25 TEXAS ADMINISRATIVE CODE

§289.229

Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices

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

(a) Purpose. This section establishes radiation safety requirements for the use of accelerators, therapeutic radiation machines, radiation therapy simulation systems (simulators), and electronic brachytherapy devices. No person shall possess, use, transfer, or acquire an accelerator, a therapeutic radiation machine, a radiation therapy simulation system (simulator), or electronic brachytherapy device, 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, radiation therapy simulation systems (simulators), and electronic brachytherapy devices 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 by or under the supervision of a physician of the healing arts or a veterinarian. Use of electronic brachytherapy devices under this section shall be by or under the supervision of a certified physician. The registrant shall be responsible for the administrative control and for directing the use of the accelerators, other therapeutic radiation machines, simulators, or electronic brachytherapy devices.

(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).

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

(c) Prohibitions.

(1) The agency may prohibit use of accelerators, therapeutic radiation machines, simulators, or electronic brachytherapy devices 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.

(2) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a physician of the healing arts. For electronic brachytherapy devices, individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a certified physician. 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, CFR Part 46 and Title 21, CFR Part 56. The IRB shall include at least one physician 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 physicians, 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)(G) 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) Absorbed dose (D)--The mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

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

(3) Air kerma--The kinetic energy released in air by ionizing radiation. Kerma is the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

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

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

(6) Beam-flattening filter--(See field-flattening filter).

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

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

(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 scattering foil--A thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

(12) 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.

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

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(14) 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:

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

where: s = estimated standard deviation of the population

$\overline{X}$ = mean value of observations in sample

X_i = ith observation in sample

n = number of observations in sample.

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

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

(17) 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.

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

(19) 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.

(20) Detector--(See definition for radiation detector).

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

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

(23) Dosimetry system--A system of devices used for the detection, measurement, and display of qualitative and quantitative radiation exposures.

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

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

(26) Electronic brachytherapy source--The x-ray tube component used in an electronic brachytherapy device.

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

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

(29) 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.

(30) Filter--Material placed in the useful beam to change beam quality in therapeutic radiation machines subject to subsection (h) of this section.

(31) 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.

(32) Gantry--That part of the radiation therapy system supporting and allowing possible movements of the radiation head about the center of rotation.

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

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

(35) 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.

(36) 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.

(37) 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.

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

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

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

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

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

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

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

(45) 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.

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

(47) Licensed medical physicist--An individual holding a current Texas license under the Medical Physics Practice Act, Texas Occupations Code, Chapter 602, with a specialty in therapeutic radiological physics.

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

(49) mA--Milliampere.

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

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

(52) Mobile electronic brachytherapy device--An electronic brachytherapy device that is transported from one address to be used at another address.

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

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

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

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

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

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

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

(58) Physician--An individual licensed by the Texas Medical Board.

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

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

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

(62) 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 delivered.

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

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

(65) 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.

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

(67) Radiation detector--A device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring 1 or more quantities of incident radiation.

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

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

(70) Radiation oncologist--A physician with a specialty in radiation therapy.

(71) 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.

(72) Radiation therapy system--An x-ray system that utilizes prescribed doses of ionizing radiation for treatment.

(73) 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.

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

(75) Scan sequence--A preselected set of 2 or more scans performed consecutively under preselected CT conditions of operation.

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

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

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

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

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

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

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

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

(84) 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 physician's control. The physician or veterinarian assumes full responsibility for these tasks and shall assure that the tasks will be administered correctly.

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

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

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

(88) 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.

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

(90) 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.

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

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

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

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

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

(1) Registration. Each person possessing an accelerator for non-human use, shall apply for and receive a certificate of registration from the agency before beginning use of the accelerator. A person may energize the accelerator for purposes of installation and acceptance testing before receiving a certificate of registration from the agency in accordance with §289.226(i)(1) of this title.

(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.

(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 initial survey report for inspection by the agency in accordance with subsection (l) 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.

(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 7 calendar days.

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

(B) Each registrant shall develop and implement written operating and safety procedures. The procedures may be documented in an electronic reporting system and shall include, but 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;

(vi) personnel monitoring;

(vii) maintenance of records; and

(viii) procedures for necessary area surveys and time intervals.

(C) The registrant shall ensure that radiation measurements are performed with a calibrated dosimetry system. The dosimetry system calibration shall be traceable to a national standard. The calibration interval shall not exceed 24 months. 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.

(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 (l) of this section.

(G) The registrant shall perform radiation surveys and contamination smears prior to the transfer or disposal of an accelerator operating at or above 10 MeV. Such survey(s) shall be documented and maintained by the registrant for inspection by the agency in accordance with subsection (l) of this section.

(H) The registrant shall retain records of receipt, transfer, and disposal of all radiation machines specific to each authorized use location. The records shall include 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.

(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.

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

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

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

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

(B) Each person possessing a simulator, a therapeutic radiation machine capable of operating below 1 MeV, and/or an electronic brachytherapy device, 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) The electronic brachytherapy registrant shall require the physician to be:

(i) licensed by the Texas Medical Board; and

(ii) certified in:

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

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

(E) Operators of the electronic brachytherapy device shall complete device-specific training as follows:

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

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

(iii) The registrant shall retain a record of each individual's device-specific training in accordance with subsection (l) of this section for inspection by the agency.

(F) Each facility, including facilities using electronic brachytherapy devices, shall develop a quality assurance program in writing or in an electronic reporting system. The quality assurance program shall be implemented as a method of minimizing deviations from facility procedures and to document preventative measures taken prior to serious patient injury or therapeutic misadministration.

(i) The quality assurance program shall include but not be limited to the following topics:

(I) treatment planning and patient simulation;

(II) charting and documenting treatment field parameters;

(III) dose calculation and review procedures;

(IV) review of daily treatment records; and

(V) for electronic brachytherapy, verification of catheter placement and device exchange procedures;

(ii) A written directive shall be prepared prior to administration of a therapeutic radiation dose except where a delay to provide a written directive would jeopardize the patient's health. The information contained in the oral directive shall be documented immediately in the patient's record and a written directive prepared within 24 hours of the oral directive.

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

(iv) Deviations from the prescribed treatment, from the facilities quality assurance program, and from the operating and safety procedures shall be investigated and brought to the attention of the certified physician or licensed medical physicist, and the radiation safety officer (RSO).

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

(vi) The discovery of each medical event or misadministration shall be reported in accordance with subsection (i) or (j) of this section.

(vii) The review of the quality assurance program shall include all the deviations from the prescribed treatment and shall be conducted at intervals not to exceed 14 months. A signed record of each dated review shall be maintained for inspection by the agency in accordance with subsection (l) of this section and shall include evaluations and findings of the review.

(G) Written operating and safety procedures shall be developed by a licensed medical physicist with a specialty in therapeutic radiological physics and shall include any restrictions required for the safe operation of the particular therapeutic radiation machine. These procedures shall be available in the control area of the therapeutic radiation machine and an electronic brachytherapy device. The operator(s) shall be able to demonstrate familiarity with these procedures. These procedures shall include, but are not limited to the following:

(i) therapeutic radiation machines shall not be used for irradiation of patients unless full calibration measurements and quality assurance checks have been completed;

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

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

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

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

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

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

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

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

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

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

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

(xiii) procedures for restriction and alignment of beam for simulators in accordance with paragraph (4)(B)(iii) of this subsection.

(H) 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 (l) of this section.

(I) The registrant shall perform radiation surveys and contamination smears prior to the transfer or disposal of an accelerator operating at or above 10 MeV. Such survey(s) shall be documented and maintained by the registrant for inspection by the agency in accordance with subsection (l) of this section.

(J) Where applicable, the licensed medical physicist shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. In the absence of such a published protocol, the manufacturer's current protocol shall be followed.

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

(A) Equipment requirements.

(i) When the tube is operated at its leakage technique factors, the leakage radiation 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.

TABLE I

System	Leakage Limit	Measurement Location
0-150 kVp (manufactured or installed prior to March 1, 1989)	1 R (10 mGy) in1 hr	1 meter (m) from source
0-150 kVp (manufactured on or after March 1, 1989)	100 mR (1mGy) in 1 hr	1 m from source
151-499 kVp	1 R (10 mGy) in1 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:

(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) (300 mGy/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;

(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 1 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 5 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.

(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 m from the source shall be reduced to less than 100 mR/hr (1 mGy/hr).

(D) Surveys, calibrations, and spot checks.

(i) Surveys shall be performed as follows.

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

(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 (l) 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 1 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 radiation therapy system is operating in compliance with the design specifications;

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

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

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

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

(V) Records of calibration measurements specified in clause (ii) of this subparagraph shall be maintained by the registrant in accordance with subsection (l) 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, or documented in an electronic reporting system, 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 5 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 with a specialty in therapeutic radiological physics 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.

(VI) Records of written spot checks and any necessary corrective actions shall be maintained by the registrant in accordance with subsection (l) 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.

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

(A) Equipment requirements.

(i) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (mGy) due to leakage radiation, including x rays, electrons, and neutrons, 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 (mGy) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters (cm^2) 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 cm^2. 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 (l) 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. Equipment manufactured after March 1, 1989, 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 console, 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 console 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 console.

(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.

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;

(-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) Equipment manufactured after March 1, 1989, shall be provided with at least 2 independent radiation detectors. The detectors shall be incorporated into 2 independent dose monitoring systems.

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

(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 equipment manufactured after March 1, 1989, the design of the dose monitoring systems shall assure that the malfunctioning of 1 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 console. For equipment manufactured after March 1, 1989, 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 15-minute period of time in the event of a power failure.

(v) In equipment manufactured after March 1, 1989, inherently capable of producing useful beams with unintentional asymmetry exceeding 5.0%, 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 console; and if this difference exceeds 10% of the central axis dose rate, the irradiation shall be terminated.

(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 console.

(II) The preselected number of dose monitor units shall be displayed at the treatment console 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 equipment manufactured after March 1, 1989, after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

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

(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 console has been detected by the secondary dose monitoring system.

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

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

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

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

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

(xi) Timers shall meet the following requirements.

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

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

(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 1 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 console.

(II) An interlock system shall be provided to:

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

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

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

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

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

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

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

(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 console.

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

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

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

(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 console.

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

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

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

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

(-b-) For equipment manufactured after March 1, 1989, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5.0% 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 equipment manufactured after March 1, 1989, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in subparagraph (iv) of this paragraph may form part of this system. In addition, the dose monitor unit rate shall be displayed at the treatment console. If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided that terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be in a record maintained by the registrant in accordance with subsection (l) 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.

(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 console 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 console.

(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 console 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 console.

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

(i) Surveys shall be performed as follows.

(I) All new and existing facilities not previously surveyed shall have an initial survey made by a licensed medical physicist with a specialty in therapeutic radiological physics, who shall provide a written report of the survey to the registrant. 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 console, therapeutic radiation machine, and associated equipment;

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

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

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

(-e-) survey data including:

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

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

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

(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, or documented in an electronic reporting system, 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, would be accepted as an established protocol. 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 is traceable to a national standard and at an interval not to exceed 24 months;

(-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.

(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) Calibration of therapeutic systems containing asymmetric jaws, multileaf collimation, or dynamic/virtual wedges shall be performed with an established protocol. The procedures shall be developed by a licensed medical physicist with a specialty in therapeutic radiological physics and shall be in writing or documented in an electronic reporting system. Current recommendations by a national professional association as the American Association of Physicists in Medicine, Task Group 142 report: "Quality Assurance of Medical Accelerators" published August 17, 2009, would be considered an established protocol.

(VII) 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 (l) of this section for inspection by the agency.

(VIII) 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 radiation 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 5 treatment days. Such radiation output measurements shall meet the following requirements.

(I) The spot check procedures shall be performed in accordance with established protocol, shall be in writing, or documented in an electronic reporting system, and shall have been developed by a licensed medical physicist with a specialty in therapeutic radiological physics. Either 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, or Task Group 142 report: Quality Assurance of Medical Accelerators, published by American Association of Physicists in Medicine on August 17, 2009, are accepted as an established protocol. At a minimum, the spot check protocol shall include items in subclauses (III) - (VI) of this clause.

(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 5 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 (l) of this section for inspection by the agency.

(VIII) Spot checks shall be obtained using a system satisfying the requirements of clause (ii)(III) of this subparagraph.

(iv) Facilities with therapeutic radiation machines with energies of 1 MeV and above 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.

(4) Radiation therapy simulators.

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

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

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

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

(I) Protective devices shall be made of no less than 0.25 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 (l) 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 6 feet from the source of radiation or protected by an apron, gloves, or other shielding having a minimum of 0.25 mm lead equivalent material.

(vi) Holding of 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.

(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 3 months.

(III) Darkroom light leak tests shall be performed and any light leaks corrected at intervals not to exceed 6 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 (l) 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 (l) 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 (l) of this section for inspection by the agency.

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

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

(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.

HALF-VALUE LAYER FOR SELECTED kVp

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

(ii) 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 ±10% of the indicated setting.

(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.

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(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 X_1 and X_2 are the average mR/mAs values obtained at each of two consecutive tube current settings:

$$\left|\overline{X}_1 - \overline{X}_2\right| \leq 0.10\left(\overline{X}_1 + \overline{X}_2\right)$$

(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 5 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.

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

(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.

(-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 console.

(-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 1 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. If the CT system is used for simulation purposes only, the following requirements do not apply. If the unit is also used for diagnostic procedures, the measurements shall be performed as follows:

(-a-) within 30 days after installation and thereafter, at intervals not to exceed 14 months;

(-b-) when major maintenance 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 calibration shall be traceable to a national standard. The calibration interval shall not exceed 24 months.

(III) Records of dose measurements specified in clause (iii) of this subparagraph shall be maintained by the registrant in accordance with subsection (l) of this section for inspection by the agency.

(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

(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 (l) 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.

(i) Medical events (misadministrations).

(1) Medical events involving equipment operating at energies below 1 MeV and electronic brachytherapy devices, shall be reported when:

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

(B) the treatment consists of 3 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) Medical 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 3 or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose;

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

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

(j) Reports of medical events (misadministrations).

(1) For a medical 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

(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 (l) 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) Additional requirements for electronic brachytherapy devices.

(1) Technical requirements for electronic brachytherapy devices.

(A) 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 1 second;

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

(vi) be accurate to within 1.0% of the selected value or 1 second, whichever is greater.

(B) The control panel, in addition to the displays required in subparagraph (A) of this paragraph, 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) means for indicating x-rays are being produced;

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

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

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

(2) Surveys, calibrations, and spot checks.

(A) Surveys shall be performed as follows.

(i) All facilities having electronic brachytherapy device(s) shall have an initial survey made by a licensed medical physicist, with a specialty in therapeutic radiological physics, who shall provide a written report of the survey to the registrant. Additional surveys shall be done as follows:

(I) when making any change in the portable shielding;

(II) when making any change in the location where the electronic brachytherapy device is used within the treatment room; and

(III) when relocating the electronic therapy device.

(ii) The registrant shall maintain a copy of the initial survey report and all subsequent survey reports in accordance with subsection (l) 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.

(B) Calibrations shall be performed as follows.

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

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

(iii) The calibration of the electronic brachytherapy device shall be performed after change of the x-ray tube 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 water or plastic phantom can be calculated to within an uncertainty of 5.0%.

(iv) The calibration of the radiation output of the electronic brachytherapy device 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.

(v) The calibration of the therapeutic electronic brachytherapy device shall include verification that the electronic brachytherapy device is operating in compliance with the design specifications.

(vi) Calibration of the radiation output of the electronic brachytherapy device shall be performed with a calibrated dosimetry system. The dosimetry calibration shall be traceable to a national standard. The calibration interval shall not exceed 24 months.

(vii) Records of calibration measurements shall be maintained by the registrant in accordance with subsection (l) of this section for inspection by the agency.

(viii) A copy of the latest calibrated absorbed dose rate measured on the electronic brachytherapy device shall be available at a designated area within the therapy facility housing the electronic brachytherapy device.

(C) Spot check procedures.

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

(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 2 treatment days and a record made of the review.

(iii) The written spot check procedures shall specify the operating instructions that shall be carried out whenever a parameter exceeds an acceptable tolerance as established by the licensed medical physicist.

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

(v) Records of the written spot checks and any necessary corrective actions shall be maintained by the registrant in accordance with subsection (l) 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.

(vi) Spot checks shall be obtained using a dosimetry system satisfying the requirements of subparagraph (B)(vi) of this paragraph.

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

Name of Record	Rule Cross-Reference	Time Interval Required for Record Keeping
Accelerators used for research and development and industrial operations		
(A) Initial surveys	(f)(2)(C)(iii)	Until termination of registration
(B) Tests and repairs	(f)(3)(A)(x)	5 years
(C) Calibration, surveys	(f)(3)(F)	5 years
(D) Contamination smears for units operating greater than 10 MeV	(f)(3)(G)	Until termination of registration
(E) Receipt, transfers and disposal	(f)(3)(H)	Until termination of registration
(F) Training for operators	(f)(4)(B)	Until 2 years after the individual terminated employment

Name of Record	Rule Cross-Reference	Time Interval Required for Record Keeping
Therapeutic radiation machines, simulators, and electronic brachytherapy devices		
(G) Credentials of operators	(h)(1)(C)	Until 2 years after the individuals leave the facility
Electronic brachytherapy Device Operators	(h)(i)(E)(iii)	Until 2 years after the individuals leave the facility
(H) Review of quality assurance program	(h)(1)(F)(vii)	5 years
(I) FDA Variances	(h)(1)(H)	Until transfer of machine or termination of registration
(J) Initial surveys		
Therapy (below 1 MeV)	(h)(2)(D)(i)(II)	Until termination of registration
Therapy (1 MeV and above)	(h)(3)(C)(i)(III)	Until termination of registration
Electronic brachytherapy	(k)(2)(A)(ii)	Until termination of registration
(K) Calibration		
Therapy (below 1 MeV)	(h)(2)(D)(i)(II)	5 years
Therapy (1 MeV and above)	(h)(3)(C)(ii)(VI)	5 years
Electronic brachytherapy Device	(k)(2)(B)(vi)	5 years
(L) Contamination Smears for units operating greater than 10 MeV	(h)(1)(I)	Until termination of registration
(M) Spot checks and corrective actions		
Therapy (below 1 MeV)	(h)(2)(D)(iii)(VI)	5 years after spot check
Therapy (1 MeV and above)	(h)(3)(C)(iii)(VII)	5 years after spot check
Electronic brachytherapy Device	(k)(2)(C)(v)	5 years after spot check

Name of Record	Rule Cross-Reference	Time Interval Required for Record Keeping
Therapeutic radiation machines, simulators, and electronic brachytherapy devices		
(N) Leakage measurements Therapy (1 MeV and above)	(h)(3)(A)(i)	5 years
(O) Protective devices for simulators	(h)(4)(A)(iii)(II)	3 years
(P) Film processing records for simulators	(h)(4)(A)(viii)(VI) and (ix)	3 years
(Q) Digital imaging acquisition systems	(h)(4)(A)(x)	3 years
(R) CT dose measurements	(h)(4)(D)(iii)(III)	5 years
(S) CT films resulting from quality control tests	(h)(4)(D)(iv)(II)	1 year or until a new phantom image is performed
(T) Record of device-specific training for electronic brachytherapy devices	(h)(1)(E)(iii)	Until 2 years after the individual leaves the facility