addition to the requirements in subsections (f)(1), (2), (3)(C)-(F), and (5) of this section, accelerators used for industrial radiography shall meet the applicable requirements of §289.255 of this title.

(h) Therapeutic radiation machines and simulators used in the healing arts and veterinary medicine.

(1) General requirements.

(A) Each person possessing a therapeutic radiation machine capable of operating at or above 1 million electron volts (MeV) shall apply for and receive a certificate of registration from the agency before activation of the radiation machine, including acceptance testing.

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

(C) Individuals who operate radiation machines for human use shall meet the appropriate credentialing requirements issued in accordance with the Medical Radiologic Technologist Certification Act, Texas Occupations Code, Chapter 601. Copies of the credentialing document shall be maintained at the locations(s) where the individual is working.

(D) Each registrant shall develop and implement written operating and safety procedures. These procedures shall be made available to each individual operating radiation machines and simulators, including any restrictions of the operating technique required for the safe operation of the particular therapeutic radiation system. These procedures shall include, but are not limited to the following:

(i) use of a technique chart in accordance with paragraph (4)(A)(i) of this subsection for simulators;

(ii) radiation dose requirements in accordance with §289.231(m) and (o) of this title;

(iii) personnel monitoring requirements in accordance with §289.231(n) of this title;

§289.229(h)(1)(D)(iv)

(iv) use of protective devices in accordance with paragraph (4)(A)(iii) of this subsection for simulators;

(v) credentialing requirements for individuals operating radiation machines in accordance with subparagraph (C) of this paragraph;

(vi) exposure of individuals other than the patient in accordance with paragraphs (2)(D)(iv)(IV), and (3)(C)(v)(I) of this subsection;

(vii) film processing program in accordance with paragraph (4)(A)(vii) and (viii) of this subsection for simulators;

(viii) procedures for restriction and alignment of beam in accordance with paragraph (4)(B)(iii) of this subsection;

(ix) posting notices to workers in accordance with §289.203(b) of this title;

(x) instructions to workers in accordance with §289.203(c) of this title;

(xi) notifications and reports to individuals in accordance with §289.203(d) of this title; and

(xii) posting of a radiation area in accordance with §289.231(x) and (y) of this title.

(E) Registrants with equipment that has been issued variances by the United States Food and Drug Administration (FDA) to Title 21, CFR Part 1020 shall maintain copies of those variances at authorized use locations in accordance with subsection (k) of this section.

(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 shall not exceed the values specified at the distance stated for the classification of that 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.

§289.229(h)(2)(A)(i)

TABLE I.

System	Leakage Limit	Measurement Location
Contact Therapy	100 mR/hr	5 cm from surface of tube housing
0-150 kVp (manufactured or installed prior to March 1, 1989)	1 R in 1 hr	1 m from source
0-150 kVp (manufactured on or after March 1, 1989)	100 mR in 1 hr	1 m from source
151-499 kVp	1 R in 1 hr	1 m from source

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

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

(I) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1.0% 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 installed before March 1, 1989, shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5.0% of the useful beam at the maximum kVp and maximum treatment filter.

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

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

§289.229(h)(2)(A)(iv)(I)

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

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

(III) the radiation at 5 centimeters (cm) from the filter insertion slot opening does not exceed 30 roentgens per hour (R/hr) 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 shall appear on the wedge or wedge tray.

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

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

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

(viii) The timer shall:

(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. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero;

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

(IV) permit selection of exposure times as short as one second;

(V) not permit an exposure if set at zero;

§289.229(h)(2)(A)(viii)(VI)

(VI) 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

(VII) be accurate to within 1.0% of the selected value or one second, whichever is greater.

(ix) The control panel, in addition to the displays required in clause (viii)(I) of this subparagraph, shall 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 that will prevent unauthorized use of the therapeutic radiation system (a computerized pass-word system would also constitute a locking device);

(VI) for therapeutic radiation systems manufactured after March 1, 1989, a positive display of specific filters in the beam; and

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

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

(xi) Unless it is possible to bring the radiation output to the prescribed exposure parameters within five seconds, the beam shall 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 shall be controlled electrically by the operator from the control panel. An indication of shutter position shall appear at the control panel.

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

§289.229(h)(2)(B)

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

(i) Provision shall 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 system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

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

(II) In a facility that has a primary viewing system by electronic means and an alternate viewing system, should both viewing systems described in clause (ii) of this subparagraph fail or be inoperative, treatment shall 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 shall be provided with primary and/or secondary barriers as are necessary to assure compliance with §289.231(m) and (o) of this title. All protective barriers shall be fixed except for entrance doors or beam interceptors.

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

(iii) Interlocks shall be provided such that all entrance doors shall be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel. When any door is opened while the x-ray tube is activated, the exposure at a distance of 1 meter (m) from the source shall be reduced to less than 100 mR/hr.

(D) Surveys, calibrations, spot checks, and additional operating procedures.

(i) Surveys shall be performed as follows.

§289.229(h)(2)(D)(i)(I)

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

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

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

(ii) Calibrations shall be performed as follows.

(I) The calibration of a therapeutic radiation system shall be performed at intervals not to exceed one year and after any change or replacement of components that could cause a change in the radiation output. The calibrations shall be such that the dose at a reference point in a water or plastic phantom can be calculated to within an uncertainty of 5.0%.

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

(III) The calibration of the therapeutic radiation system shall include, but not be limited to, the following determinations:

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

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

(-c-) the exposure 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 shall be within 5 mm for any field edge.

§289.229(h)(2)(D)(ii)(IV)

(IV) Calibration of the radiation output of a therapeutic radiation system shall be performed with a calibrated dosimetry system. The dosimetry system shall be calibrated within the previous 24 months and shall be traceable to a national standard. During the calendar year in which the dosimetry system is not calibrated, an intercomparison to a system calibrated within the previous 12 months shall be performed.

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

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

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

(I) The spot check procedures shall be in writing and shall 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 spot check measurements, the results of the spot check measurements shall 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 5.0% from the expected value, a licensed medical physicist shall be notified immediately.

(III) The written spot check procedures shall specify the frequency that tests or measurements are to be performed and that the spot check shall 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 shall be stated.

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

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

§289.229(h)(2)(D)(iii)(VI)

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

(VII) Spot checks shall be obtained using a system satisfying the requirements of clause (ii)(IV) of this subparagraph or that has been intercompared with a system meeting those requirements within the previous year.

(iv) In addition to the items listed in paragraph (1)(D) of this subsection, operating and safety procedures shall also include procedures to ensure the following requirements are met.

(I) Therapeutic radiation systems shall not be left unattended unless the system is secured against unauthorized use.

(II) Restraining or mechanical supporting devices shall be used when a patient or port film must be immobilized in position for radiation therapy.

(III) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

(IV) For therapeutic radiation systems operating at or below 150 kVp, no individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of §289.231(o) of this title. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation systems operating above 150 kVp.

(V) The therapeutic radiation system shall not be used in the administration of radiation therapy unless the requirements of clauses (ii) and (iii)(V) of this subparagraph have been met.

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

(A) Equipment requirements.

§289.229(h)(3)(A)(i)

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

(ii) Each wedge filter that is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. The wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge tray is damaged, the wedge transmission factor shall be redetermined. New equipment shall meet the following requirements.

(I) Irradiation shall not be possible until a selection of a filter or a positive selection to use “no filter” has been made at the treatment control panel, either manually or automatically.

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

(III) A display shall be provided at the treatment control panel showing the beam quality in use.

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

(iii) The registrant shall determine data sufficient to assure that 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 shall not exceed the values stated in the following Table II. Linear interpolation shall be used for values not stated.

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 shall be determined using:

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

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

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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 shall be determined by measurements made as follows:

(-a-) within a tissue equivalent phantom using an instrument that will allow 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 that can be removed without the use of tools, except for beam scattering or beam-flattening filters; and

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

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

(I) New equipment shall be provided with at least two independent radiation detectors. The detectors shall be incorporated into two independent dose monitoring systems.

(II) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

§289.229(h)(3)(A)(iv)(III)

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

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

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

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

(-d-) For new equipment, the design of the dose monitoring systems shall assure that the malfunctioning of one system shall not affect the correct functioning of the secondary system; and failure of any element common to both systems that could affect the correct function of both systems shall terminate irradiation.

(-e-) Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

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

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

(-3-) utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

(-4-) retain the dose monitoring information in at least one system for a 20-minute period of time in the event of a power failure.

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

§289.229(h)(3)(A)(vi)

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

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

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

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

(IV) For new equipment, after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

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

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

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

(III) For new equipment, a secondary dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10% or 25 dose monitoring units, whichever is smaller, above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

(IV) For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

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

§289.229(h)(3)(A)(ix)

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

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

(xi) Timers shall meet the following requirements.

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

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

(III) For new equipment, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

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

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

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

(II) An interlock system shall be provided to:

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

§289.229(h)(3)(A)(xii)(II)(-b-)

(-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 control panel;

(-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 shall be displayed at the treatment control panel before and during irradiation.

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

(I) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

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

(III) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

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

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

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

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

§289.229(h)(3)(A)(xiv)(IV)

(IV) For new equipment, an interlock system shall be provided to terminate irradiation if movement of the gantry occurs during stationary beam therapy or stops during moving beam therapy unless such stoppage is a preplanned function.

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

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

(-b-) For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5.0% 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 shall be as required by clause (vii) of this subparagraph.

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

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

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

(B) Facility and shielding requirements.

§289.229(h)(3)(B)(i)

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

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

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

(iv) Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the control panel.

(I) Should the viewing system described in clause (iv) of this subparagraph fail or be inoperative, treatment shall not be performed with the unit until the system is restored.

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

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

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

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

(C) Surveys, calibrations, spot checks, operational requirements, and additional operating procedures.

§289.229(h)(3)(C)(i)

(i) Surveys shall be performed as follows.

(I) All new and existing facilities not previously surveyed shall have a survey made by a licensed medical physicist with a specialty in therapeutic radiological physics or medical health physics, who shall provide a written report of the survey to the registrant. The physicist who performs the survey shall be a person who did not consult in the design of the therapeutic radiation machine installation and is not employed by or within any corporation or partnership with the person who consulted in the design of the installation. In addition, such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

(II) The survey report shall include, but not be limited to the following:

(-a-) a diagram of the facility that details building structures and the position of the control panel, 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 shall maintain a copy of the survey report and a copy of the survey report shall be provided to the agency within 30 days of completion of the survey. Records of survey report shall be maintained in accordance with subsection (k) of this section for inspection by the agency.

§289.229(h)(3)(C)(i)(IV)

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

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

(I) The calibration of systems subject to this subsection shall be performed in accordance with an established calibration protocol before the system is first used for irradiation of a patient and thereafter at time intervals that do not exceed 12 months and after any change that might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The calibration procedures shall be in writing, and shall have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics. The calibration protocol entitled, "Protocol for Clinical Reference Dosimetry of High-Energy Photon and Electron Beams," Task Group 51, Radiation Therapy Committee, American Association of Physicists in Medicine, Medical Physics 26(9): 1847-1870, September 1999, is accepted as an established protocol. If Task Group 51 protocol for calibration is not used, at a minimum the calibration protocol shall include items in subclauses (III)-(V) of this clause below.

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

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

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

(-b-) that has been calibrated within the previous 24 months and after any servicing that may have affected its calibration. During the calendar years in which the dosimetry system is not calibrated, an intercomparison to a system calibrated within the previous 12 months shall be performed;

(-c-) that has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

(-d-) that has had constancy checks performed on the system as specified by the licensed medical physicist with a specialty in therapeutic radiological physics.

§289.229(h)(3)(C)(ii)(IV)

(IV) Calibrations shall be in sufficient detail that the dose at a reference point in a tissue equivalent phantom can be calculated to within an uncertainty of 5.0%.

(V) The calibration of the therapy unit shall include, but not be limited to, 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-) The absorbed dose rate at various depths in a tissue equivalent phantom for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

(-c-) The uniformity of the radiation field to include symmetry, flatness, and dependence on 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/or universal and custom made beam modifying devices.

(VI) Records of calibration measurements specified in subclause (I) of this clause and dosimetry system calibrations specified in subclause (III) of this clause shall be maintained by the registrant in accordance with subsection (k) of this section for inspection by the agency.

(VII) A copy of the latest calibrated absorbed dose rate measured in accordance with subclause (I) of this clause shall be available at a designated area within the facility housing that therapy system.

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

§289.229(h)(3)(C)(iii)(I)

(I) The spot check procedures shall be performed in accordance with established protocol, shall be in writing, and shall have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics. The spot check protocol entitled, "Comprehensive QA for Radiation Oncology," Task Group 40, Radiation Therapy Committee, American Association of Physicists in Medicine, Medical Physics 21(4): 581-618, April, 1994, is accepted as an established protocol. If Task Group 40 protocol for spot checks is not used, at a minimum, the spot check protocol shall include items in subclauses (III)-(VI) of this clause below.

(II) If a licensed medical physicist does not perform the spot check measurements, the results of the spot check measurements shall 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 3.0% from the expected value, a licensed medical physicist shall be notified immediately.

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

(IV) Where a system has built-in devices that provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.

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

(VI) Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in a licensed medical physicist's written procedures, the system shall be recalibrated, as required in this clause of this subparagraph.

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

(VIII) Spot checks shall be obtained using a system satisfying the requirements of subclause (III) of this clause or that has been intercompared with a system meeting those requirements within the previous year.

§289.229(h)(3)(C)(iv)

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

(I) The physicist shall be responsible for:

(-a) calibration of radiation machines;

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

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

(-d) establishment of quality assurance procedures and performance of spot check review; and

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

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

(v) In addition to the items listed in paragraph (1)(D) of this subsection, operating and safety procedures shall also include procedures to ensure the following requirements are met.

(I) No individual other than the patient shall be in the treatment room during treatment of a patient.

(II) Restraining or mechanical supporting devices shall be used if a patient or port film must be immobilized in position during treatment.

(III) The therapeutic system shall not be used in the administration of radiation therapy unless the requirements of clauses (i)-(iv) of this subparagraph have been met.

(4) Radiation therapy simulators.

(A) General requirements. In addition to the general requirements in subsections (h)(1)(B)-(E) of this section, radiation therapy simulators shall comply with the following:

§289.229(h)(4)(A)(i)

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

(ii) Operating and safety procedures. Each registrant shall have and implement written operating and safety procedures in accordance with subsection (h)(1)(D) of this section.

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

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

(II) Protective devices, including aprons, gloves, and shields shall be checked annually for defects, such as holes, cracks, and tears. These checks may be performed by the registrant by visual, tactile, or x-ray imaging. If a defect is found, equipment shall be replaced or removed from service until repaired. A record of this test shall be made and maintained by the registrant in accordance with subsection (k) of this section for inspection by the agency.

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

(v) Operator position. The operator's position during the exposure shall be such that the operator's exposure is as low as reasonably achievable (ALARA) and the operator is a minimum of six 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 tube. In no case shall an individual hold the tube or tube housing assembly supports during any radiographic exposure.

(vii) No individuals other than the patient and the operator(s) shall be in the treatment room during operation of the simulator.

(viii) Film processing.

§289.229(h)(4)(A)(viii)(I)

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

(II) Chemicals shall 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 shall be performed and any light leaks corrected at intervals not to exceed six months.

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

(V) Corrections or repairs of the light leaks or other deficiencies in subclauses (II), (III), and (IV) of this clause shall be initiated within 72 hours of discovery and completed no longer than 15 days from detection of the deficiency unless a longer time is authorized by the agency. Records of the correction or repairs shall include the date and initials of the individual performing these functions and shall be maintained in accordance with subsection (k) of this section for inspection by the agency.

(VI) Documentation of the items in subclauses (II), (III), and (V) of this clause shall be maintained at the site where performed and shall include the date and initials of the individual completing these items. These records shall be kept in accordance with subsection (k) of this section for inspection by the agency.

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

(B) Additional requirements for radiation therapy simulators used in the general radiographic mode of operation.

§289.229(h)(4)(B)(i)

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

TABLE IV.

X-Ray tube voltage (kilovolt peak)	Measured HVL (mm of AL)	
Designed operating range	Measured operating potential	
Below 50-----	30	0.3
	40	0.4
	49	0.5
50 to 70-----	50	1.2
	60	1.3
	70	1.5
Above 70-----	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(ii) Technique and exposure indicators.

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

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

§289.229(h)(4)(B)(iii)

(iii) Beam limitation.

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

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

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

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

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

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

(v) AEC. When an AEC is provided, an indication shall 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 shall 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 shall not exceed 0.05. This requirement applies to clinically used techniques.

§289.229(h)(4)(B)(viii)

(viii) Linearity. The average ratios of exposure mR to the indicated mAs product obtained at any two consecutive mA or mAs settings shall not differ by more than 0.10 times their sum, where \bar{X}_1 and \bar{X}_2 are the average mR/mAs values obtained at each of two consecutive tube current settings:

$$*\bar{X}_1 \& \bar{X}_2* \# 0.10 (\bar{X}_1 \% \bar{X}_2)$$

(C) Additional requirements for radiation therapy simulators utilizing fluoroscopic capabilities.

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

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

(iii) The SSD shall not be less than the 20 cm for image-intensified fluoroscopes used for examinations as specified in the registrant's operating and safety procedures. The written operating and safety procedures shall provide precautionary measures to be adhered to during the use of this device. The procedures shall 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 shall meet the following requirements.

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

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

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

(vi) Simulators shall duplicate the geometric conditions of the radiation therapy equipment plan and therefore measurements regarding geometric conditions shall be performed in accordance with subsection (h)(3)(C)(iii)(I) of this section.

§289.229(h)(4)(D)

(D) Additional requirements for radiation therapy simulators utilizing CT capabilities. CT simulators producing digital images only are exempt from the requirements of this subparagraph and paragraph (h)(4)(A)(i), (viii), and (ix) of this subsection.

(i) Equipment requirements.

(I) Tomographic systems shall meet the following requirements.

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

(-b-) For any multiple tomogram system, means shall 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 shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(II) The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On 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 shall be visible from any position from which scan initiation is possible.

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

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

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

(VI) Termination of exposure shall be as follows.

§289.229(h)(4)(D)(i)(VI)(-a-)

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

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

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

(VII) CT x-ray systems containing a gantry manufactured after September 3, 1985, shall meet the following requirements.

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

(-b-) If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 second. Indicators at or near the gantry shall 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 shall not exceed ± 1 mm with any mass from 0 to 100 kilograms (kg) resting on the support device. The patient support device shall 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) Facility design requirements.

(I) Provision shall 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 shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

§289.229(h)(4)(D)(ii)(II)(-a-)

(-a-) Should the viewing system described in subclause (II) of this clause fail or be inoperative, treatment shall not be performed with the unit until the system is restored.

(-b-) In a facility that has a primary viewing system by electronic means and an alternate viewing system, should both viewing systems described in subclause (II) of this clause fail or be inoperative, treatment shall not be performed with the unit until one of the systems is restored.

(iii) Dose measurements of the radiation output of the CT x-ray system.

(I) Dose measurements of the radiation output of the CT x-ray system shall be performed by a licensed medical physicist with a specialty in diagnostic radiological physics. The measurements shall be performed as follows:

(-a-) at intervals not to exceed 12 months;

(-b-) when major maintenance, except x-ray tube replacement, that could affect radiation output is performed; or

(-c-) when a major change in equipment operation (e.g. introduction of a new software package) is accomplished.

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

(III) Records of dose measurements shall be maintained by the registrant in accordance with subsection (k) of this section.

(iv) A maintenance schedule shall be developed in accordance with the manufacturer's United States Department of Health and Human Services maintenance schedule. The schedule shall include, but need not be limited to the following:

(I) dose measurements required by clause (iii)(I) of this subparagraph; and

§289.229(h)(4)(D)(iv)(II)

(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 clause (iii)(I) of this subparagraph. The registrant shall retain either of the following in accordance with subsection (k) of this section for inspection by the agency:

(-a-) photographic copies of the images obtained from the image display device; or

(-b-) images stored in digital form.

(5) Records/documents.

(A) The registrant shall maintain copies of the following records/documents at each authorized use location in accordance with subsection (k) of this section for inspection by the agency:

(i) current applicable sections of this chapter as listed on the certificate of registration;

(ii) current certificate of registration;

(iii) current operating and safety procedures in accordance with subsection (h)(1)(D) of this section;

(iv) receipt, transfer, and disposal of radiation machines specific to that location including the date, manufacturer name, model and serial number from the control panel or console of the radiation machine and identification of the person making the record;

(v) credentials of operators of radiation machines operating at that location in accordance with subsection (h)(1)(C) of this section;

(vi) film processing records for that location in accordance with subsection (h)(4)(A)(viii) and (ix) of this section, as applicable;

(vii) FDA variances of machines at that location in accordance with subsection (h)(1)(E) of this section;

(viii) CT dose measurements and CT quality control films or images at that location in accordance with subsection (h)(4)(D)(iii)(III) and (iv)(II) of this section;

§289.229(h)(5)(A)(ix)

(ix) therapy (below 1 MeV) surveys, calibrations of equipment, and spot checks at that location in accordance with subsection (h)(2)(D)(i)(II) and (ii)(IV) of this section;

(x) therapy (1 MeV and above) surveys, calibrations of equipment, and spot checks at that location in accordance with subsection (h)(3)(C)(i)(III), (ii)(IV), and (iii)(VII) of this section;

(xi) records, notices, and reports of therapy events in accordance with subsection (j) of this section; and

(xii) notice of violations from last inspection, if applicable, and documentation of corrections of any violations.

(B) Records specified in subparagraph (A) may be maintained in electronic format.

(i) Therapy events (misadministrations).

(1) Therapy events involving equipment operating at energies below 1 MeV shall be reported when:

(A) the event involves the wrong individual, 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% of the total prescribed dose; or

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

(2) Therapy events involving equipment operating with energies of 1 MeV and above shall 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% of the total prescribed dose; or

§289.229(i)(2)(C)

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

(j) Reports of therapy events (misadministrations).

(1) For a therapy event, a registrant shall do the following:

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

(B) notify the referring physician and also notify the patient of the event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the patient or that, based on medical judgement, 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 shall notify the patient as soon as possible thereafter. 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 agency within 15 days after the discovery of the event. The report shall not include the patient's name or other information that could lead to identification of the patient. The written report shall 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

§289.229(j)(1)(C)(ix)

(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 agency; 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 agency can be obtained from the registrant.

(2) Each registrant shall retain a record of each event in accordance with subsection (k) of this section for inspection by the agency. The record shall contain the following:

(A) the names of all individuals 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 recurrence.

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

(k) Records/documents for agency inspection. Each registrant shall make the following records/documents available to the agency for inspection, upon reasonable notice.

§289.229(k)

Name of Record/Document	Rule Cross-Reference	Time Interval for Keeping Record/Document
Accelerators used for research and development and industrial operations		
Initial surveys	(f)(2)(C)	Until termination of registration
Tests and repairs	(f)(3)(A)(x)	3 years
Calibration, surveys	(f)(3)(F)	3 years
Receipt, transfers, and disposal	(f)(5)(A)(viii)	Until termination of registration
Training for operators	(f)(4)(B)	Until individual terminates employment
Therapeutic radiation machines and simulators		
Credentials of Operators	(h)(1)(C)	Until individuals leaves the facility
FDA variances	(h)(1)(E)	Until transfer of machine or termination of registration
Surveys		
Therapy (below 1 MeV	(h)(2)(D)(i)(II)	Until termination of registration
Therapy (1 MeV and above)	(h)(3)(C)(i)	Until termination of registration

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Name of Record/Document	Rule Cross-Reference	Time Interval for Keeping Record/Document
Calibration		
Therapy (below 1 MeV)	(h)(2)(D)(ii)(V)	3 years
Therapy (1 MeV and above)	(h)(3)(C)(ii)(VI)	3 years
Spot checks and corrective actions		
Therapy (below 1 MeV)	(h)(2)(D)(iii)(VI)	3 years after the spot checks
Therapy (1 MeV and above)	(h)(3)(C)(iii)(VII)	3 years after the spot checks
Leakage measurements		
Therapy (1 MeV and above)	(h)(3)(A)(i)	3 years
Protective devices for simulators	(h)(4)(A)(iii)(II)	3 years
Film Processing records for simulators	(h)(4)(A)(viii) and (ix)	3 years
CT dose measurements	(h)(4)(D)(iii)(III)	3 years
CT films resulting from quality control tests	(h)(4)(D)(iv)(II)	1 year or until a new phantom image is performed

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Name of Record/Document	Rule Cross-Reference	Time Interval for Keeping Record/Document
Current 25 TAC §289.229 of this title and other applicable sections of this chapter as listed in the certificate of registration	(h)(5)	Until termination of registration
Receipts, transfer, disposal	(h)(5)(A)(iv)	Until termination of registration
Records, notices, and reports of events	(j)(2)	3 years