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Minnesota Department of Health
Proposed Permanent Rules Relating to Radiation Therapy
Chapter 4733 Radiation Therapy Rules

Subject of Rules: The Minnesota Department of Health requests comments on its possible new rule governing machine-produced radiation therapy. The Department is considering repealing the rule parts encompassing machine-produced radiation therapy that are currently in Ionizing Radiation Rules, Chapter 4732, and establishing an independent machine-produced radiation rule as Chapter 4733 to specifically address this type of radiation therapy.

MDH adopted Chapter 4732, rules that govern ionizing radiation sources other than radioactive materials, which included machine-produced radiation therapy, on November 5, 2007. This chapter includes rules for machine-produced radiation therapy equipment; however, the proposed rules would remove the radiation therapy parts from the current chapter, correct and clarify the rules, and expand them to address newer technologies. Establishing the machine-produced radiation therapy in a separate rule will make it easier for all to understand and easier for the regulated community to comply with.

Persons Affected. The proposed Chapter 4733 would apply to all persons who own, possess, or use of the machine-produced radiation therapy equipment. The purpose of Chapter 4733 is to protect the registrant, patient, and the general public from unwanted or unsafe exposures to radiation from machine-produced radiation therapy equipment. These proposed rules would likely affect registrants currently regulated by the state under Chapter 4732; individuals serving as radiation safety officers; qualified medical physicists in the subfield of therapeutic radiation; radiation oncologists; patients; and the general public within the State of Minnesota.

Statutory Authority. *Minnesota Statutes*, sections 144.12, subdivision 1, item (15), authorize the MDH to adopt rules that allow the state to regulate radiation from machine-produced radiation therapy equipment for the safety of the patients needing this therapy and the public.

Public Comment. Interested persons or groups may submit comments or information on these proposed rules in writing until MDH publishes it in the State Register. MDH will not publish a notice of intent to adopt the rules until more than 60 days have elapsed from the date of the request for comments, which was published in the *State Register* on November 16, 2009.

Rules Drafts. A free paper copy or CD of the proposed rules is available upon request from the agency contact listed below.

Agency Contact Person. Written comments, questions, and requests for more information on these possible rules should be directed to: Susan McClanahan at Minnesota Department of Health, 625 Robert Street North, P.O. Box 64975, St. Paul, Minnesota 55164-0975, Phone (651) 201- 4527, FAX: (651) 201-4606. TTY users may call the Department at (651) 201-5797.

Alternative Format. Upon request, the agency can provide this Request for Comments in an alternative format, such as large print, Braille, or cassette tape. To make such a request, please contact the agency contact person at the address, or telephone number listed above.

NOTE: Comments received in response to this notice will not necessarily be included in the formal rulemaking record submitted to the Administrative Law Judge (ALJ) if and when a proceeding to adopt rules is started. The agency is required to submit to the ALJ only those written comments received in response to the rules after they are proposed. If you submitted comments during the development of the rules and you want to ensure that the ALJ reviews the comments, you should resubmit the comments after the rules are formally proposed.

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4733.0100 PURPOSE AND SCOPE.

Subpart 1. **Purpose.** The purpose of this chapter is to control and prevent hazards to health and safety from machine produced ionizing radiation without limiting or interfering with its therapeutic uses. Therefore, this rule does not include any medical radiation therapy involving the use of radioactive materials.

Subp. 2. **Scope.** This rule establishes the requirements, for which the registrant is responsible, for use of machine produced radiation therapy equipment.

Subp. 3. **Additional requirements.** In addition to the requirements established in this chapter, the commissioner must impose upon any registrant any requirements deemed appropriate or necessary to minimize danger to public health and safety. The use of machine produced radiation therapy equipment must be by qualified individuals as set forth in this chapter.

4733.0105 DEFINITIONS.

Subpart. 1. **Scope.** For purposes of this chapter, the terms in this part have the meanings given them.

Subp. 2. **Absorbed dose (D).** "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The unit of absorbed dose is the rad under the conventional system and is the gray (Gy) under the SI system.

Subp. 3. **Absorbed dose rate.** "Absorbed dose rate" means absorbed dose per unit time, for machine with timers, or dose-monitor unit per unit time for linear accelerators.

Subp. 4. **Accelerator.** "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV. For purposes of this definition, linear accelerator, particle accelerator, linear

accelerator-based robotic or non-robotic stereotactic radiosurgery radiation therapy units are included.

Subp. 5. **Audit.** "Audit" means a planned and documented activity performed according to procedures to determine by examination and evaluation of objective evidence the adequacy of and extent to which applicable elements of the quality management program have been developed, documented, and effectively implemented.

Subp. 6. **Beam axis.** "Beam axis" means the axis of rotation of the beam limiting device for therapy systems.

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

Subp. 8. **Beam-monitoring system.** "Beam-monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

Subp. 9. **Beam-scattering filter or foil.** "Beam-scattering filter" or "foil" means a thin piece of material placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Subp. 10. **Bent beam linear accelerator.** "Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

Subp. 11. **Calibration.** "Calibration" means:

A. the determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument;

B. the determination of the radiation dose or exposure rate at a designated distance from a radiation source under specified conditions of measurement;

C. to check, adjust, or systematically standardize to graduations of a quantitative measuring instrument; and

D. to check, adjust, or systematically bring radiation-producing equipment into manufacturer's specifications.

Subp. 12. **Changeable filter.** "Changeable filter" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

Subp. 13. **Commissioner.** "Commissioner" means the commissioner of the Department of Health.

Subp. 14. **Computed tomography or CT.** "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Subp. 15. **Contact therapy system.** "Contact therapy system" means a radiation therapy machine with a short target to skin distance (TSD), usually less than five centimeters.

Subp. 16. **Dose-monitoring system.** "Dose-monitoring system" means a system of devices for the detection, measurement, and display of quantity of radiation that can be related to the absorbed dose at a given location within a defined geometry.

Subp. 17. **Dose-monitor unit.** "Dose-monitor unit" means a unit response from the dose-monitoring system from which the absorbed radiation dose can be calculated.

Subp. 18. **Electron-beam generator.** "Electron-beam generator" means a type of electron accelerator in which the electron beam is brought out into the atmosphere for irradiation purposes.

Subp. 19. **Electronic brachytherapy.** "Electronic brachytherapy" means a method of radiation therapy using electrically generated x-rays to deliver a radiation dose:

A. at a distance of up to a few centimeters by intracavitary, intraluminal or interstitial application; or

B. by applications with the source in contact with the body surface or very close to the body surface.

Subp. 20. **Electronic brachytherapy device or device.** "Electronic brachytherapy device" or "device" means the system, including the x-ray tube, the control mechanism, the cooling system, and the power source, used to produce and deliver therapeutic radiation.

Subp. 21. **Emergency cut-off switch.** "Emergency cut-off switch" means a switch that interrupts power to the radiation therapy system from the main power supply such as the circuit breaker or Buss.

Subp. 22. **Emerging technologies.** "Emerging technologies" means advancing technologies not currently in use for radiation therapy or therapy simulation, other than research, and, therefore, not included in this chapter.

Subp. 23. **External beam radiation therapy.** "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is outside of the body.

Subp. 24. **Field-flattening filter.** "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

Subp. 25. **Filter.** "Filter" means material placed in the useful beam to change beam quality in radiation therapy systems.

Subp. 26. **Gantry.** "Gantry" means that part of the ~~radiation therapy~~ system supporting and allowing movements of the radiation head.

Subp. 27. **Gray or Gy.** "Gray" or "Gy" means the SI unit of absorbed dose, kerma and specific energy imparted to matter equal to one joule per kilogram. The conventional system equivalent is 100 rad.

Subp. 28. **Half-value layer (HVL).** "Half-value layer (HVL)" means the thickness of any given absorber that will reduce the intensity of a beam of radiation to one-half of its initial value.

Subp. 29. **Helical tomotherapy.** "Helical tomotherapy" means a treatment system utilizing CT-guided intensity-modulated radiation therapy delivered in a CT ring.

Subp. 30. **High Radiation area.** "High radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a radiation dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

Subp. 31. **Image-guided radiation therapy or IGRT.** "Image-guided radiation therapy" or "IGRT" means a radiation therapy with the ability for frequent imaging of the

patient during a radiation therapy course used to improve the precision and accuracy of radiation delivery.

Subp. 32. **Intensity-modulated radiation therapy or IMRT.** "Intensity-modulated radiation therapy" or "IMRT" means radiation therapy that uses non-uniform radiation beam intensities which has been determined by various computer-based optimization techniques to improve the precision and accuracy of radiation delivery.

Subp. 33. **Interlock.** "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Subp. 34. **Irradiation.** "Irradiation" means the exposure of a living being or matter to ionizing radiation.

Subp. 35. **Isocenter.** "Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

Subp. 36. **Kerma (K).** "Kerma (K)" means the kinetic energy released in matter by ionizing radiation. Kerma is determined as 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 matter of mass dM. The special name for the unit of kerma is the gray (Gy).

Subp. 37. **Kilovolt (kV) or (kilo electron volt (keV).** "Kilovolt (kV)" or "kilo electron volt (keV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of ~~one thousand~~ 1,000 volts in a vacuum. Current convention is to use kV for photons and keV for electrons.

Subp. 38. **Lead equivalent.** "Lead equivalent" means the thickness of material in question affording the same attenuation as lead under specified conditions.

Subp. 39. **Leakage radiation.** "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

Subp. 40. **Licensed practitioner of the healing arts.** "Licensed practitioner of the healing arts" means health professionals for diagnostic or healing treatment of human and animal maladies, which are licensed under Minnesota Statutes, Chapters 147 or 156, for the lawful practice of medicine or veterinary medicine.

Subp. 41. **Light field.** "Light field" means the area illuminated by light that simulates the radiation field.

Subp. 42. **Linear accelerator-based robotic stereotactic radiosurgery radiation therapy.** "Linear accelerator-based robotic stereotactic radiosurgery radiation therapy" means a type of stereotactic radiation therapy in which beams are delivered from multiple locations outside of the body using robotics to control patient position or the primary linear accelerator beam.

Subp. 43. **mA.** "mA" means milliamperere.

Subp. 44. **Medical dosimetrist.** "Medical dosimetrist" means an individual, other than a licensed practitioner of the healing arts, who:

A. performs, assists, or directs the treatment planning process under the general supervision of a licensed practitioner of the healing arts and qualified medical_qualified physicist and if applicable, can deliver the course of radiation therapy treatment on human beings;

B. has satisfactorily completed a nationally recognized examination in dosimetry and who maintains the registration or certification of the examining organization; and

C. is certified by the Medical Dosimetrist Certification Board (MDCB) in radiation dosimetry; or

D. in a certification program that demonstrate compliance with the standards for medical dosimetry through accreditation by:

(1) the National Commission for Certifying Agencies, NCCA Standards for the Accreditation of Certification Programs; or

(2) the American National Standards Institute (ISO/IEC-CD 17024) General Requirements for Bodies Operating Certification Systems of Persons.

Subp. 45. **Medical event.** "Medical event" means any event, except for an event that results from patient intervention, in which the therapeutic administration of radiation results in:

A. the wrong individual or wrong treatment site;

B. treatment with the wrong modality;

C. a dose to tissue other than the treatment site that is 50 percent or more of the dose expected from the administration defined in the written directive;

D. a total radiation dose delivered that differs from the prescribed dose by 20 percent or more; or

E. a fractionated radiation dose delivered that differs from the prescribed dose, for a single fraction, by 50 percent or more.

Subp. 46. **Megavolt (MV) or mega electron volt (MeV).** "Megavolt (MV)," or "mega electron volt, (MeV)," means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000,000 volts in a vacuum. Current convention is to use MV for photons and MeV for electrons.

Subp. 47. **Monitor unit (MU).** "Monitor unit" see Dose-Monitoring Unit.

Subp. 48. **Mobile electronic brachytherapy device.** "Mobile electronic brachytherapy device" means an electronic brachytherapy device that is transported from one address to be used at another address.

Subp. 49. **Moving beam radiation therapy.** "Moving beam radiation therapy" means radiation therapy with relative movement of the useful beam or the patient during irradiation. It may include skip, rotational IMRT, and rotational therapy.

Subp. 50. **Multimode therapy system.** "Multimode therapy system" means a radiation therapy system which is capable of different energies, particles and x-ray for treatment.

Subp. 51. **Nominal treatment distance.** "Nominal treatment distance" means:

A. for electron irradiation, distance from the scattering foil, virtual source, or exit window of the useful beam;

B. for x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam; and

C. for non-isocentric equipment, the distance specified by the manufacturer.

Subp. 52. **Patient.** "Patient" means an individual or veterinary practice animal subjected to machine produced external beam radiation for the purposes of medical therapy.

Subp. 53. **Peak tube potential.** "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

Subp. 54. **Periodic quality control check.** "Periodic quality control check" means a procedure which is performed to ensure that a previous QC test result continues to be valid.

Subp. 55. **Phantom.** "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Subp. 56. **Physician assistant.** "Physician assistant" means a person licensed under Minnesota Statutes Chapter 147A, who is qualified by academic training, practical training, or both to provide patient services in radiation therapy according to physician- physician assistant agreement authorized under Minnesota Statutes, section 147A.20.

Subp. 57. **Port film or portal imaging.** "Port film" or "portal imaging" means a radiographic film or electronic image taken with a therapy simulation system to verify proper setup of the treatment field.

Subp. 58. **Portable shielding.** "Portable shielding" means shielding than can be easily moved into the primary beam or secondary radiation in order to reduce the radiation exposure to the patient, occupational worker, or member of the public while using a portable electronic brachytherapy device.

Subp. 59. **Prescribed dose.** "Prescribed dose" means 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 that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

Subp. 60. **Primary dose-monitoring system.** "Primary dose-monitoring system" means a system which will monitor the useful beam during irradiation and will terminate irradiation when a preselected number of dose monitor units have been acquired.

Subp. 61. **Primary protective barrier.** "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce radiation levels for protection purposes.

Subp. 62. **Qualified medical physicist.** "Qualified medical physicist" means an individual qualified to practice independently in the subfields for therapeutic radiological physics who:

A. is certified in radiological physics or therapeutic radiological physics by the American Board of Radiology;

B. is certified in therapeutic radiological physics by the American Board of Medical Physics;

C. is certified in therapeutic radiological physics by the Canadian College of Medical Physics; or

D. holds a masters degree or doctor's degree in medical physics, radiological sciences, or an equivalent field involving graduate study in physics applied to the application of radiation to humans from an accredited college or university and have at least one year of full-time practical training and experience involving work in a radiation therapy facility under an individual who meets the qualifications in this item or item A, B, or C.

Subp. 63. **Quality management program.** "Quality management program" means an all-encompassing program, including quality control that extends to administrative, education, and preventive maintenance methods. It includes a continuing evaluation of the adequacy and effectiveness of the overall therapy program, with a view to initiating corrective measures when necessary. The nature and extent of this program will vary with the size and type of the facility, and the type of activities conducted.

Subp. 64. **Quality control.** "Quality control" means a series of distinct technical procedures that ensure the production of a satisfactory, dependable and economic product. The quality control tests, results, and evaluations must be included in the quality management program. The quality control procedures are concerned directly with the equipment.

Subp. 65. **Radiation area.** "Radiation area" means an area accessible to individuals in which the radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Subp. 66. **Radiation detector.** "Radiation detector" means a device that detects the presence of ionizing radiation. The detector must be able to measure the type of radiation being measured. Some radiation detectors can also identify the characteristics of the radiation.

Subp. 67. **Radiation field.** "Radiation field" has the meaning given "useful beam".

Subp. 68. **Radiation head.** "Radiation head" means the structure from which the useful beam emerges.

Subp. 69. **Radiation therapy simulation system.** "Radiation therapy simulation system" means a radiographic, fluoroscopic, stereotactic, or CT x-ray system including all software applicable to the process intended for:

- A. localizing the volume to be exposed during radiation therapy; and
- B. reproducing the position and size of the therapeutic irradiation field.

Subp. 70. **Radiation therapist or radiation therapeutic technologist.** "Radiation therapist or radiation therapeutic technologist" means a person, other than a licensed practitioner of the healing arts, who:

A. performs procedures and applies ionizing radiation emitted from x-ray machines or accelerators to human beings or animals for therapeutic purposes while under the general supervision of a license;

B. is a member of the radiation oncology team who sees the patient daily and is responsible for treatment delivery and daily assessment of patient tolerance to treatment; and

C. has satisfactorily completed a nationally recognized examination in radiography or radiation therapy and maintains the registration of the examining organization. Nationally recognized examinations are provided by the American Registry of Radiologic Technologists for either radiography (ARRT) (R) or therapy ARRT (T).

Subp. 71. **Radiation therapy system.** "Radiation therapy system" means x-ray, electron, proton, deuteron or other charged particles created or accelerated in a vacuum designed and used for radiation therapy. This includes electronic brachytherapy.

Subp. 72. **Redundant beam-monitoring system.** "Redundant beam-monitoring system" means a combination of two dose-monitoring systems in which each system is designed to terminate irradiation according to a preselected number of dose monitor units.

Subp. 73. **Registrant.** "Registrant" means a person having administrative control of any radiation therapy system or therapy simulation system and who is legally obligated to register with the commissioner according to this chapter.

Subp. 74. **Scattered radiation.** "Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered

radiation which has been deviated in direction only by materials irradiated by the useful beam.

Subp. 75. **Secondary dose-monitoring system.** "Secondary dose-monitoring system" means a system that will terminate irradiation in the event of failure of the primary dose-monitoring system.

Subp. 76. **Secondary protective barrier.** "Secondary protective barrier" means a barrier placed in the useful beam to reduce radiation levels for protection purposes.

Subp. 77. **Shutter.** "Shutter" means a device attached to the tube housing assembly that can totally intercept the useful beam and that has a lead equivalency not less than the tube housing assembly.

Subp. 78. **Sievert (Sv).** "Sievert (Sv)" means the SI unit of dose equivalent. The conventional system of dose equivalent is 100 rem.

Subp. 79. **Source.** "Source" means the target or focal spot of the x-ray tube or accelerator from which the radiation emanates.

Subp. 80. **Spot check.** "Spot check" means an abbreviated calibration procedure that is performed to assure that a previous calibration continues to be valid.

Subp. 81. **Stationary beam radiation therapy.** "Stationary beam radiation therapy" means radiation therapy without relative movement of the useful beam and the patient during irradiation.

Subp. 82. **Stray radiation.** "Stray radiation" means the sum of leakage and scattered radiation.

Subp. 83. **Supervising physician.** "Supervising physician" means a Minnesota licensed physician who accepts full medical responsibility for the performance, practice, and activities of a registered radiologist assistant, a radiology practitioner assistant, or a physician assistant according to Minnesota Statutes, section 147A.20.

Subp. 84. **Survey or radiation survey.** "Survey or radiation survey" means an evaluation of the radiological conditions and potential hazards in all directions, incident to the use of radiation-producing equipment. When appropriate, such evaluation includes, but is not limited to, tests, physical examination, and measurements of levels of radiation.

Subp. 85. **Target.** "Target" means the part a radiation-producing system used to intercept a beam of accelerated particles and cause emission of other radiation.

Subp. 86. **Target-skin distance (TSD).** "Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the target or electron virtual source to the surface of the irradiated object or patient.

Subp. 87. **Termination of irradiation.** "Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Subp. 88. **Therapeutic-type protective tube housing.** "Therapeutic-type protective tube housing" means:

A. for x-ray therapy equipment not capable of operating at 500 kilovolt peak (kVp) or above, an x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed 1.0 rad (0.01 Gy) in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential; or

B. for x-ray therapy equipment capable of operation at 500 kilovolt peak (kVp) or above, an x-ray tube housing so constructed that leakage radiation at a distance of one meter from the source does not exceed either 1.0 rad (0.01 Gy) in an hour or 0.1 percent of the useful beam dose rate at one meter from the source, whichever is greater, when the machine is operated at its maximum rated continuous current for the maximum rated accelerating potential; and

C. in either case, small areas of reduced protection are acceptable provided the average reading over any 100 square centimeters area at one meter distance from the source does not exceed the values given in items A or B.

Subp. 89. **Traceable to a standard.** "Traceable to a standard" means a comparison, either directly or indirectly, to a standard maintained by the National Institute of Standards and Technology (NIST) and that all comparisons have been documented.

Subp. 90. **Treatment planning.** "Treatment planning" means the process used to determine the number, orientation, type, and characteristics of the radiation beams or electronic brachytherapy used to deliver a large dose of radiation to a patient in order to control or cure a cancerous tumor or other problem. The Radiation Treatment Planning (RTP) system consists of a software package, hardware platform, and associated peripheral devices.

Subp. 91. **Useful beam.** "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the radiation therapy system to produce radiation.

Subp. 92. **Very high radiation area.** "Very high radiation area" means an area accessible to individuals, where radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rad (5 Gy) in one hour at one meter from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (rads and grays) are appropriate, rather than units of dose equivalent (rems and sieverts).

Subp. 93. **Virtual source.** "Virtual source" means a point from which radiation appears to originate.

Subp. 94. **Wedge filter.** "Wedge filter" means an added filter which effects continuous change in transmission over all or a part of the useful beam.

Subp. 95. **Written directive.** "Written directive" means a dated prescription or order either in writing or electronically for a specific patient, specific procedure, and has the signature, initials or other identification of the licensed practitioner of the healing arts ordering the procedure.

Subp. 96. **X-ray tube or tube.** "X-ray tube or tube" means an electron tube that is designed to be used primarily for the production of x-rays.

GENERAL ADMINISTRATION

4733.0110. DATA PRIVACY. Collection, security, and dissemination of information gathered for registration is governed by Minnesota Statutes, Chapter 13.

4733.0115. EMPLOYEE PROTECTION. Employee protection and employment discrimination issues are governed by Minnesota Statutes, sections 181.931 to 181.935.

4733.0120. DELIBERATE MISCONDUCT. For purposes of this chapter, “deliberate misconduct” means a registrant, employee of a registrant, or service provider who knowingly:

A. engages in deliberate misconduct that causes or would have caused, if not detected, a registrant to be in violation of this chapter; or

B. deliberately submits to the commissioner or the registrant information that the person submitting the information knows to be incomplete or inaccurate in some respect.

4733.0125. VARIANCE IONIZING RADIATION RULES. Except for parts 4733.0200 and 4733.0205, the commissioner may, according to the procedures and criteria in parts 4717.7000 to 4717.7050, grant a variance from the requirements of this chapter if it:

A. is determined to be authorized by law;

B. would not endanger life or property; and

C. it is otherwise in the public interest.

4733.0130. INSPECTIONS AND TESTING.

Subpart 1. **Inspections.** At all reasonable times during the hours of operation, each registrant must allow the commissioner or commissioner's designee access to the facilities and premises where the radiation therapy and therapy simulator systems are used or stored to inspect and test the equipment. Access also includes inspection of all records under the registrant's control that are required to be kept according to part 4733.0145.

Subp. 2. **Tests.** Each registrant must perform, or cause to be performed, reasonable procedures that are necessary to ensure radiation safety including, but not limited to, tests of radiation therapy systems, therapy simulation systems, treatment planning systems, radiation detection and monitoring devices.

4733.0135. VIOLATIONS AND ENFORCEMENT REQUIREMENTS.

Subpart 1. **Notice of violation.** Unless otherwise specified, within 30 days of receipt of a written notice of violation issued by the commissioner, the regulated facility must submit a written explanation or statement in reply including:

A. the corrective steps that have been taken by the registrant and the results achieved through verification tests; or

B. if it cannot be achieved within the 30 days, a plan to correct the identified deficiencies and the date when full compliance will be achieved; and

C. the corrective action that will be taken to prevent a recurrence.

Subp. 2. **Notice of enforcement.** All violations are subject to possible penalty under Minnesota Statutes, sections 144.989 to 144.993.

4733.0140. POSTING WORKER NOTICES.

Subpart 1. **Notice to employees.** Each registrant must prominently post a MDH Form 3, "Notice to Employees," provided by the commissioner. A copy of any revision of the Notice to Employees must be posted within 30 days of receiving the revised notice from the commissioner. Copies of the Notice to Employees may be obtained by writing to the Radiation Control Unit, Minnesota Department of Health, 625 Robert Street N, P.O. Box 64975, St. Paul, MN 55164-0975.

Subp. 2. **Posting locations.** Notices posted according to this part must:

A. appear in a sufficient number of places to permit individuals engaged in using radiation therapy or simulation equipment to observe them on the way to or from the location to which the document applies;

B. be conspicuous; and

C. be replaced if defaced or altered.

4733.0145. RECORDS.

Subpart 1. **Requirements.** Any facility required to register with the commissioner must maintain records according to this chapter. If there is a conflict between this chapter and other required retention periods for the same type of record, the longest retention period specified takes precedence.

A. Each registrant must maintain records showing the receipt, transfer, and disposal of all radiation therapy or simulation systems.

B. Records of individual monitoring, radiation monitoring, radiation surveys, calibrations, and equipment performance measurements for therapy and therapy simulation equipment must be kept according to this part.

C. These records must be available at the time of inspection required under part 4733/0130, subpart 1.

D. At all times, the registrant is responsible for record retention required by this chapter. If the registrant ceases operation for any reason, provisions must be made for record retention required by this chapter.

Subp. 2. Format and safeguarding records.

A. A record required under this chapter must be legible throughout the specified retention period. The record can be:

- (1) the original;
- (2) a reproduced copy;
- (3) a microfilm, if the microfilm is capable of producing a legible copy; or
- (4) stored in electronic media with the capability for producing a legible copy.

B. Records such as letters, drawings, and specifications, must include all pertinent information.

C. Registrants must maintain adequate safeguards against tampering with and loss of records.

Subp. 3. Reporting units. As appropriate, a registrant must use the units of rad, roentgen, or rem or the equivalent international system of units (SI), including the multiples and subdivisions. The registrant must clearly indicate the units on all records required by this chapter.

Subp. 4. Record retention. The registrant must ensure that, when applicable, the records are retained in the facility until the inspection by the commissioner. The following records specified in this subpart must be maintained:

- A. quality control records that include documentation of:
- (1) equipment performance evaluations complete with all numerical values and appropriate films;
 - (2) calibrations performed at the time of installation; and
 - (3) all corrective actions and results of verification tests;

- B. employee training documentation including training content, dates, and attendees;
- C. individual monitoring dosimetry results kept according to part 4733.0170;
- D. registration information;
- E. manufacturer's specifications on any new therapy equipment;
- F. shielding plans and associated radiation verification surveys;
- G. results of quality management program audits;
- H. calibration records for instruments, survey meters, and electronic devices; and
- I. current copy of the agreement between the supervising physician-physician assistant authorized under Minnesota Statutes, section 147A.20.

REPORTS AND NOTIFICATIONS

4733.0160. EXPOSURE NOTIFICATIONS AND REPORTS.

Subpart 1. **Notification of exposure that exceeds occupational dose limits.** A registrant must notify the commissioner of any individual worker who was exposed beyond the worker's occupational dose under part 4733.0305 within 30 days of discovery. The registrant must also notify the individual and provide a copy of the report. Each notification and report must:

- A. include the dose data and results obtained under this chapter, as shown in records maintained by the registrant according to part 4733.0145;
- B. be in writing;
- C. include appropriate identifying data, including the name of the registrant, the name of the exposed individual worker, and the date of the dose; and
- D. include the individual's exposure information.

Subp. 2. **Report for former employee.** At the request of a worker formerly engaged in activities controlled by the registrant, the registrant must furnish to the worker a report of the worker's exposure to radiation as shown in records maintained by the registrant according to part 4733.0145 for each year the worker was required to be monitored under part 4733.0210. The report required by this subpart must:

- A. be furnished within 30 days from the time the request is made or within 30 days after the exposure of the individual has been determined by the registrant, whichever is later; and

B. cover the period of time that the worker's activities involved exposure to radiation registered by the commissioner.

Subp. 3. **Report upon termination.** When a worker who is terminating employment requests a report of their radiation dose, the registrant must furnish a radiation dose report. The report must:

A. be provided to the worker within 30 days after the exposure has been determined by the registrant;

B. cover the annual periods in which the worker's activities involved exposure to radiation; and

C. include the dates and locations of work under the registrant.

4733.0170. RECORDS; DOSE TO INDIVIDUAL MEMBERS OF THE PUBLIC.

A registrant must maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public under part 4733.0315. Records must be maintained until the commissioner terminates the registration requiring the record.

4733.0180. REPORTS OF MEDICAL EVENTS.

Subpart 1. **Notification within 24 hours.** A registrant possessing any radiation therapy systems must notify the commissioner within 24 hours of discovering any medical event.

Subp. 2. **Written report information.** In addition to any notification required by subpart 1, the registrant must submit a written report within 30 days to the commissioner. The report must include:

A. the registrant's name;

B. the name of the prescribing physician;

C. a brief description of the event;

D. why the event occurred;

E. the effect, if any, on the individual who received the radiation dose;

F. names and titles of individuals involved in the event;

G. what actions, if any, have been taken or planned actions to prevent recurrence;

H. the date when all actions including any additional training will be completed; and

I. verification that the registrant has notified the individual or the individual's responsible relative or guardian and, if not, why.

Subp. 3. Notification of patient.

A. A registrant must provide notification of a medical event to the referring physician and also notify the patient who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the registrant ~~either~~ that the physician will inform the patient or that, based on medical judgment, telling the patient would be harmful.

B. A registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or the affected patient cannot be reached within 24 hours, the registrant must notify the individual as soon as possible thereafter.

C. A registrant must not delay any appropriate medical care for the patient because of any delay in notification.

D. To meet the notification requirements in this subpart, notification of the patient who is the subject of the medical event may be made instead to the patient's responsible relative or guardian.

E. If a verbal notification is made, the registrant must inform the patient, or appropriate responsible relative or guardian that a written description of the event can be obtained from the registrant upon request. The registrant must provide a written description if requested.

Subp. 4. Rights or duties. Aside from the notification requirement, nothing in this part affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by a medical event, or to that individual's responsible relatives or guardians.

Subp. 5. Patient identification. A registrant must:

- A. annotate a copy of the report provided to the commissioner with:
- (1) the name of the patient who is the subject of the event;
 - (2) the Social Security number or other identification number, if one has been assigned, of the patient who is the subject of the event;
 - (3) the estimates of the patient's dose; and
 - (4) the corrective actions taken or planned to ensure against a recurrence; and

B. provide a copy of the annotated report to the referring physician, if other than the registrant, no later than 30 days after the discovery of the medical event.

REGISTRATION REQUIREMENTS

4733.0200. REGISTRATION REQUIREMENTS FOR RADIATION THERAPY FACILITIES.

Subpart 1. **Registration.** The person having administrative control of any radiation therapy system, electronic brachytherapy system or therapy simulation system must complete the registration form and submit the applicable fee according to Minnesota Statutes, section 144.121. The registrant must keep the registration information current.

Subp. 2. **Change of control.** If a change of administrative control results in a change to the registrant's program, the registrant must notify the commissioner of that change.

Subp. 3. **Equipment Maintenance.** Persons with administrative control of the radiation therapy or simulation systems must be responsible for maintaining equipment in compliance with a nationally recognized standard such as:

- A. Code of Federal Regulations, title 21, section 890;
- B. Code of Federal Regulations, title 21, section 1020.30;
- C. manufacturer's specifications; or
- D. the standards specified in this chapter, and
- E. copy of the manufacturer's specifications or applicable Code of Federal Regulations

must be kept on site.

Subp. 4. **New facility.** For a new facility, a registration application must be submitted to the commissioner prior to the operation of the equipment. Application for registration must be completed on forms furnished by the commissioner or an acceptable alternative and must be completed and accurate. The application must include the appropriate fee specified in Minnesota Statutes, section 144.1212, subdivision 1a.

- A. The registrant is subject to all applicable requirements of this chapter;
- B. The registrant should notify the commissioner within 30 days of the following changes when:

- (1) relocating equipment within the facility;
- (2) there is a change in radiation-producing equipment status, including sale, lease, or transfer;
- (3) there is a change in location or disposition of any registered equipment;
- (4) there is any change in the facility that might impact radiation exposures such as remodeling involving removal of shielded walls or barriers;
- (5) there is a change administrator; or
- (6) there is a change in radiation safety officer or other personnel identified on the registration as having responsibility for radiation safety within the facility.

C. In advertisements, a person may not refer, to the fact that the ionizing radiation-producing equipment is registered with the commissioner or state or imply that the commissioner has approved any activity under the registration.

Subp. 5. Issuance of notice of registration.

A. Upon receipt of registration, the commissioner shall issue a notice of registration. Each notice of registration shall expire at the end of the indicated month and year.

B. The commissioner may incorporate in the registration at the time of issuance or thereafter any additional requirements with respect to the registrant's receipt, possession, use, and transfer of radiation-producing equipment as the commissioner deems appropriate or necessary.

Subp. 6. Renewal of registration.

A. Renewal of registration must be submitted according to this subpart. Each registrant must renew following the schedule in subpart 5 as long as the activity requiring registration continues.

B. The registrant must certify by signature or electronic signature that the information is accurate and complete.

C. If there has been any additional radiation-producing equipment or other substantial change made after the existing registration or renewal, the registrant must include all pertinent information regarding the addition or change.

Subp. 7. Staggered schedule for renewal of registration. Each registration under this chapter must be renewed on or before the first day of the calendar quarter specified in items A to D. The following schedule is based on the registrant's business address within the state:

A. January 1: Hennepin County registrants including the University of Minnesota, Minneapolis campus;

B. April 1: Ramsey, Anoka, Dakota, and Washington County registrants;

C. July 1: Aitkin, Benton, Carlton, Cass, Chisago, Cook, Crow Wing, Isanti, Itasca, Kanabec, Koochiching, Lake Mille Lacs, Morrison, Pine, St. Louis, Becker, Beltrami, Big Stone, Chippewa, Clay, Clearwater, Douglas, Grant, Hubbard, Kittson, Lac Qui Parle, Lake of the Woods, Mahnomen, Marshall, Norman, Otter Tail, Pennington, Polk, Pope, Red Lake, Roseau, Stearns, Stevens, Swift, Todd, Traverse, Wadena, and Wilkin County registrants, and registrants whose business addresses are outside the state; and

D. October 1: Brown, Carver, Cottonwood, Faribault, Jackson, Kandiyohi, Lincoln, Lyon, Martin, McLeod, Meeker, Murray, Nicollet, Nobles, Pipestone, Redwood, Renville, Rock, Sherburne, Sibley, Watonwan, Wright, Yellow Medicine, Blue Earth, Dodge, Fillmore, Freeborn, Goodhue, Houston, Le Sueur, Mower, Olmsted, Rice, Scott, Steele, Wabasha, Waseca, and Winona County registrants.

Subp. 8. **Renewals affected by change of location.** A registrant whose business address changes from one county to another must renew the registration with the county of relocation according to the schedule in subpart 7. The registrant shall not be assessed penalty fees for not renewing with the county of previous location.

Subp. 9. **Change of ownership.** In addition to the notification required in subpart 1, the registration of the facility is not transferable as part of a change in ownership.

Subp.10. **Responsibilities of registrant.** The registrant must:

A. ensure compliance with applicable parts of this chapter and in the operation of the equipment that is consistent with the registrant's area of use;

B. notify the commissioner within 30 days of any change in the ownership, addition of, or disposition of registered radiation therapy, electronic brachytherapy or simulation equipment; and

C. designate an individual as the radiation safety officer according to part 4733.0400.

Subp. 11. **Submissions.**

A. Any submission of any information provided to the commissioner by a registrant must be complete and accurate in all material submitted.

B. All communications and reports concerning these regulations, applications, and violation filed there under, must be addressed to or delivered to the Minnesota Department of Health, Radiation Control Unit, 625 Robert Street North, P.O. Box 64975, St. Paul, Minnesota 55164-0975.

4733.0205. REGISTRATION FEES. The initial registration application or renewal for registration of radiation-producing therapy, electronic brachytherapy, or simulation equipment required under part 4733.0200 must be accompanied by the fee specified in Minnesota Statutes, section 144.121, subdivision 1A. The registration fee is nonrefundable.

4733.0210. GENERAL REQUIREMENTS FOR RADIATION THERAPY (INCLUDING ELECTRONIC BRACHYTHERAPY) FACILITIES.

Subpart 1. **Applicability.** Facilities using a radiation therapy system or therapy simulation system must comply with the requirements in this part and other pertinent requirements in this chapter.

Subp. 2. **Operations.**

A. A registrant must not permit an individual to act as an operator of a radiation therapy system or therapy simulator system until the individual:

(1) has been instructed in and has demonstrated an understanding of radiation safety;

(2) has been made aware of how to obtain copies of this chapter and instruction in the applicable requirements of this chapter, the registrant's operating and emergency procedures, and demonstrated an understanding of these requirements and procedures;

(3) has demonstrated competence in the use of the radiation therapy system, electronic brachytherapy, therapy simulation system, related equipment, and the radiation survey instruments employed.

B. In addition to the general program audit required in part 4733.0430, each operator's performance during an actual radiation therapy, electronic brachytherapy, or therapy simulation

system operation must be audited at least every 12 months by the radiation safety officer or designee.

C. If an operator has not participated in a radiation therapy system, electronic brachytherapy, or therapy simulation system operation for more than six months since the last audit, the individual's performance must be observed and recorded at the first opportunity the individual participates in a radiation therapy system or therapy simulation system operation.

D. Records of the audits must be maintained according to part 4733.0145.

Subp. 3. **Individual monitoring.** In addition to the requirements of part 4733.0320, individual monitoring devices must be required for all individuals entering any area for which interlocks are required unless:

A. a radiation survey of that area has determined that radiation levels are below that of a high radiation area; and

B. power to an radiation therapy system cannot be activated; or

C. an accelerated beam cannot be directed to the area.

Subp. 4. **Operating and emergency procedures.**

A. Radiation therapy systems, when not in operation, must be secured to prevent unauthorized use.

B. Unless otherwise specified in this chapter, all safety and warning devices, including interlocks, must be checked for proper operation:

(1) emergency cut-off switches must be tested prior to initial use and after modification or repair;

(2) safety interlocks and couch interlocks must be tested weekly;

(3) warning devices must be tested at intervals not to exceed three months; and

(4) results of these tests must be maintained at the facility for inspection by the commissioner according to part 4733.0145.

C. The registrant's operating and emergency procedures must at a minimum, include the following:

(1) operation and safety instructions for the therapy and simulation systems to be used;

(2) methods for controlling access to restricted areas;

- (3) methods and occasions for locking and securing the radiation therapy system;
- (4) use of individual monitoring equipment;
- (5) steps to be taken in the case of an emergency;
- (6) procedures for notifying proper personnel in the event of an accident;
- (7) inspections and maintenance of the therapy and simulation systems; and

D. A copy of the current operating and emergency procedures must be available at the radiation therapy system control panel.

Subp. 5. **Records.** All records must be kept according to part 4733.0145.

4733.0220. EMERGING TECHNOLOGIES.

A. A person must not utilize any radiation therapy system designed to deliver therapeutic radiation which is not specifically included in this chapter unless the following information in items B and C is provided to the commissioner:

B. The applicant or registrant has, at a minimum, provided to the commissioner the following:

- (1) a detailed description of the system and its intended application;
- (2) facility design requirements, including shielding and access control;
- (3) documentation of appropriate training for radiation oncologist, licensed practitioner of the healing arts, qualified medical physicist, radiation therapist and medical dosimetrist;

(4) methodology for measurement of doses to be administered to patients or human research subjects;

(5) documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

(6) radiation safety precautions and instructions; and

(7) other information required by the commissioner in its review of the application for registration and use.

C. The applicant or registrant must receive written approval from the commissioner to utilize the device in accordance with:

- (1) any applicable regulations; and

- (2) all specific conditions identified by the commissioner.

SHIELDING REQUIREMENTS

4733.0250. FACILITY DESIGN REQUIREMENTS.

Subpart 1. **Shielding plan.** The registrant is required to complete a shielding plan for new constructions or structural remodeling of their radiation therapeutic or simulation areas.

Subp. 2. **Barriers.** Except for electronic brachytherapy below 150 kV, facilities that have radiation therapy systems must be designed with primary and secondary barriers to ensure compliance with the dose limits in parts 4733.0300 to 4733.0315. The barriers must:

- A. be fixed except for entrance doors or beam interceptors; and

- B. have shielding for neutrons, as applicable, if the radiation therapy system can operate above ten MeV.

Subp. 3. **Control Console.** Except for electronic brachytherapy below 150 kV, the radiation therapy system control console must be located outside the high radiation area. Instrumentation, readouts, and controls on the radiation therapy system control console must be clearly identified and easily discernible.

Subp. 4. **Shielding documentation.** All registrants must maintain documentation of the radiation shielding installed in their facility. The documentation must be:

- A. a blue print or architectural drawing indicating installed shielding; or

- B. a shielding plan that was completed by a service provider for simulation equipment or a qualified medical physicist in therapeutic radiological physics for therapy machine installations;

- C. If the registrant cannot verify shielding compliance, a detailed radiation survey covering the radiation levels at the operator position and at pertinent points outside the room during normal operation must be completed and the documentation maintained. The radiation survey must be performed with the radiation therapy system in a "BEAM-ON" condition, with the largest available field and with a scattering phantom in the useful beam of radiation, if

applicable, to ensure that radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in this chapter.

Subp. 5. **Warning Lights.** Except for electronic brachytherapy below 150 kV, radiation therapy system room entrances must be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is in the "on" position.

Subp. 6. **Emergency cut-off switches.** An emergency cutoff switch must be located on either side of the primary beam and easily identifiable in all high radiation areas. The cutoff switch must include a manual reset so that the therapy system cannot be restarted from the therapy system control console without resetting the cutoff switch;

Subp. 7. **Interlocks.** Except for electronic brachytherapy below 150 kV, interlocks or safety devices must be in place so all access into the room is blocked before irradiation is initiated or continued. If the useful radiation beam is interrupted by any door opening or tripping of the safety device, it must not be possible to restore the system to operation without closing the door or resetting the safety device and reinitiating irradiation by manual action at the control panel.

A. each entrance into a target area or other high radiation area must be provided with two safety interlocks that shut down the machine when the barrier is breached;

B. each safety interlock must be on a circuit that allows it to operate independently of the therapy system; and

C. all safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents operation of the radiation therapy system.

Subp. 8. **Patient viewing system.** Closed-circuit television, or an equivalent system, must be provided to permit continuous observation of the patient during irradiation and must be located so the operator may at all times observe the patient from the control panel.

Subp. 9. **Communication.** Two-way audio communication between the patient and the operator must be provided at the control panel. However, where excessive noise levels or treatment requirements make audio communication impractical, other methods of communication must be used.

4733.0260. MODIFICATION OF A THERAPY ROOM.

Subpart 1. **Unrestricted area exposure levels.** If radiation surveys indicate that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by this chapter before use, the registrant must:

- A. equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with parts 4733.0250 to 4733.0275.
- B. perform a follow-up radiation survey; and
- C. document the modification(s) made and the results of all surveys; or
- D. request and receive written authorization to operate the radiation therapy system from the commissioner.

Subp. 2. **Corrective actions.** If, after initial use, the results of the radiation surveys indicate any radiation levels in excess of the limits in this chapter, the registrant must lock the control in the "OFF" position and not use the unit except as follows:

- A. if necessary to repair, replace, or test the radiation therapy system or the shielding; or
- B. until the registrant has submitted a corrective action plan and received authorization in writing from the commissioner.

4733.0265. RADIATION SURVEYS.

Subpart 1. **Radiation surveys.** A radiation survey must encompass all directions around the equipment and surrounding areas and must be performed:

- A. prior to use;
- B. after making any change in the shielding;
- C. after installing or relocating the accelerator; and
- D. before using the accelerator in a manner that could result in increased radiation levels in areas outside shielded area.

Subp. 2. **Performance method.** The radiation survey must be performed with the equipment in a "BEAM-ON" condition, using the largest available field and with a scattering phantom in the useful beam of radiation, if applicable, to ensure that radiation levels in restricted areas are not likely to cause exposures to the personnel in excess of the limits of this chapter.

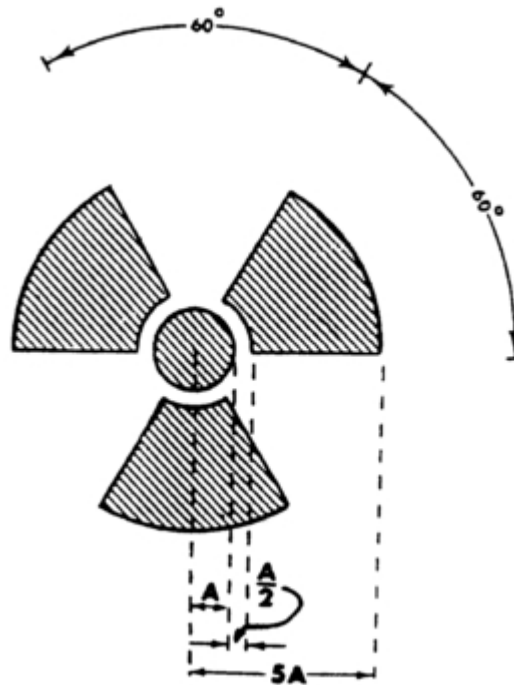
Subp. 3. **Radiation survey record.** The radiation survey record must also include:

- A. date of the measurements;
- B. the reason for the survey;
- C. the calibrated instruments used to measure radiation levels;
- D. a diagram or sketch of the areas surrounding the shielded areas that were surveyed;
- E. the measured dose rate at several points in each area expressed in millirems or microsieverts per hour;
- F. the calculated maximum level of radiation over a period of one year for each restricted and unrestricted area; and
- G. the name of the individual responsible for conducting the survey.

Subp. 4. **Records.** Records must be maintained according to part 4733.0145.

4733.0270. CAUTION SIGNS.

Subpart 1. Standard radiation symbol and labeling. Each radiation sign or label must bear the standard symbol specified in this subpart and the printed warning, in capital block letters, specified in subpart 4. The standard symbol for designating any radiation hazard is a circle with three propeller-like blades arranged around it as illustrated:



- A. cross-hatched area must be magenta, purple, or black; and

B. the background must be yellow.

Subp. 2. **Additional information on signs and labels.** In addition to the contents of signs and labels prescribed in this part, the registrant must provide, on or near the required signs and labels additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

Subp. 3. **Prohibitions on use of symbol.** The use of the specified radiation symbol for any purpose other than designating or referring to an area of applicable radiation levels is prohibited.

Subp. 4. **Posting and labeling requirements.** Conspicuous radiation warning labels must be posted in areas in which a radiation hazard may exist.

A. The warning "CAUTION RADIATION AREA" or "DANGER RADIATION AREA" must appear on signs in an area in which a radiation hazard may exist.

B. The warning "CAUTION HIGH RADIATION AREA" or "DANGER HIGH RADIATION AREA" must appear on signs in an area in which a high radiation hazard may exist.

C. The warning "CAUTION VERY HIGH RADIATION AREA" or "DANGER VERY HIGH RADIATION AREA" must appear on signs in an area in which a very high radiation hazard may exist.

Subp. 5. **Exceptions to posting requirements.** Rooms in hospitals or clinics that are used for radiation therapy are exempt from the requirement to post caution signs under this part if:

A. access to the room is controlled according to 4733.0275; and

B. personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this chapter.

4733.0275. WARNING AND CONTROL DEVICES FOR HIGH AND VERY HIGH RADIATION AREAS. Each entrance or access point to a high or very high radiation area must be:

A. equipped with a control device that causes the level of radiation to be reduced so that an individual cannot receive a dose in excess of 100 millirems (1.0 mSv) in one hour upon entry into the area; and

B. equipped with a warning device that energizes a visible or audible alarm to alert an individual entering the high or very high radiation area and other nearby non-occupationally exposed workers; or

C. monitored or supervised.

DOSE REQUIREMENTS

4733.0300. DETERMINATION OF ACCUMULATED OCCUPATIONAL DOSE.

Subpart 1. **Determination of prior occupational dose.** For each individual who is likely to receive in a year, an occupational dose requiring monitoring according to part 4733.0305, the registrant must:

A. determine the occupational radiation dose previously received during the current year; and

B. attempt to obtain the records of the cumulative occupational radiation dose.

Subp. 2. Complying with determination of prior occupational dose.

A. A registrant may:

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

(2) accept as the record of cumulative radiation dose, an up-to-date form, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant.

B. The registrant must record all the required history in a legible record.

C. If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant must assume the allowable dose limits

for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

Subp. 3. **Record.** A registrant must maintain records of doses received by all individuals for whom monitoring is required under part 4733.0320 and records of doses received during accidents or emergency conditions.

4733.0305. OCCUPATIONAL DOSE LIMITS FOR ADULTS.

Subpart 1. **Occupational dose control.** The registrant must control the occupational dose to individual adults to the following annual dose limit, which is the more limiting of:

- A. the total effective dose equivalent being equal to five rem (0.05 Sv); or
- B. the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv); and
- C. the annual limits to the lens of the eye, to the skin, and to the extremities, which are:
 - (1) a lens dose equivalent of 15 rem (0.15 Sv); and
 - (2) a shallow dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

Subp. 2. **Dose equivalent.**

A. The assigned deep dose equivalent and shallow dose equivalent must be for the portion of the body receiving the highest exposure.

B. The deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.

C. When a protective apron is worn while working with fluoroscopic equipment and monitoring is conducted as specified in part 4733.0320, the effective dose equivalent for external radiation must be determined as follows:

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

(2) when only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent value multiplied by 0.3 must be the effective dose equivalent for external radiation; or

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

D. Any alternative method of determining dose must be approved by the commissioner.

Subp. 3. **Reduction of dose.** The registrant must reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year.

Subp. 4. **Dose information.** The employee must supply information to the registrant about other current occupational doses received due to employment at multiple facilities.

Subp. 5. **Records.** A registrant must retain the records of monitored individual's doses for the lifetime of the individual worker or a minimum of 30 years after termination of employment with the facility, whichever is less.

4733.0310. DOSE EQUIVALENT TO AN EMBRYO OR FETUS.

A. When a woman declares her pregnancy in writing, the registrant must ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). Records must be kept according to part 4733.0145.

B. The registrant must make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the limit in item A.

C. A registrant must make a reasonable effort to limit the occupational dose to the embryo or fetus to 0.05 rem (0.5 mSv) in any one month of pregnancy, excluding medical exposure.

D. If the dose to the embryo or fetus is found to have exceeded 0.5 rem (5 mSv) or is within 0.05 rem (0.5 mSv) of this dose by the time the woman declares her pregnancy, the registrant must ensure that additional occupational dose equivalent to the embryo or fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

4733.0315. RADIATION DOSE LIMITS FOR THE PUBLIC.

A. A registrant must not use radiation-producing equipment in a manner that could result in an individual member of the public receiving an annual effective dose equivalent in excess of 0.1 rem (1.0 mSv).

B. A registrant must conduct operations so that the dose in any unrestricted area does not exceed 0.002 rem (0.02 mSv) in any one hour.

C. The registrant must show compliance with the annual public dose limit in this part, by demonstrating by measurement or calculation that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the registered operation does not exceed the annual dose limit.

4733.0320. INDIVIDUAL MONITORING.

Subpart 1. **Exposure levels.** A registrant must monitor exposures to radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this chapter.

Subp. 2. **Requirements for individual monitoring.** Each registrant must supply the following personnel with appropriate individual monitoring devices and require personnel to wear the monitoring devices:

A. adults likely to receive, in one year, a dose in excess of ten percent of the limits in part 4733.0305;

B. minors likely to receive, in one year, greater than ten percent of the annual occupational dose limits specified for adult workers in part 4733.0305,

C. declared pregnant women likely to receive, during the entire pregnancy, a dose in excess of 0.1 rem (1.0 mSv). All of the occupational doses under part 4733.0305 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded; and

D. individuals entering a high or very high radiation area.

Subp. 3. **Required instruction.** All individuals who, in the course of employment, are likely to receive in a year an occupational dose in excess of 100 millirems (1 mSv) must be:

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

B. instructed in and required to observe, to the extent within the worker's control, the applicable provisions of this chapter that protect personnel from exposure to radiation;

C. instructed of their responsibility to report promptly to the registrant any condition that may lead to or cause a violation of this chapter or any unnecessary exposure to radiation;

D. instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation; and

E. advised as to the radiation exposure reports that workers may request according to part 4733.0170.

Subp. 4. **Monitoring exposure.** In determining which individuals are subject to subpart 2, a registrant must take into consideration an individual's assigned activities during normal and abnormal situations involving exposure to radiation that can reasonably be expected to occur during the life of a registered facility. The extent of the instructions must be commensurate with potential radiological health protection problems present in the work place.

4733.0325. INDIVIDUAL MONITORING RESULTS.

Subpart 1. **Required records.** A registrant must maintain records of doses received by all individuals for whom monitoring is required under part 4733.0320, and records of doses received during accidents and emergency conditions.

Subp. 2. **Record keeping frequency.** Each registrant must make dose information available to individual worker as shown in records maintained by the registrant under the provisions of 4733.0320 annually if:

A. the individuals occupational dose exceeds 100 mrem (1 mSv) TEDE; or

B. the individual requests his or her report.

Subp. 3. **Embryo/fetus records.** A registrant must maintain the records of the dose to an embryo/fetus and, if applicable, the records of the dose to the declared pregnant woman.

Subp. 4. **Record retention.** A registrant must retain the records of individual doses for the lifetime of the individual worker or a minimum of 30 years after termination of employment with the facility, whichever is less.

RADIATION SAFETY

4733.0400. REGISTRANT'S SAFETY RESPONSIBILITIES.

Subpart 1. **Applicability.** The registrant is responsible for the operation of radiation therapy systems, electronic brachytherapy, and therapy simulation systems under the registrant's administrative control and must ensure that the requirements of this chapter are met.

Subp. 2. Designation of radiation safety officer.

A. If the registrant is not the radiation safety officer; the registrant must appoint a radiation safety officer. The individual must be qualified by training and knowledge concerning radiation hazards and precautions involved in the operation of the radiation therapy system and therapy simulation systems.

B. The individual designated as a radiation safety officer must be either a licensed practitioner of the healing arts or an individual who has completed training in the following items:

- (1) fundamentals of radiation safety;
- (2) familiarization with facility's radiation-producing equipment;
- (3) film processing, if applicable;
- (4) quality management program;
- (5) audits of the quality management program;
- (6) audits of the radiation therapists and medical dosimetrists;
- (7) the registrant's written operating and emergency procedures;
- (8) proper use of individual monitoring, if applicable; and
- (9) requirements of pertinent state rules.

C. The radiation safety officer must agree in writing using MDH "Delegation of Authority" or equivalent to be responsible for implementing the Quality Management program.

D. The registrant must provide the radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

- (1) identify radiation safety problems;
- (2) initiate, recommend, or provide corrective actions;
- (3) stop unsafe operations; and
- (4) verify implementation of corrective actions.

E. The registrant, through the radiation safety officer, must ensure that radiation safety activities are being performed according to registrant-approved procedures and this chapter.

Subp. 3. **Records.** Records must be maintained according to part 4733.0145.

4733.0405. RADIATION SAFETY OFFICER RESPONSIBILITIES.

Subpart 1. **RSO Responsibilities.** The radiation safety officer must:

A. establish a quality management program for compliance with the applicable requirements of this chapter;

B. establish and oversee operating, emergency, and ALARA (as low as reasonably achievable) procedures;

C. implement or arrange to implement other procedures as required by this chapter;

D. review the established quality management program procedures, content and implementation at intervals not to exceed 12 months;

E. ensure that individual monitoring devices are calibrated and used properly;

F. investigate and report to the commissioner each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter, to determine the cause, and to take steps to prevent it recurrence;

G. ensure that personnel are complying with this chapter and the operating and emergency procedures; and

H. oversee and approve all phases of the annual instructions or training program for radiation therapy personnel on the radiation therapy systems, electronic brachytherapy and therapy simulator systems.

Subp. 2. **Additional responsibilities.** In addition to subpart 1, the individual who is the radiation safety officer must:

- A. ensure that inspection and maintenance programs are performed according to this chapter and the manufacturer's specifications;
- B. perform or arrange to have performed:
 - (1) radiation surveys;
 - (2) audits of the program and the therapists and dosimetrists;
 - (3) calibrations;
 - (4) equipment performance evaluations;
 - (5) review of quality control tests and checks; and
 - (6) review individual monitoring reports, if applicable.
- C. ensure that any required interlock switches and warning signals are checked;
- D. assume control and institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions; and
- E. ensure documentation and records training, equipment tests, calibrations, radiation surveys, equipment performance, and maintenance of the radiation therapy systems, electronic brachytherapy, and therapy simulation systems are maintained according to part 4733.0145.

4733.0410. QUALIFIED MEDICAL PHYSICIST SUPPORT.

Subpart 1. **Physicist responsibilities.** The registrant must obtain the support of a qualified medical physicist. The qualified medical physicist must be responsible for:

- A. full calibrations required by this chapter and radiation surveys required by parts 4733.0265; 4733.0505; and 4733.0530.
- B. supervision and review of dosimetry;
- C. beam data acquisition, transfer for computerized dosimetry, and supervision of its use;
- D. quality management including quality control check reviews, as required;
- E. consultation for treatment planning, as needed; and
- F. performing calculations and assessments regarding medical events.

Subp. 2. **Availability.** If the qualified medical physicist is not immediately available, the operating procedures required by this chapter must address the specific actions, if any, to be taken in the event of problems, failures, or emergencies.

4733.0420. FACILITY REQUIREMENTS FOR SAFETY TRAINING.

Subpart 1. Training requirements.

A. An individual operating a radiation therapy system or therapy simulation system must be instructed initially in facility specific and system specific operating procedures, emergency procedures, quality control procedures, and the shielding to be used. Additional training must be conducted at the time of any change to the quality management program or to the radiation output due to the use of a new modality, technology, new radiation or simulation equipment when applicable.

B. The registrant must also comply with the training requirements under part 4733.0320 if an individual is required to be monitored for their occupational radiation dose.

Subp.2. Exposure of individuals other than patient.

A. During any radiation therapy system use or therapy simulator system use, any door that is part of the protective barrier must be closed.

B. No individual other than the patient can be in a therapy treatment room during exposures from a therapeutic system operating above 150 kVp.

Subp. 3. **Records.** Records of exposure and training must be maintained according to part 4733.0145.

QUALITY MANAGEMENT PROGRAM

4733.0425. QUALITY MANAGEMENT PROGRAM.

Subpart 1. **General requirements.** A registrant using a radiation therapy system, electronic brachytherapy, or a therapy simulation system must implement a site-specific quality management program. The program must include:

A. a description of the quality control procedures for radiation protection;

B. initial and annual training and documentation for employees as specified in part 4733.0420;

C. the equipment performance tests for a therapy simulation system and related evaluation documentation, including films, as appropriate, as specified in:

- (1) Code of Federal Regulations, title 21, for therapeutic simulation equipment;
- (2) the manufacturer's specifications; or
- (3) this chapter;

D. the documentation of any deficiencies found during the equipment performance tests and the corrective actions taken;

E. calibrations and documentation as required in this chapter. This includes the calibration record of any electronic equipment used in quality control tests; and

F. radiation program audits as specified in part 4733.0430.

Subp. 2. **Out-of-limits parameters.** When an operating parameter has been exceeded, the radiation therapy or simulation system must not be used or must be limited to those uses permitted by the registrant, radiation safety officer, or qualified medical physicist until corrective actions have been taken and verified to have corrected the out-of-limits parameters.

A. The registrant must establish procedures governing such use; and

B. such use cannot exceed 14 days.

Subp. 3. **Additions.** In addition to subpart 1, each registrant with radiation therapy systems must also make spot checks as specified in parts 4733.0500 through 4733.0535.

Subp. 4. **Records.** The registrant must maintain the quality management program records according to part 4733.0215.

4733.0430. RADIATION PROGRAM AUDITS.

Subpart 1. **Program review.** A registrant must ensure that the quality management program, its content, and implementation are reviewed annually. The radiation program audit in this part must be reviewed for compliance with this chapter.

Subp. 2. **Procedures.** The registrant must ensure that all quality management program audits are performed according to procedures established by the registrant or radiation safety officer. The audits must review:

- A. equipment quality control tests, evaluations, and any corrective actions taken;
- B. simulation system quality control tests, evaluations, and any corrective actions taken;
- C. treatment planning system quality control tests, evaluations, and any corrective actions taken;
- D. written procedures for transfer and verification of simulation views to treatment planning to radiation therapy system and any corrective actions taken;
- E. performance of the operators; and
- F. other parts of the quality management program specific to the facility identified by either the registrant or qualified medical physicist.

Subp. 3. **Corrective actions.** Any noncompliance issues found during the audit must be corrected and documented. The radiation safety officer must review any corrective actions.

Subp. 4. **Records.** A record of each audit must be prepared and maintained at the facility according to the record retention requirements in part 4733.0145.

4733.0435. ORDERING OF RADIOGRAPHIC OR THERAPEUTIC PROCEDURES.

Subpart 1. **Meeting therapeutic procedures.** The registrant must be responsible for ensuring that the requirements in this part for ordering simulation or therapeutic procedures are met.

Subp. 2. **Therapeutic procedure orders.**

A. The order for radiation therapeutic or electronic brachytherapy treatments can be made only by:

- (1) a licensed practitioner of the healing arts;
- (2) a physician assistant supervised by a therapeutic radiologist or a radiation oncologist. The physician assistant must show eligibility to order therapeutic procedures according to the physician-physician assistant agreement authorized under Minnesota Statutes, section 147A.20.

B. An order for radiation therapeutic treatments must be available to personnel at the time of the treatment.

C. The order for a therapeutic procedure must include:

- (1) identification of the patient;
- (2) identification of the individual ordering the treatment, through a signature, an electronic signature, or equivalent procedure;
- (3) exact anatomical area to be treated;
- (4) total dose to be delivered to the treatment site;
- (5) dose per fraction; and
- (6) overall treatment time period.

D. The operator must not carry out radiation therapeutic treatments unless ordered by individuals listed in this subpart.

Subp. 3. **Identification prior to administration of treatment.** Prior to each administration of a treatment series, the patient's identity must be verified as the individual named in the procedure order. This should be done using two means of identification.

Subp. 4. **Order for therapy simulator system procedures.**

- A. The order for a simulation examination can be made only by:
 - (1) a licensed practitioner of the healing arts;
 - (2) certified clinical nurse specialist;
 - (3) certified nurse practitioner; or
 - (4) physician assistant. The physician assistant must show eligibility to order simulation procedures according to the physician-physician assistant agreement authorized under Minnesota Statutes, section 147A.20, with a copy at the facility.
- B. The order for a simulation procedure must include:
 - (1) identification of the patient;
 - (2) identification of the individual ordering the examination through a signature, an electronic signature, or equivalent procedure;
 - (3) clearly stated clinical indications for the examination;
 - (4) exact anatomical part to be examined; and
 - (5) the examination to be performed.
- C. Any diagnostic imaging to be done on a CT simulator or other simulator system cannot be done by the radiation therapist or dosimetrist unless the individual meets the requirements in Radiation Rules, Chapter 4732.

Subp. 5. **Records.** Records of the order for the therapy treatment and the simulation procedures must be kept in the patient's chart for review by the commissioner according to part 4733.0145.

CALIBRATIONS

4733.0440. RADIATION SURVEY OR MEASUREMENT INSTRUMENTS.

Subpart 1. **Requirements.** To ensure correct response to radiation, each radiation survey instrument must be calibrated at intervals not to exceed 12 months and after each servicing:

- A. be calibrated at energy levels and over a range appropriate for the use;
- B. be calibrated to accuracy within plus or minus 20 percent over the applicable range of the instrument;
- C. have records of the calibrations maintained;
- D. the calibration of any electronic equipment must be traceable to its calibration standard at the National Institute of Standards and Technology (NIST); and
- E. non-invasive kVp meters must be calibrated by the manufacturer or an accredited calibration laboratory.

Subp. 2. **Records.** The registrant must maintain the records of the tests and calibrations according to part 4733.0145.

4733.0445. DOSE MONITORING SYSTEM.

Subpart 1. **Requirements.** The registrant must have a calibrated dose monitoring system available for quality control measurements. The system must be calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL).

- A. For beams with energies greater than 1.0 MV (1.0 MeV), the dosimetry system must have been calibrated for Cobalt-60.
- B. For beams with energies equal to or less than 1.0 MV (1.0 MeV), the dosimetry system must have been calibrated at an energy (energy range) appropriate for the radiation being measured.

Subp. 2. Calibrations.

A. The calibration must have been performed:

- (1) within the previous 24 months; and
- (2) after any servicing that may have affected system calibration.

B. The system must have been calibrated within the previous 48 months provided that 24 months after that calibration the system has been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM.

Subp. 3. Intercomparison.

A. The results of the intercomparison must indicate that the calibration factor of the system had not changed by more than two percent. The intercomparison result cannot be used to change the calibration factor.

B. When intercomparing dose monitoring systems to be used for calibrating radiation therapy systems, a unit comparable to the therapy systems which the instrument is used to calibrate must be used.

Subp. 4. Records. The registrant must maintain a record according to 4733.0145, of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record must include:

- A. the date;
- B. the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared;
- C. the correction factors that were determined;
- D. the names of the individuals who performed the calibration, inter-comparison, or comparison; and
- E. evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a qualified medical physicist.

4733.0450. RADIATION TREATMENT PLANNING SYSTEMS.

Subpart 1. **Treatment planning.** The treatment planning system is ~~considered~~ a system whose procedures and decisions are made preceding a radiation treatment. Although the

treatment planning precedes patient treatment, it can occur frequently throughout a course of treatment as the clinical or physical factors indicate a need for treatment modification. The quality management program must include a review and verification procedure of each aspect of the physical and clinical procedural components of the treatment plan.

Subp. 2. **Duties.** The registrant must ensure:

A. the treatment planning is an integration of dosimetric principles, tumor localization studies and simulation examinations designed to individualize patient localization and individualize patient treatment plans;

B. patient data acquisition is accurate;

C. treatment decisions are made using procedures and equipment within the radiation therapy department;

D. that treatment verification is completed and signed by the qualified medical physicist and the radiation oncologist, medical dosimetrist or licensed practitioner of the healing arts;

E. that procedures and verifications are completed using a nationally recognized guidance such as the American Association of Physicist in Medicine (AAPM); and

F. that documentation is completed and maintained according to part 4733.0145.

EQUIPMENT REQUIREMENTS

4733.0500. RADIATION THERAPY SYSTEMS OF LESS THAN 500 KV.

Subpart 1. Leakage radiation

A. When the x-ray tube is operated at its maximum rated tube current and maximum kV, the leakage kerma rate must not exceed the value specified at the distance specified for that classification of radiation therapy system.

B. For each radiation therapy system, the registrant must obtain from the manufacturer documentation that the radiation system;

(1) has been measured under conditions which provide maximum leakage radiation;

(2) does not exceed the value specified at the distance specified for the classification of that x-ray system.

C. Compliance must be determined by measurements averaged over an area of 100 square centimeters.

D. Measurement must be performed at installation and whenever the tube is changed. Measures must be performed at least once every five years.

(1) for contract therapy systems, leakage kerma rate must not exceed 100 milliroentgens (mR) in one hour at five centimeters from the surface of the tube housing assembly;

(2) for systems at or below 150 kV, the leakage measured at any position five centimeters from the tube housing assembly must not exceed 100 mrad (1.0 mGy) in any one hour.

(3) for systems greater than 150 kVp and less than 500 kV, the leakage kerma rate measured at a distance of one meter from the target in any direction must not exceed 1.0 rad (1.0 cGy) in any one hour. This kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the kerma rate at a distance of five centimeters from the surface of the tube housing assembly must not exceed 30 rad (30 cGy) per hour.

E. The registrant must maintain the records on leakage radiation measurements at the facility according to part 4733.0145.

Subp. 2. Permanent diaphragms, cones, beam-limiting devices or blocks.

A. Permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.

B. Adjustable or removable diaphragms, cones, beam-limiting devices, or blocks must not transmit more than five percent of the useful beam for the most penetrating beam used. When adjustable beam-limiting devices are used, the position and shape of the radiation field must be indicated by a light beam.

Subp. 3. Filter systems. The filter system must be designed so that:

- A. filters cannot be accidentally displaced at any possible tube orientation;
- B. an interlock system must prevent irradiation if the proper filter is not in place;

C. the kerma rate escaping from the filter slot must not exceed 1.0 rad (1.0 cGy) per hour at one meter under any operating conditions; and

D. each filter is marked as to its material of construction and its thickness.

Subp. 4. X-ray tubes and tube housings.

A. The x-ray tube must be mounted so that it cannot accidentally turn or slide with respect to the housing aperture. The tube housing assembly must be capable of being immobilized for stationary portal treatments.

B. The tube housing assembly must be so marked that it is possible to determine the location of the source to within five millimeters, and such marking must be readily accessible for use during calibration procedures.

C. Contact therapy tube housing assemblies must have a removable shield equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

Subp. 5. Exposure controls, control panels and indicators.

A. A control devices and must be provided to terminate the radiation after a preset time interval has elapsed and must:

- (1) have a display at the treatment control panel;
- (2) have a preset time selector and an elapsed time or time remaining indicator;
- (3) be a cumulative timer that activates with an indication of "BEAM-ON" and

retains its reading after radiation is interrupted or terminated. After radiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator;

(4) permit accurate presetting and determination of exposure times as short as one second;

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

(6) not activate until the shutter is opened when radiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

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

B. The control panel, in addition to the provisions in item A, must have:

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

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

(3) a means for indicating kVp and x-ray tube current;

(4) the means for terminating an exposure at any time;

(5) a locking device that will prevent unauthorized use of the radiation therapy system; and

(6) for radiation therapy systems manufactured after July 9, 1997, a positive display of specific filters in the beam.

C. When a control panel can energize more than one x-ray tube:

(1) it must be possible to activate only one x-ray tube at any time;

(2) there must be an indication at the control panel identifying which x-ray tube is activated; and

(3) there must be an indication at the tube housing assembly when that tube is energized.

D. There must be a means of determining the central axis target-skin-distance to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

E. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the following conditions must be met:

(1) the beam must be attenuated by shutters having a lead equivalency not less than that of the tube housing assembly;

(2) after the unit is at operating parameters, the shutters must be controlled by the operator from the control panel; and

(3) an indication of shutter position must appear at the control panel.

F. Each radiation therapy system equipped with a beryllium or other low-filtration window must be clearly labeled as such upon the tube housing assembly and must be provided with a permanent warning device on the control panel that is activated when no additional filtration is present to indicate that the dose rate is very high.

Subp. 6. **Facility design requirements.** Except for electronic brachytherapy, these additional shielding requirements in this subpart must be met. The treatment room must have the following:

A. Provisions must be made for continuous two-way audio communication between the patient and the operator at the control panel. The radiation therapy system must not be used for irradiation of patients unless continuous two-way audio communication is possible; and

B. Windows, mirrors, closed-circuit television, or an equivalent viewing system must be provided to permit continuous observation of the patient following positioning and during irradiation and must be located so that the operator may observe the patient at all times from the treatment control panel. The radiation therapy system must not be used for patient irradiation unless at least one viewing system is operational; and

C. treatment rooms, which contain a radiation therapy system capable of operating in a range of 150 kV to 500 kV, must meet the following additional requirements:

(1) all protective barriers must be fixed except for entrance doors or beam interceptors;

(2) the control panel must be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

(3) interlocks must be provided so that all entrance doors, including doors to any interior booths, must be closed before treatment can be initiated or continued.

(4) it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(5) when a door is opened while the radiation therapy system is activated, the kerma rate at a distance of one meter from the source must be reduced to less than 100 mrad (1.0 mGy) per hour

4733.0505. FULL CALIBRATION MEASUREMENTS RADIATION THERAPY SYSTEMS OF LESS THAN 500 KV.

Subpart 1. The registrant must ensure that the corrective actions and calibrations are performed on the radiation therapy systems whenever that system does not meet the minimum equipment performance criteria in nationally recognized standards, such as:

- A. Code of Federal Regulations, title 21, section 892;
- B. the manufacturer's specifications; or
- C. the standards specified in this chapter.

Subp. 2. **Frequency.** Full system calibration must be performed by, or under the direct supervision of, a qualified medical physicist:

A. before the first irradiation of a patient following installation, reinstallation or after any change which might significantly alter the calibration or other characteristics of the therapy beam; or

B. whenever a quality control check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled.

Subp. 3. **Full Calibration.**

A. Full calibration must include measurement of all parameters in this chapter. Although it must not be necessary to complete all elements of a full calibration at the same time, all parameters, for all energies, must be completed at intervals not to exceed 12 months for machines, unless the commissioner requires a more frequent interval.

B. Calibration of the radiation output of an x-rays system must be performed with an instrument whose calibration meets requirements in part 4733.0440.

Subp. 4. Notwithstanding the requirements of this subpart:

A. full calibration of radiation therapy systems with multimode capabilities is required only for those modes or energies that are not within their acceptable range; and

B. if the repair, replacement, or modification does not affect all energies, full calibration must be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality control check procedures against the criteria in 4733.0510.

Subp. 5. **Records.** The registrant must maintain a record of each calibration for the duration of the registration according to part 4733.0145. The record must include:

- A. the date of the calibration;
- B. the manufacturer's name, model number, and serial number for both the radiation therapy system and the x-ray tube;

C. the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and

D. the signature or electronic signature of the individual responsible for performing the calibration.

4733.0510. PERIODIC QUALITY SPOT CHECKS RADIATION THERAPY SYSTEMS OF LESS THAN 500 KV.

Subpart 1. **Periodic quality spot checks.** Periodic quality spot checks must be performed on radiation therapy systems capable of operation at 150 kV or greater. To satisfy the requirements of this part, quality spot checks must meet the following requirements:

A. the registrant must perform quality spot checks according to written procedures established by the qualified medical physicist;

B. the quality control procedures must specify:

(1) the frequency at which tests or measurements are to be performed; and

(2) the quality control check is performed during calibrations

Subp. 2. **Tolerances.** The acceptable tolerance for each parameter measured in the quality control check, when compared to the value for that parameter determined in the calibration, must be stated:

A. the cause for a parameter exceeding an established tolerance must be investigated and corrected before the system is used for patient or human research subject irradiation.

B. whenever a quality control check indicates a significant change in the specified operating characteristics of a system, the system must be recalibrated.

Subp. 3. **Dosimetry system.** The registrant must use the dosimetry system described in part 4733.0445, to make the quality spot checks required in this part.

A. the registrant must have the qualified medical physicist review and sign the results of each radiation output quality control check within one month of test completion.

B. the registrant must ensure that safety quality spot checks of radiation therapy systems are performed at intervals not to exceed one month.

C. notwithstanding the requirements of this part, the registrant must ensure that no radiation therapy system is used to administer radiation to humans unless the quality spot checks required by this part are completed.

D. periodic quality spot checks must have been performed within the 30 days prior to administration.

Subp. 4. **Safety quality spot checks.** Safety quality spot checks must ensure proper operation of:

A. electrical interlocks at each external beam radiation therapy room entrance;

B. the "BEAM-ON" and termination switches;

C. beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

D. viewing systems; and

E. if applicable, electrically operated treatment room doors from inside and outside the treatment room.

Subp. 5. **Records.** The registrant must maintain a record of each quality control check for inspection by the commissioner according to part 4733.0145. The record must include:

A. the date of the quality control check;

B. the manufacturer's name, model number, and serial number for the therapeutic radiation machine;

C. the manufacturer's name, model number, and serial number of the instruments used to measure the radiation output of the radiation therapy system; and

D. the signature or electronic signature of the individual who performed the periodic quality control check.

4733.0515. OPERATING AND EMERGENCY PROCEDURES FOR RADIATION THERAPY SYSTEMS OF LESS THAN 500 KV.

Subpart 1. **Operating procedures.** The registrant must provide written operating procedures at the therapy system control console. The procedures must, at a minimum, include:

A. information on a locking device to secure the radiation therapy systems to prevent unauthorized use of the radiation therapy system;

B. how a patient will be held in position for radiation therapy and what mechanical supporting or restraining devices must be used;

C. procedures for restricting individual's from holding the tube housing assembly during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 150 kV. In these cases, the holder must wear protective apron and gloves of not less than 0.5 millimeters lead equivalency at 100 kV; and

D. procedures prohibiting individuals other than the patient in the treatment room during exposures from radiation therapy systems operating above 150 kV.

Subp. 2. **Emergency procedures.** The registrant must provide written emergency procedures available at the therapy control console. The procedures must, at a minimum, include:

A. the instructions for responding to equipment failures and the names and phone numbers of the individuals responsible for implementing corrective actions;

B. notification of the radiation safety officer, or their designee, and the registrant must be as soon as possible if the patient has a medical emergency, suffers injury or dies;

C. patient emergency procedures; and

D. notification of the manufacturer and the commissioner of the event.

Subp. 3. **Records.** The records must be maintained according to 4733.0145.

4733.0520. PHOTON AND ELECTRON PRODUCING SYSTEMS (500 KEV AND ABOVE).

Subpart 1. Leakage radiation.

A. Leakage radiation outside the maximum useful beam in photon and electron modes must meet the following:

(1) The absorbed dose due to leakage radiation, excluding neutrons, at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam must not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of

the beam at the nominal treatment distance, such as the patient plane. Measurements must be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

(2) Except for the area defined in this subpart, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window must not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters.

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

B. Leakage radiation through beam-limiting devices must meet the following:

(1) All adjustable or interchangeable beam-limiting devices must attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting devices do not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeter by 10 centimeter radiation field.

(2) All adjustable or interchangeable electron applicators must attenuate the radiation including, but not limited to, photon radiation generated by electrons incident on the beam-limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment does not exceed:

(a) a maximum of two percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line seven centimeters outside the periphery of the useful beam; and

(b) a maximum of ten percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit must apply beyond a line two centimeters outside the periphery of the useful beam.

C. Measurement of leakage radiation must meet the following:

(1) Measurements of leakage radiation through the beam-limiting devices must be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenths value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set must be measured independently at the depth of maximum dose. Measurements must be made using a radiation detector with an area not exceeding ten square centimeters.

(2) Measurements of leakage radiation through the electron applicators must be made with the electron beam directed into the air and using a radiation detector with an area up to, but not exceeding, one square centimeter suitably protected against radiation that has been scattered from material beyond the radiation detector. Measurements must be made using one centimeter of water equivalent buildup material.

Subp. 2. Filters and wedges. Filters and wedges must meet the following:

A. Each wedge filter that is removable from the system must be clearly marked with an identification number.

B. For removable wedge filters, the nominal wedge angle must appear on the wedge or wedge tray if permanently mounted to the tray.

C. If the wedge or wedge tray is significantly damaged, the wedge transmission factor must be re-determined.

D. If the absorbed dose rate information required by this subpart relates exclusively to operation with a field-flattening or beam-scattering filter in place, the filter must be removable only by the use of tools.

E. For equipment manufactured after July 9, 1997, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

(1) irradiation must not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

(2) an interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;

(3) a display must be provided at the treatment control panel showing the wedge filters; and

(4) an interlock must be provided to prevent irradiation if any filter or beam-scattering foil selection operation carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation carried out at the treatment control panel.

Subp. 3. Beam monitoring.

A. All radiation therapy systems must be provided with redundant beam monitoring systems. The sensors for these systems must be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(1) Equipment manufactured on or before July 9, 1997, must be provided with at least one radiation detector. This detector must be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated must meet the following requirements:

(a) each detector must be removable only with tools and, if movable, must be interlocked to prevent incorrect positioning; and

(b) each detector must form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated.

(2) Equipment manufactured after July 9, 1997, must be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

(3) For equipment manufactured after July 9, 1997, the design of the beam-monitoring systems must ensure that the:

(a) malfunctioning of one system must not affect the correct functioning of the other systems; and

(b) failure of any element common to both systems that could affect the correct function of both systems must terminate irradiation or prevent the initiation of radiation.

(4) Each beam-monitoring system must have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display must:

(a) maintain a reading until intentionally reset;

(b) have only one scale and no electrical or mechanical scale multiplying factors;

(c) utilize a design such that increasing dose is displayed by increasing numbers; and

(d) in the event of a power failure, the beam-monitoring information required in this subpart displayed at the control panel at the time of failure must be retrievable in at least one system for a 20-minute period of time.

(5) For equipment manufactured after July 9, 1997, the registrant must obtain data from the manufacturer or determine during acceptance testing, to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation, and stray neutron radiation in the useful x-ray beam are in compliance with the limits in this chapter. Each beam-monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation

(6) Bent-beam linear accelerators must be provided with auxiliary devices to monitor beam symmetry.

(7) The devices referenced in this subpart must be able to detect field asymmetry greater than ten percent, and must be configured to terminate irradiation if field asymmetry cannot be maintained at ten percent or less.

Subp. 4. Selection and display of dose monitor units.

A. The preselected number of dose monitor units must be displayed at the treatment control panel until reset manually.

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

C. For equipment manufactured after July 9, 1997, after termination of irradiation, it must be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

D. For equipment manufactured after July 9, 1997, a system must be provided from whose readings the kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in this subpart may form part of this system. In addition:

(1) the dose monitor unit rate must be displayed at the treatment control panel;

(2) if the equipment can deliver under any conditions an kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the

manufacturer, a device must be provided that terminates irradiation when the kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated must be a record maintained by the registrant;

(3) if the equipment can deliver under any fault conditions an kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device must be provided to prevent the kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4.0 Gy);

(4) for each radiation therapy system, the registrant must determine, or obtain from the manufacturer, the maximum values in this subpart for the specified operating conditions; and

(5) records of these maximum values must be maintained at the facility for inspection by the commissioner.

E. Termination of irradiation by the beam-monitoring system or systems during stationary beam radiation therapy.

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

(2) If the original design of the equipment included a secondary dose-monitoring system, that system must be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose-monitoring system.

(3) For equipment manufactured after July 9, 1997, an indicator on the control panel must show which monitoring system has terminated irradiation.

F. It must be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

G. If a radiation therapy system has an interrupt mode it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it must be possible to restart irradiation by operator action without any reselection of

operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements must be automatically terminated.

Subp. 5. **Timers.** A suitable irradiation control device must be provided to terminate the irradiation after a preset time interval.

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

B. The timer must be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator.

C. The timer must terminate irradiation when a preselected time has elapsed if the dose-monitoring systems have not previously terminated irradiation.

Subp. 6. **Equipment capable of multimode therapy.** Equipment capable of multi-mode therapy must meet the following additional requirements:

A. the radiation type must be selected and displayed at the treatment control panel before and during irradiation;

B. an interlock system must be provided to ensure that:

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

(2) prevention of x-ray irradiation, except to obtain a verification image, when electron applicators are fitted;

(3) prevention of electron irradiation with electrons, when accessories specific for x-ray therapy are fitted; and

(4) prevention of irradiation if any selected parameters carried out in the treatment room do not agree with the selected parameters carried out at the treatment control panel.

Subp. 7. **Radiation beams of different energies.** Equipment capable of generating radiation beams of different energies must meet the following requirements:

A. irradiation must not be possible until a selection of energy has been made at the treatment control panel;

B. the nominal energy value selected must be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it must be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

C. irradiation must not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

Subp. 8. **Stationary and moving beam radiation therapy.** Radiation therapy systems capable of both stationary beam radiation therapy and moving beam radiation therapy must meet the following requirements:

A. irradiation must not be possible until a selection of stationary beam radiation therapy or rotational arc radiation therapy has been made at the treatment control panel;

B. the mode of operation must be displayed at the treatment control panel;

C. an interlock system must be provided to ensure that the equipment can operate only in the mode that has been selected;

D. an interlock system must be provided to terminate irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

E. moving beam radiation therapy must be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

(1) an interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation differs by more than 20 percent from the selected value;

(2) where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than five percent from the dose monitor unit value selected;

(3) an interlock must be provided to prevent motion of more than five degrees beyond the selected limits during moving beam radiation therapy;

(4) an interlock must be provided to require that a selection of direction be made at the treatment control panel in all units that are capable of both clockwise and counterclockwise moving beam radiation therapy; and

(5) moving beam radiation therapy must be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

F. where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of radiation must be as required by part 4733.0500; and

G. for equipment manufactured after July 9, 1997, an interlock system must be provided to terminate irradiation if movement:

(1) occurs during stationary beam radiation therapy; or

(2) does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

Subp. 9. **Facility design requirements for radiation therapy systems operating above 500 kV.** In addition to shielding adequate to meet requirements of parts 4733.0250 through 4733.0260, the following design requirements are required:

A. Protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors.

B. The control panel must:

(1) be located outside the treatment room;

(2) provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(3) provide an indication of whether radiation is being produced; and

(4) include an access control locking device that will prevent unauthorized use of the therapeutic radiation machine.

C. Provisions must be made for continuous two-way audio communication between the patient and the operator at the control panel. The radiation therapy system must not be used for irradiation of patients unless continuous two-way audio communication is possible.

D. Windows, mirrors, closed-circuit television, or an equivalent viewing system must be provided to permit continuous observation of the patient following positioning and during irradiation and must be located so that the operator may observe the patient from the treatment control panel. The radiation therapy system must not be used for patient irradiation unless at least one viewing system is operational.

E. Treatment room entrances must be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF."

F. Interlocks must be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

G. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with part 4733.0255, interlocks must be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers.

H. At least one emergency power cutoff switch must be located in the radiation therapy room on either side of the primary beam and must terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subpart 1. All emergency power cutoff switches must include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

I. Safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

J. Surveys for residual activity must be conducted on all radiation therapy systems capable of generating photon and electron energies above 10 MV prior to removing or working on radiation therapy system components that may have become activated due to photon-neutron production.

K. A facility location authorized to use a radiation therapy system according to this part must have appropriately calibrated portable monitoring equipment. As a minimum, the equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1.0 mrem (ten μ Sv) per hour to 1,000 mrem (ten mSv) per hour. The survey instruments must be operable and calibrated according to part 4733.0440.

**4733.0525. OPERATING PROCEDURES FOR THERAPEUTIC SYSTEMS
OPERATING ABOVE 500 KV.**

Subpart 1. The registrant is required to ensure that written operating procedures include the following instructions:

A. no individual, other than the patient, must be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

B. the radiation therapy systems must not be made available for medical use unless the requirements of part 4733.0210 and this part have been met;

C. the radiation therapy systems, when not in operation, must be secured to prevent unauthorized use;

D. the position and shape of the radiation field must be indicated by a light field when adjustable beam-limiting devices are used; and

E. if a patient must be held in position during treatment, mechanical supporting or restraining devices must be used.

Subp. 2. **Records.** A copy of the current operating and emergency procedures must be maintained at the radiation therapy system control console.

**4733.0530. FULL CALIBRATION MEASUREMENTS FOR RADIATION THERAPY
SYSTEMS OPERATING ABOVE 500 KV.**

Subpart 1. The registrant must ensure that the calibrations and corrective actions are performed on the radiation therapy systems whenever that system does not meet the minimum equipment performance criteria in nationally recognized standards, such as:

A. Code of Federal Regulations, title 21, section 892;

B. the manufacturer's specifications with a copy on site; or

C. as specified in this chapter.

Subp. 2. **Full calibration.** Full calibration of a radiation therapy system must be performed by, or under the direct supervision of, a qualified medical physicist:

A. before the first medical use following installation or reinstallation of the radiation therapy system;

B. full calibration must include measurement of all parameters in this chapter.

Although it must not be necessary to complete all elements of a full calibration at the same time, all parameters, for all energies, must be completed at intervals not to exceed 12 months, unless the commissioner requires a more frequent interval;

C. before medical use under the following conditions:

(1) whenever quality control check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled. Radiation therapy systems with multi-energy or multimode capabilities, or both, must only require measurements for those modes or energies that are not within their acceptable range; and

(2) following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement, or modification does not affect all modes or energies, full calibration must be performed on the effected energy or mode that is in most frequent clinical use at the facility. The remaining energies or modes may be validated with quality control check procedures against the criteria in this subpart.

Subp. 3. **Dosimetry system.** The registrant must use the dosimetry system described in part 4733.0440 to measure the radiation output for one set of exposure conditions.

Subp. 4. **Records.** The registrant must maintain a record of each calibration for the duration of the registration according to 4733.0145. The record must include:

A. the date of the calibration;

B. the manufacturer's name, model number, and serial number for the therapeutic radiation machine;

C. the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and

D. the signature or electronic signature of the individual responsible for performing the calibration.

4733.0535. PERIODIC QUALITY SPOT CHECKS FOR RADIATION THERAPY SYSTEMS OPERATING ABOVE 500 KV.

Subpart 1. The registrant must use a dosimetry system that has been intercompared within the previous 24 months with the dosimetry system described in part 4733.0445, to make the periodic quality spot checks required in this subpart.

Subp. 2. **Review results.**

A. The registrant must review the results of each periodic radiation output check according to the following procedures:

(1) the registrant and qualified medical physicist must be immediately notified if any parameter is not within its acceptable tolerance. The radiation therapy system must not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within their acceptable tolerances;

(2) if all quality control check parameters appear to be within their acceptable range, the quality control check must be reviewed and signed by either the registrant or qualified medical physicist within seven working days; and

(3) the qualified medical physicist must review and sign the results of each radiation output quality control check within 30 working days of completion.

D. The registrant must promptly repair any system identified in this subpart that is not operating properly.

Subp.3. **Requirements.** To satisfy the requirement of this subpart, safety spot checks must ensure proper operation of:

- A. electrical interlocks at each external beam radiation therapy room entrance;
- B. proper operation of the "BEAM-ON," interrupt, and termination switches;
- C. beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
- D. viewing systems;
- E. audio systems; and
- F. electrically operated treatment room doors from inside and outside the treatment room.

Subp. 4. **Emergency cut-off switches.** Emergency power cut-off switches must be checked for proper operation at installation and any time there is a modification or repair of the emergency switch circuit.

Subp. 5. **Records.** The registrant must maintain records according to part 4733.0145. The record must include:

- A. the date of the quality control check;
- B. the manufacturer's name, model number, and serial number for the therapeutic radiation machine;
- C. the manufacturer's name, model number, and serial number of the instruments used to measure the radiation output of the radiation therapy system; and
- D. the signature or electronic signature of the individual who performed the periodic quality control check.

4733.0600. LINEAR ACCELERATOR-BASED ROBOTIC STEREOTACTIC RADIOSURGERY SYSTEMS.

Subpart 1. **Registrant's responsibilities.** In addition to other applicable parts of this chapter, the registrant must:

- A. provide individual monitoring according to part 4733.0320;
- B. ensure that only medical personnel trained in the safe use of the robotic stereotactic radiosurgery systems will be delivering the treatment;
- C. ensure that maintenance is completed and documented according to written procedures from the manufacturer's specifications or radiation safety officer;
- D. ensure that periodic spot checks are completed and documented;
- E. provide a copy of the current written operating and emergency procedures and be physically located at the control console, and
- F. document training, audits, quality control tests, calibrations and other related records are maintained according to part 4733.0145.

Subp. 2. **Shielding requirements.** The registrant must comply with the shielding requirements found in parts 4733.0250 through 4733.0275.

Subp. 3. **Training.**

- A. Initial training for staff of a linear accelerator-based robotic stereotactic radiosurgery system must be completed prior to using the system. This training must include:
 - (1) basic radiation safety;

(2) manufacturer's equipment specific training based on what treatment modalities the equipment is capable of;

(3) knowledge of the written operating and emergency procedures;

(4) knowledge of periodic spot checks;

(5) the daily quality control procedures the operators are required to perform; and

(6) other topics the registrant and radiation safety officer deem appropriate.

B. Records must be kept on all training according to part 4733.0145.

Subp. 4. **Operating procedures.** The registrant must provide written operating procedures available at the therapy system control console. The procedures must, at a minimum, include:

A. information on securing the radiation therapy system to prevent unauthorized use;

B. methods for controlling access to restricted areas;

C. how a patient will be held in position for radiation therapy and what mechanical supporting or restraining devices must be used;

D. procedures prohibiting individuals other than the patient in the treatment room during treatment;

E. procedures for verification of the treatment plan transfer to the therapy computer prior to treatment; and

F. procedures for contacting needed personnel such as the registrant, radiation safety officer, and physicist.

Subp. 5. **Emergency procedures.** The registrant must provide written emergency procedures available at the therapy control console. The procedures must, at a minimum, include:

A. the instructions for responding to equipment failures and the names and phone numbers of the individuals responsible for implementing corrective actions;

B. notification of the radiation safety officer, or their designee, and the registrant must be as soon as possible if the patient has a medical emergency, suffers injury or dies.;

C. patient emergency procedures; and

D. notification of the manufacturer and the commissioner of the event.

Subp. 6. **Calibrations.** Calibrations of the radiosurgery system, the x-ray tubes, on-board imaging system, and other imaging systems used for simulations must be completed according to this chapter. Instrumentation used for calibration must meet the requirements in part 4733.0440.

Subp. 7. **Quality control requirements.** The quality control tests must be conducted using written procedures from the system manufacturer or the qualified medical physicist or 4733.1012 to ensure compliance with this chapter.

Subp. 8. **Records.** Records must be kept according part 4733.0145.

4733.0700. HELICAL TOMOTHERAPY SYSTEMS.

Subpart 1. **Registrant's responsibilities.** In addition to other appropriate parts of this chapter, the registrant or radiation safety officer must:

- A. provide individual monitoring according to part 4733.0320;
- B. ensure that only medical personnel trained in the safe use of the helical tomotherapy system will be delivering the treatment;
- C. ensure the survey instruments must be operable and calibrated in accordance with 4733.0440;
- D. ensure that calibrations required in this chapter are completed and documented for review by the commissioner;
- E. ensure that maintenance is completed and documented according to written procedures from the system manufacturer or the radiation safety officer;
- F. ensure that periodic spot checks are completed and documented;
- G. provide a copy of the current written operating and emergency procedures physically located at the control console, and
- H. ensure that document training, audits, quality control tests, calibrations and other related records are maintained in accordance with part 4733.0145.

Subp. 2. **Shielding requirements.** The registrant must comply with the shielding requirements found in parts 4733.0250 through 4733.0275.

Subp. 3. **Training requirements.** All helical tomotherapy operators must be trained initially on site-specific system, manufacturer's requirements and this chapter. The training must include:

- A. basic radiation safety;
- B. the daily quality control procedures the operators are required to perform;
- C. registrant's operating and emergency procedures;
- D. basic CT scanners knowledge, anatomy and techniques based on operator's background; and
- E. other topics the registrant and radiation safety officer deem appropriate.

Subp. 4. **Operating procedures.** The registrant must provide written operating procedures available at the therapy system control console. The procedures must, at a minimum, include:

- A. information on securing the radiation therapy system to prevent unauthorized use;
- B. methods for controlling access to restricted areas;
- C. how a patient will be held in position for radiation therapy and what mechanical supporting or restraining devices must be used;
- D. procedures prohibiting individuals other than the patient in the treatment room during treatment; and
- E. procedures for verification of the treatment plan transfer to the therapy unit prior to treatment; and
- F. procedures for contacting needed personnel such as the registrant, radiation safety officer, and physicist.

Subp. 5. **Emergency procedures.** The registrant must provide written emergency procedures available at the therapy control console. The procedures must, at a minimum, include:

- A. the instructions for responding to equipment failures and the names and phone numbers of the individuals responsible for implementing corrective actions;
- B. notification of the radiation safety officer, or their designee, and the registrant must be as soon as possible if the patient has a medical emergency, suffers injury or dies.;
- C. patient emergency procedures; and

D. notification of the manufacturer and the commissioner of the event.

Subp. 6. **Calibrations.** Calibrations of the CT, any radiographic or fluoroscopic x-ray tubes, and imaging systems used for simulations must be completed in accordance with this chapter. Instrumentation used for calibration must meet the requirements in part 4733.0440.

Subp. 7. **Quality control requirements.** The quality control tests must be performed using procedures established by a qualified medical physicist or the system manufacturer. Any service or repairs must be performed by a service representative of the manufacturer. Minimum quality control tests can be found in 4733.1075.

4733.0800. ELECTRONIC BRACHYTHERAPY SYSTEMS.

Subpart 1. **Applicability.** Electronic brachytherapy systems are subject to the requirements of applicable parts this chapter and are exempt from part 4733.0500.

Subp. 2. **Registrant's responsibilities for electronic brachytherapy systems.** The registrant must:

A. use an electronic brachytherapy system specifically approved by the U.S. Food and Drug Administration (FDA) and utilized for approved human use applications; or

B. be participating in a research study approved by the registrant's Institutional Review Board (IRB); or.

C. do research, according to an active investigational device exemption application accepted by the Food and Drug Administration; and

D. ensure that an electronic brachytherapy system that does not meet these requirements is not be used for irradiation of patients.

E. provide individual monitoring according to part 4733.0320, if applicable;

F. ensure compliance with all applicable parts of this chapter;

G. ensure that only medical personnel trained in safe use of the electronic brachytherapy system including the manufacturer's device-specific training will be delivering the treatment;

(1) the understanding of radiation therapy using electronic brachytherapy;

(2) the radiation safety issues in using electronic brachytherapy;

H. ensure that the required radiation surveys are completed;

I. possess survey instruments capable of measuring dose rates over the range one mrem (ten μ Sv) per hour to 1000 mrem (ten mSv) per hour. The survey instruments must be operable and calibrated in accordance with 4733.0440;

J. ensure that maintenance is completed and documented according to written procedures from the manufacturer or the radiation safety officer;

K. ensure the radiation safety activities are performed according the approved procedures and regulatory requirements in the daily operation of the electronic brachytherapy devices;

L. ensure that appropriate periodic spot checks are completed and documented;

M. provide a copy of the current operating and emergency procedures and be physically located at the control console. If the control console is integral to the electronic brachytherapy system, the required procedures must be kept where the operator is located during the system operation;

N. ensure that provisions are made to prevent simultaneous operation of more than one radiation therapy system in a treatment room; and

O. ensure that documenting of training, audits, quality control tests, calibrations and other related records are maintained in accordance with part 4733.0145.

Subp. 3. Facility design requirements for electronic brachytherapy systems.

In addition to applicable shielding and facility design requirements in parts 4733.0250 to 4733.0275, the treatment room must meet the following design requirements:

A. access to the treatment room must be controlled by a door at each entrance;

B. the electronic brachytherapy system must not be used for patient irradiation unless the patient can be observed;

C. for electronic brachytherapy systems operating below 150 kV, radiation shielding for the staff in the treatment room must be available, either as a portable shield and/or as localized shielding material around the treatment site;

D. for electronic brachytherapy systems capable of operating at greater than 150 kV, if applicable:

(1) the control panel must be located outside the treatment room; and

(2) electrical interlocks must:

(a) be provided for all doors to the treatment room that will prevent the operator from initiating the treatment cycle unless each treatment room entrance is closed,

(b) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(c) cause the x-ray tube to be shielded when an entrance door is opened; and

(d) prevent the x-ray tube from being exposed following an interlock interruption until all treatment room entrance doors are closed and the x-ray tube on-off control is reset at the console.

E. electrical safety for electronic brachytherapy systems:

(1) the high voltage transformer must be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment;

(2) the high voltage transformer must be isolated from operator and the environment by a protective housing requiring special tools to open or with electrical interlocks to prevent operation while open;

(3) the high voltage transformer must have appropriate safety labels warning personnel of potential electrical shock and heat-related injuries; and

(4) equipment must be in compliance with the most current revision of the following International Electrotechnical Commission (IEC) Documents:

(a) IEC 60601-1:1998+A1+A2:1995;

(b) IEC 60601-1-2:2001;

(c) IEC 60601-2-8:1999; and

(d) IEC 60601-2-17:2004.

F. the control panel, in addition to the displays required by part 4733.0250 to 4733.0275, must:

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

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

(3) provide a means for indicating electronic brachytherapy x-ray tube potential and current;

(4) provide the means for terminating an exposure at any time; and

(5) include a locking device that will prevent unauthorized use of the electronic brachytherapy system.

G. a suitable irradiation timer must:

(1) be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor;

(2) be provided at treatment control panel and indicate planned setting and the time elapsed or remaining time;

(3) be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator;

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

(5) permit setting of exposure times as short as 0.1 second;

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

(7) be accurate to within one percent of the selected value or 0.1 second, whichever is greater.

Subp. 4. **Training.** The registrant must ensure operators of the electronic brachytherapy system are qualified by knowledge and experience. The registrant must provide instruction as follows:

A. for individuals who operate the electronic brachytherapy system initially and at least annually, as appropriate to the individual's assigned duties in the operating procedures and if the interval between patients exceeds one year, retraining of the individuals must be provided and must cover:

(1) system-specific radiation safety requirements;

(2) system operation;

(3) clinical uses approved by the FDA;

(4) emergency procedures, including an emergency drill; and

(5) the registrant's quality management program

D. The registrant must retain a record of individuals receiving instruction according to part 4733.0145.

Subp. 5. **Qualified medical physicist support.** The services of a qualified medical physicist are required in facilities having electronic brachytherapy systems. The qualified medical physicist must be responsible for the electronic brachytherapy must:

- A. evaluate of the output from the electronic brachytherapy x-ray tube;
- B. generate of the necessary dosimetric information;
- C. supervise and review of treatment calculations prior to initial treatment of any treatment site;
- D. establish the appropriate periodic and day-of-use spot checks and reviewing the data from those checks as required in this part;
- E. consult and review with the radiation oncologist or a licensed practitioner of the healing arts for the treatment planning, as needed;
- F. perform calculation and assessments regarding patient treatments that may constitute a medical event; and
- G. be physically present during the initiation and available during-each patient treatment.

Subp. 6. **Operating procedures.** The registrant must have written procedures developed, implemented, and maintained for proper use of the electronic brachytherapy system. The registrant is responsible for establishing operating procedures for brachytherapy activities and making the procedures available at the control consoled. If the control console is integral to the electronic brachytherapy system, the required procedures must be kept where the operator is located during the system operation. The procedures must require that:

- A. only individuals approved by the registrant, radiation safety officer or qualified medical physicist can be present in the treatment room during treatment;
- B. electronic brachytherapy systems must not be made available for medical use unless the requirements of this chapter have been met;
- C. any quality control tests must be completed prior to the use on the patient on any given day;
- D. the electronic brachytherapy system must be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

E. the electronic brachytherapy system operator must monitor the position of all persons in the treatment room during operation and all persons entering the treatment room to prevent persons from unshielded exposure; and

F. if a patient must be held in position during treatment, mechanical supporting or restraining devices must be used.

Subp.7. **Emergency procedures.** The registrant must have written emergency procedures developed, implemented, and maintained for responding to an abnormal situation and available at the control console. If the control console is integral to the electronic brachytherapy system, the required procedures must be kept where the operator is located during the system operation. These procedures must include:

A. instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

B. the names and telephone numbers of the administration, qualified medical physicist, and the radiation safety officer to be contacted if the system or console operates abnormally;

C. instructions for notification of the radiation safety officer, or their designee, and the registrant must be as soon as possible if the patient has a medical emergency, suffers injury or dies; and

D. instructions for informing the manufacturer and the commissioner of the event.

Subp. 8. **Safety precaution requirements.**

A. When shielding is required, a survey meter to verify proper placement of the shielding must be used before the initiation of treatment. Alternatively, a qualified medical physicist must designate shielded locations sufficient to meet the requirement of parts 4733.0300 through 4733.0315 for any individual, other than the patient, in the treatment room;

B. A qualified medical physicist and either a radiation oncologist or licensed practitioner of the healing arts who have been trained in the operation and emergency response for the electronic brachytherapy system, must be physically present during the initiation of all patient treatments involving the electronic brachytherapy system;

C. An operator who has been trained in the operation and emergency response for the electronic brachytherapy system must be physically present during the initiation and available during patient treatments; and

D. All personnel in the treatment room are required to remain behind shielding during treatment. A qualified medical physicist must approve any deviation from this requirement and must designate alternative radiation safety protocols compatible with patient safety to provide an equivalent degree of protection.

Subp. 9. Electronic brachytherapy x-ray tube calibration measurements.

A. Calibration of the electronic brachytherapy x-ray tube output for an electronic brachytherapy system must be performed by, or under the direct supervision of, a qualified medical physicist;

B. Calibration of the electronic brachytherapy x-ray tube output must be made for each electronic brachytherapy system:

- (1) after any repair affecting the x-ray beam generation; or
- (2) when indicated by the electronic brachytherapy x-ray tube spot checks;

C. Calibration of the electronic brachytherapy x-ray tube output must utilize a dosimetry system in part 4733.0445;

D. Calibration of the electronic brachytherapy x-ray tube output must include, as applicable, determination of:

- (1) the output within two percent of the expected value, if applicable, or determination of the output if there is no expected value;
- (2) timer accuracy and linearity over the typical range of use;
- (3) proper operation of backup exposure control devices;
- (4) evaluation that the relative dose distribution about the x-ray tube is within five percent of that expected; and
- (5) x-ray tube positioning accuracy to within one millimeter within the applicator.

E. Calibration of the x-ray tube output required above must be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy. In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration procedures must be followed.

F. The registrant must maintain a record of each calibration in an auditable form for the duration of the registration. The record must include:

- (1) date of the calibration;

- (2) manufacturer's name;
- (3) model number and serial number for the electronic brachytherapy system;
- (4) model numbers and serial numbers of the instruments used to calibrate the electronic brachytherapy system; and
- (5) the name and signature of the qualified medical physicist responsible for performing the calibration.

Subp. 10. Periodic and day-of-use spot checks.

A. Spot checks must be performed on each electronic brachytherapy system:

- (1) at the beginning of each day of use;
- (2) each time the system is moved to a new room or site; and
- (3) after each x-ray tube installation.

B. The registrant must perform required periodic spot checks according to procedures established by the manufacturer's specifications or qualified medical physicist;

C. To satisfy the requirements of subpart 2, radiation output spot checks must include as a minimum:

(1) verification that output of the electronic brachytherapy x-ray tube falls within three percent of expected values, as appropriate for the system, as determined by either the output as a function of time or the output as a function of setting on a monitor chamber.

(2) verification of the consistency of the dose distribution to within three percent of that found during calibration; and

(3) validation of the positioning methods to ensure that the treatment dose exposes the intended location within one millimeter; and

D. The registrant must review the results of each radiation output quality control check according to the following procedures:

(1) a radiation oncologist or licensed practitioner of the healing arts and the qualified medical physicist must be notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy system must not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within their acceptable tolerances;

(2) if all radiation output quality control check parameters appear to be within their acceptable range, the quality control check must be reviewed and signed by either the oncologist or licensed practitioner of healing arts or physicist within two days; and

(3) the qualified medical physicist must review and sign the results of each radiation output quality control check at intervals not to exceed 30 days.

E. To satisfy the requirements of subpart 2, safety system spot checks must, at a minimum, assure:

(1) proper operation of radiation exposure indicator lights on the electronic brachytherapy system and on the control console;

(2) proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

(3) proper operation of radiation monitors, if applicable;

(4) the integrity of all cables, catheters or parts of the device that carry high voltages; and

(5) that connecting guide tubes, transfer tubes, transfer-tube applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

F. If the results of the safety system spot checks required by this part indicate the malfunction of any system, the registrant must secure the control console in the OFF position and not use the electronic brachytherapy system except as may be necessary to repair, replace, or check the malfunctioning system.

G. The registrant must maintain a record of each required quality control check in an auditable form until the next inspection by the commissioner. The record will include:

(1) the date of the quality control check;

(2) model number and serial number for the electronic brachytherapy system;

(3) the name and signature of the individual who performed the periodic quality control check; and

(4) the name and signature of the qualified medical physicist who reviewed the quality control check.

(5) for radiation output spot checks, the record must:

(a) include the unique identifier for the electronic brachytherapy x-ray tube;

(b) the manufacturer's name;

(c) model number and serial number for the instruments used to measure the radiation output of the electronic brachytherapy system.

Subp. 11. Required quality control tests for electronic brachytherapy systems.

Quality control testing schedule for electronic brachytherapy systems can be found in part 4733.1014.

4733.0805. MOBILE ELECTRONIC BRACHYTHERAPY SERVICE.

In addition to other applicable parts of this chapter, the registrant providing mobile electronic brachytherapy service must:

A. ensure that all survey instruments are checked before medical use at each address of use or on each day of use, whichever is more restrictive;

B. account for the electronic brachytherapy x-ray tube in the electronic brachytherapy system before departure from the client's address;

C. perform, at each location on each day of use, all of the required spot checks in this part to assure proper operation of the system; and

D. ensure that there is a qualified medical physicist, radiation oncologist, radiation therapist, or licensed practitioner of the healing arts present during the procedure.

4733.0900. SIMULATION SYSTEM REQUIREMENTS.

Subpart 1. **Generally.** Equipment and mechanical parameters of any simulation system are subject to the same rigorous quality control testing as the treatment unit. The various simulator system motions should be as accurate as those of the radiation therapy system. In addition, all the elements in the simulator system needed for good image quality must be tested, reviewed and evaluated.

Subp. 2. **Equipment requirements.** All therapy simulator systems including stereo x-ray targeting, cone beam CT, CT scanner, radiographic and fluoroscopy systems must meet the requirements of:

A. nationally recognized standards such as Code of Federal Regulations, title 21;

B. the manufacturer's specifications with a copy on site;

- C. this part and other pertinent requirements in this chapter; and
- D. the quality control testing of image processing, when appropriate.

Subp. 3. **Registrant's responsibilities.** The registrant must ensure:

- A. that compliance with applicable parts of this chapter and in the operation of the equipment that are consistent with the equipment use;
- B. that written operating and emergency procedures for the simulation system are provided and available at the control console;
- C. the equipment performance tests are completed at intervals not to exceed 24 months, except for cone beam CT, CT and Fluoroscopic equipment which need to be completed at intervals not to exceed 12 months;
- D. the initial staff training is completed and additional training is completed anytime there is a change in program, technology, or new simulation equipment;
- E. the documentation required by part 4733.0145 is complete and maintained for inspection by the commissioner;
- F. that any required spot checks for simulation equipment are performed at intervals not to exceed 12 months to verify the system's integrity;
- G. the spot checks for the simulation systems equipment are performed at intervals not to exceed 12 months using procedures from either the manufacturer or qualified medical physicist; and
- H. the annual audit of the quality management program includes the simulation system information and the radiation therapists and dosimetrists.

Subp. 4. **Facility design requirements.** The requirements include:

- A. a control panel must meet the requirements in part 4733.0250; or
- B. if the control booth is within the simulation room, the control booth must meet the requirements of part 4733.0255;
- C. shielding and facility designs of the room must meet the requirements in 4733.250 through 4733.0275; and
- D. a radiation survey made to identify radiation levels at the control panel and spaces adjoining the room for all simulation systems installed and those systems not previously surveyed. In addition, the radiation surveys must be completed after any

change in the facility or equipment which might cause a significant increase in radiation hazard. The radiation survey records must be maintained by the registrant according to part 4733.0145.

Subp. 5. Equipment performance measurements.

A. The registrant must ensure that the equipment performance measurements in this chapter are performed at install and at intervals not to exceed 24 months and for cone beam CT, CT, or fluoroscopic equipment at intervals not to exceed 12 months or after change or replacement of components that could cause an increase in radiation hazard or that could result in the minimum performance criteria not being met;

B. The equipment performance measurement of the radiation output of the simulation system must be performed by a registered service provider or physicist;

C. The measurements of the radiation output of the simulation system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard according to part 4733.0440. The dosimetry system must have been calibrated within the preceding 24 months;

D. The appropriate dosimetry phantoms must be used in determining the radiation output of a simulation system. The phantoms must comply with Code of Federal Regulations, title 21;

E. For a computed tomography simulation system:

(1) the CT unit must meet Code of Federal Regulations, title 21, 1020.33 or manufacturer's specifications with a copy on site or part 4733.1015;

(2) the control console must provide an audible signal of the termination of the exposure and indicator lights must be operational;

(3) dose index (CTDI) must be completed using the CT dosimetry phantom;

(4) for the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be used.

(5) the dose measurements must be made for standard head and body scan modes of operation used at the facility; and

(6) the image quality measurements must be made using a typical clinical technique in the standard head and body scan modes of operation.

F. For a radiographic simulation system:

- (1) the control must comply with Code of Federal Regulations, title 21, section 1020.31 or manufacturer's specifications with a copy on site or part 4733.1015;
- (2) the control must be mounted behind a protective barrier that meets requirements of part 4733.0250;
- (3) the control console must provide an audible signal of the termination of the exposure;
- (4) console indicator lights must be operational;
- (5) if automatic exposure control is provided, the control must meet Code of Federal Regulations, title 21, section 1020.31;
- (6) the control must be provided with a means of beam limitation to the area of clinical interest; and
- (7) means must be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the target-skin distance.

G. For a fluoroscopic simulation system, if the equipment has the capabilities of performing fluoroscopic procedures, the fluoroscopic simulation system must:

- (1) meet Code of Federal Regulations, title 21, section 1020.32 or manufacturer's specifications with a copy on site or part 4733.1015;
- (2) be designed and used so that no individual other than the patient is in the simulation room when the system is producing x-rays;
- (3) have a means to indicate the cumulative time that an individual patient has been exposed to x-rays. Procedures must require, in such cases, that the timer be reset between examinations; and
- (4) control console must be mounted behind a protective barrier that meets part 4733.0250.

H. The x-ray control may be operated in the simulation room and essential personnel may remain the room during the fluoroscopic procedures provided they:

- (1) have been trained on radiation safety issues of fluoroscopy;
- (2) are wearing personal protective garments; and
- (3) have individual personal monitoring devices.

Subp. 6. **Equipment performance measurements performed by the simulation system operator.** If the registrant, manufacturer, or the qualified medical physicist has measurements that are performed by the operator, an operator must:

A. complete the daily or monthly equipment performance procedures using written procedures from either the manufacturer's specifications with a copy on site, or the qualified medical physicist; and

B. acquire images obtained with the simulation dosimetry phantoms using the same processing mode and conditions of operation that are used to perform the equipment performance measurements; and

C. documentation of the equipment performance measurements must be maintained according to part 4733.0145 for inspection by the commissioner

Subp. 7. **Operating procedures.** The registrant is responsible for establishing operating procedures for the simulation activities and must be available at the control console. The registrant must ensure that:

A. the simulation system is operated by a qualified individual who:

(1) has been specifically trained by the manufacturer or equivalent; and

(3) has had training in appropriate positioning and anatomy for procedures performed at the facility; and

B. information about the system must be available at the control panel regarding the operation. The information must include the following:

(1) a current technique chart available at the control panel, which specifies for each routine examination the conditions of operation and the number of films or scans per examination; and

(2) instructions on the use of the dosimetry or image quality phantoms including the allowable variations for the indicated parameters.

Subp. 8. **Emergency procedures.** The registrant must have written emergency procedures developed, implemented and maintained for responding to an abnormal situation available at the control console. These procedures must:

A. include instructions for responding to equipment failures and the names of the individual responsible for implementing corrective actions;

B. include the names and telephone numbers of the registrant, qualified medical physicist and the radiation safety officer to be contacted if the system operates abnormally; and

C. include instructions for notification of the radiation safety officer, or their designee, and the registrant as soon as possible if the patient's radiation exposure has a medical emergency, suffers injury or dies.

Subp. 9. Corrective actions.

A. Correction of the problem must take place and be verified by performing the equipment performance measurements according to Code of Federal Regulations, title 21, the manufacturer's specifications with a copy on site, or part 4733.1015.

B. Corrective action must take place if the equipment performance measurements or spot checks of the simulation system indicate that a system operating parameter has exceeded a tolerance established:

- (1) in part 4733.1015;
- (2) by the manufacturer;
- (3) by qualified medical physicist; or
- (3) by a registered service provider.

C. When an operating parameter has been exceeded, the simulation system must not be used on patients or must be limited to those uses permitted by established written instructions until the corrective actions have been taken and verification of the correction has been made and documented.

Subp 10. Simulator Training. The radiation therapists and dosimetrists must be trained on all the simulation systems within the facility. This includes:

- A. equipment information;
- B. anatomical knowledge for the respective simulation equipment such as cross-section anatomy for a CT simulator;
- C. operating and emergency procedures for the simulation equipment; and
- D. other topics the radiation safety office, qualified medical physicist or radiation oncologist deems necessary.

Subp.11. **Records.** The registrant will ensure that all the required documents for the simulation system are maintained according to part 4733.0145.

4733.1000. THERAPEUTIC EQUIPMENT PERFORMANCE TESTS AND LIMITS FOR MEASUREMENT EQUIPMENT.

Subpart 1. Required tests.

A. Installation acceptance calibration tests must be conducted prior to any patient use. These tests must be conducted to Code of Federal Regulations, title 21, section 892, or manufacturer's specifications with a copy of the specifications on site to ensure compliance with this chapter.

B. The registrant must develop and implement performance tests for the radiation therapy equipment that comply with:

- (1) parts 4733.1000-4733.1015 of this chapter;
- (2) requirements of any other nationally recognized organization as recognized by MDH for this purpose; or
- (3) requirements of the equipment manufacturer, if the above items do not apply.

C. The registrant must identify and document the source of the specifications or standards in item B that is used for each therapy system.

D. The equipment performance tests must be conducted over all applicable energy ranges.

E. For equipment performance tests, any adjustments must be made to bring equipment to compliance with this chapter prior to use.

Subp. 2. **Documentation of tests.** The qualified medical physicist must identify and provide reasons for not performing specific tests according to the performance test procedures identified in subpart 1, item B.

Subp. 3. **Frequency and tolerances.** The frequencies and tolerances in the performance test procedures cannot be exceeded. In the absence of any published tolerances, manufacturer's recommendations must be used.

Subp. 4. Local standard instrument.

TESTS	FREQUENCY	TOLERANCE
A. AAPM - accredited dosimetry calibration laboratory calibration	Intercomparison every 12 months; At intervals not to exceed 24 months traceable to NIST Standard	Documented and correction applied or noted in report of measurement when appropriate
B. Linearity	At intervals not to exceed 48 months	0.5 percent
C. Venting	At intervals not to exceed 48 months	Documented and correction applied
D. Extracameral signal	Initial use	0.5 percent
E. Leakage	Each use	0.1 percent
F. Recombination	Initial use	Documented and correction applied
G. Collecting potential	Each use	Documented and correction applied

Subp. 5. Other field instruments.

TESTS	FREQUENCY	TOLERANCE
A. Local standard comparison	At intervals not to exceed 24 months	one percent
B. Linearity	At intervals not to exceed 24 months	Documented and correction applied
C. Venting	At intervals not to exceed 24 months	Documented and correction applied
D. Extracameral signal	At intervals not to exceed 24 months	Documented and correction applied
E. Leakage	Each use	one percent
F. Recombination	Initial use	Documented and correction

		applied
G. Collecting potential	Each use	Documented and correction applied

Subp. 6. Relative dosimetry equipment.

TESTS	FREQUENCY	TOLERANCE
A. Thermoluminescent Dosimeter		
(1) Calibration	Each batch or box	Documented and correction applied
(2) Linearity	Initial use	Documented and correction applied
B. Film		
(1) Dose and response	Each batch or box	Documented and correction applied
(2) Densitometer linearity	At intervals not to exceed 12 months	Documented and correction applied
C. Air ionization chamber system		
(1) Linearity	At intervals not to exceed 12 months	Documented and correction applied
(2) Extracameral signal	Initial use	one percent
D. Diode system		
(1) Energy dependence	Initial use	Documented and correction applied
(2) Extracameral signal	Initial use	Documented and correction applied
(3) Linearity	Initial use	Documented and correction applied

Subp. 7. Radiation survey instruments.

TESTS	FREQUENCY	TOLERANCE
A. Calibration	At intervals not to exceed 12 months	Documented and correction applied
B. Linearity	At intervals not to exceed 12 months	Documented and correction applied
C. Constancy	Each use	Five percent

Subp. 8. Positioning equipment lasers. (Not required for use for stereotactic robotic equipment)

TESTS	FREQUENCY	TOLERANCE
A. Accuracy	Daily before patient use	Two mm
B. Hysteresis	Each use	Two mm

Subp. 9. Phantoms and attenuators.

TESTS	FREQUENCY	TOLERANCE
A. Thickness	Initial use	Documented and correction applied
B. Density	Initial use	Documented and correction applied
C. Phantom stacked density	Initial use	Documented and correction applied
D. Detector fit	Initial use	Documented and correction applied
E. Phantom use for specific treatment modalities	Initial use	Documented and correction applied

Subp. 10. Accessory equipment.

TESTS	FREQUENCY	TOLERANCE
A. Thermometer calibration	Initial use	0.1 degree/C
B. Barometer (aneroid &		

digital)		
(1) Calibration Hg	Initial use	One mm Hg
(2) Intercomparison	At intervals not to exceed 12 months	One mm Hg
(3) accuracy	At intervals not to exceed 12 months	One mm Hg

4733.1010. QUALITY CONTROL TESTS FOR LINEAR ACCELERATOR EQUIPMENT

Subpart 1. Mechanical.

TESTS	FREQUENCY	TOLERANCE
A. Light field and radiation field agreement	Monthly	2 mm
B. Optical Distance Indicator (SSD lights)	Monthly	2 mm
C. Localizing Lasers	Monthly	2 mm
D. Mechanical Front Pointer (Mechanical Distance Pins)	Monthly	2 mm
E. Gantry Angle Indicator (Scale Readouts)	Monthly	1 degree
F. Collimator Angle Indicator (Scale Readouts)	Monthly	1 degree
G. Couch Position Indicators (Scale Readouts)	Monthly	2 mm or 1 degree
H. Field Size Indicators (Scale Readouts)	Monthly	2 mm
I. Mechanical integrity of blocks, wedges, & compensators	Monthly	Functional
J. Mechanical integrity of Electron Applicators	Monthly	Functional

K. Jaw Symmetry	Annually	2 mm
L. Coincidence of collimator (jaw) and gantry axes	Annually	2 mm
M. Stability of gantry arm and bearing under rotation	Annually	2 mm
N. Couch motion and tabletop sag	Annually	2 mm

Subp. 2. Radiation Constancy

TESTS	FREQUENCY	TOLERANCE
A. X-Ray output constancy	Weekly	3 percent
B. Electron output constancy	Weekly	3 percent
C. X-Ray output constancy	Monthly	2 percent
D. Electron output constancy	Monthly	2 percent
E. X-Ray PDD constancy	Monthly	2 percent
F. Electron PDD constancy	Monthly	2 mm at therapeutic depth
G. X-Ray beam flatness constancy	Monthly	3 percent
H. X-Ray beam symmetry constancy	Monthly	3 percent
I. Electron beam flatness constancy	Monthly	5 percent
J. Electron beam symmetry constancy	Monthly	5 percent
H. Backup monitor constancy	Monthly	2 percent
I. Central axis dose calibration (all energies)	Annually	2 percent
J. Field size dependence of X-ray output constancy	Annually	2 percent

K. Central axis parameter constancy (PDD)	Annually	2 percent
L. X-ray output constancy vs. gantry angle	Annually	2 percent
M. Electron output constancy vs. gantry angle	Annually	2 percent
N. Wedge transmission factor	Annually	2 percent
O. Transmission factor constancy for all treatment accessories	Annually	2 percent
P. (19) Monitor chamber linearity	Annually	1 percent
Q. Timer linearity & error	Annually	1 percent
R. Arc Mode	Annually	Manufacturer's Specifications

Subp. 3. Safety Systems

TESTS	FREQUENCY	TOLERANCE
A. Proper operation of "BEAM-ON", interrupt, and termination switches.	Daily	Functional
B. Proper operation of beam condition Indicator lights on the access doors, control console, and in the radiation therapy room.	Daily	Functional
C. Proper operation of viewing systems.	Daily	Functional
D. Proper operation of audio systems.	Daily	Functional
E. Proper operation of electronically operated treatment room doors inside and outside the treatment room.	Daily	Functional
F. Emergency off switches	Monthly	Functional

4733.1012. QUALITY CONTROL TESTS FOR LINEAR ACCELERATOR-BASED ROBOTIC STEREOTACTIC RADIOSURGERY SYSTEMS.

Where there is no tolerance level or corrective action the registrant must determine the tolerance levels, appropriate corrective actions. This may be accomplished either by the radiation safety officer, qualified medical physicist, a nationally recognized standard or the manufacturer’s recommendations.

Subpart 1. **Daily tests:** The tests are completed once during every treatment day and separated by at least 12 hours and at a minimum, must include:

TESTS	TOLERANCE	CORRECTIVE ACTION
System status check	Functional	Function restored
Linear accelerator output	2 percent electrons or 2 percent photons	3 percent electrons and 3 percent photons
Constancy check	Manufacturer’s recommendations	Manufacturer’s recommendations
Safety interlock check	Functional	Function restored
Patient audio-visual monitors	Functional	Function restored
Lasers/crosswires	1 mm	2 mm

Subp. 2. **Monthly tests.** The tests are completed once every four weeks and at intervals of between three and five weeks and at a minimum, must include:

TESTS	TOLERANCE	CORRECTIVE ACTION
Beam parameters	2 percent	3 percent
Robot mastering visual check	Manufacturer’s recommendations	Manufacturer’s recommendations
Imaging targeting check	Manufacturer’s recommendations	Manufacturer’s recommendations
Imaging alignment	1 mm	2 mm
Beam energy	Manufacturer’s recommendations	Manufacturer’s recommendations

Film phantom target test	Manufacturer's recommendations	Manufacturer's recommendations
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Subp. 3. **Quarterly tests.** Completed once every 12 weeks and at intervals of between 11 and 13 weeks at a minimum, must include:

TESTS	TOLERANCE	CORRECTIVE ACTION
Target locating system tracking tests and after significant change due to maintenance	Manufacturer's recommendations	Manufacturer's recommendations
Linear accelerator laser mechanical alignment check	Manufacturer's recommendations	Manufacturer's recommendations
Linear accelerator laser/radiation field alignment check	Manufacturer's recommendations	Manufacturer's recommendations

Subp. 4. **Annually tests.** Completed once every 12 months and at intervals of between 10 and 13 months and at a minimum, must include:

TESTS	TOLERANCE	CORRECTIVE ACTION
Beam commissioning spot checks	Manufacturer's recommendations	Manufacturer's recommendations
Treatment planning system	Manufacturer's recommendations	Manufacturer's recommendations
Beam calibration check	Manufacturer's recommendations	Manufacturer's recommendations
Safety systems	Manufacturer's recommendations	Manufacturer's recommendations
Robot mastering, electronic	Manufacturer's recommendations	Manufacturer's recommendations
Couch indexing accuracy	Manufacturer's recommendations	Manufacturer's recommendations

4733.1013 QUALITY CONTROL TESTS HELICAL TOMOTHERAPY EQUIPMENT.

Where there is no tolerance level or corrective action the registrant must determine the tolerance levels, appropriate corrective actions. This may be accomplished either by the radiation safety officer, qualified medical physicist, a nationally recognized standard or the manufacturer’s recommendations.

Subpart 1. **Daily tests.** The tests are done once during every treatment day and separated by at least 12 hours and at a minimum, must include:

TESTS	TOLERANCE	CORRECTIVE ACTION
Red Laser Alignment	Manufacturer's recommendations	Manufacturer's recommendations
Stationary Laser Alignment:		
Vertical	5 mm +/- 2 mm	Manufacturer's recommendations
Lateral	0 mm +/- 2 mm	Manufacturer's recommendations
Moveable Lasers Home Position (to coincide with the stationary lasers)	+/- 1 mm	Manufacturer's recommendations
Moveable Laser Alignment:		
Overhead sagittal laser moves laterally	+/- 2 mm + 2 cm	Manufacturer's recommendations
Overhead transverse laser moves longitudinally	+8 cm +/- 2 mm	Manufacturer's recommendations
Side coronal lasers move vertically	+4 cm +/- 2 mm 850 +/- 30 cGy (3.5 percent) at 1.5 cm depth, seen 2 percent	Manufacturer's recommendations
Output Consistency:		
Energy Ratio 10 cm/1.5 cm	0.61 +/- 0.02 (3.3 percent)	Manufacturer's

	Seen 2 percent	recommendations
TPR 5/20	+/- 2 percent	Manufacturer's recommendations
Output Ramp up time	< 10 seconds	Manufacturer's recommendations
Lateral Profile constancy	+/- 2 percent	Manufacturer's recommendations
Synchrony of Helical Delivery:		
MVCT Image Evaluation	Manufacturer's recommendations	Manufacturer's recommendations
Automatic image	Manufacturer's recommendations	Manufacturer's recommendations
Registration (software)	Manufacturer's recommendations	Manufacturer's recommendations
Couch Movement accuracy (distance traveled from reference lasers)	Manufacturer's recommendations	Manufacturer's recommendations
Beam quality check (PDD Ratio)	Manufacturer's recommendations	Manufacturer's recommendations

Subp. 2. **Monthly tests.** The monthly tests are completed once every four weeks and at intervals of between three and five weeks and at a minimum, must include:

TESTS	TOLERANCE	CORRECTIVE ACTIONS
MLC and Gantry Isocenter Alignment	Manufacturer's recommendations	Manufacturer's recommendations
Primary Jaw Divergence	Manufacturer's recommendations	Manufacturer's recommendations
Laser Alignment (Green and Red)	Manufacturer's recommendations	Manufacturer's recommendations

Gantry Rotation and MLC Synchronicity	Manufacturer's recommendations	Manufacturer's recommendations
Interrupt/Complete procedure	Manufacturer's recommendations	Manufacturer's recommendations
Output calibration	Manufacturer's recommendations	Manufacturer's recommendations
Beam Profile	Manufacturer's recommendations	Manufacturer's recommendations
Evaluation of couch motion	Manufacturer's recommendations	Manufacturer's recommendations
MVCT Image Quality	Manufacturer's recommendations	Manufacturer's recommendations

Subp. 3. **Annual and target replacement tests.** These tests are completed once every 12 months and at intervals of between 10 and 13 months and at a minimum, must include all daily and monthly checks plus the following:

TESTS	TOLERANCE	CORRECTIVE ACTIONS
PDD for each jaw setting	Manufacturer's recommendations	Manufacturer's recommendations
Profile for each setting	Manufacturer's recommendations	Manufacturer's recommendations
MLC Tongue and Groove	Manufacturer's recommendations	Manufacturer's recommendations
MLC Leaf Latency	Manufacturer's recommendations	Manufacturer's recommendations
Primary Jaw Sweep	Manufacturer's recommendations	Manufacturer's recommendations
Couch Drive Speed	Manufacturer's recommendations	Manufacturer's recommendations

Couch Sag	Manufacturer's recommendations	Manufacturer's recommendations
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4733.1015. INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR RADIOGRAPHIC SIMULATION EQUIPMENT.

Subpart 1. Tests required.

A. Installation calibration tests must be conducted prior to any patient use. Any adjustments must be made to bring the equipment up to a nationally recognized standard such as Code of Federal Regulations, title 21, section 1020, or the manufacturer's specifications with a copy of the specifications on site, and to ensure compliance with this chapter prior to first use.

B. Equipment performance tests must be conducted over all clinical ranges, when applicable. For equipment performance tests, any adjustments must be made to bring equipment to a nationally recognized standard or manufacturer's specifications; and to ensure compliance with this chapter prior to using the equipment again.

Subp. 2. **Frequency of tests.** The tests in this part are to be made at the time of installation and as specified.

Subp. 3. **General simulation requirements as appropriate for the simulation equipment.**

TESTS	FREQUENCY	TOLERANCE
Localizing lasers	Daily	2 mm
Distance indicator	Daily	2 mm
Field size indicator	Monthly	2 mm
Gantry/collimator angle indicators	Monthly	1 degree
Cross-hair centering	Monthly	2 mm diameter
Focal spot-axis indicator	Monthly	2 mm
Collision avoidance	Monthly	Functional
Light/radiation field coincidence	Monthly	2 mm or 1 percent
Collimator rotation isocenter	At intervals not to exceed 12 months	2 mm diameter

Gantry rotation isocenter	At intervals not to exceed 12 months	2 mm diameter
Couch rotation isocenter	At intervals not to exceed 12 months	2 mm diameter
Coincidence of collimator, gantry, couch axes, and isocenter	At intervals not to exceed 12 months	2 mm diameter
Table top sag	At intervals not to exceed 12 months	2 mm
Vertical travel of couch	At intervals not to exceed 12 months	2 mm
Exposure rate	At intervals not to exceed 12 months	Established baseline
kVp and mAs calibration	At intervals not to exceed 12 months	Established baseline
High and low contrast resolution	At intervals not to exceed 12 months	Established

Subp. 4. Radiographic tubes used as simulators.

TESTS	FREQUENCY	TOLERANCE
SID indicator accuracy	At intervals not to exceed 24 months	± 2 percent of indicated value
X-ray and light field alignment	At intervals not to exceed 24 months	± 2 percent of SID any one direction, ± 3 percent of SID, both directions (total)
Exposure reproducibility	At intervals not to exceed 24 months	Coefficient of variation < 5 percent
Timer accuracy	At intervals not to exceed	Three phase, high

	24 months	frequency, and constant potential: use ± 5 percent of selected time when measured > 100 milliseconds.
kVp accuracy	At intervals not to exceed 24 months	± 5 percent of indicated kVp

Subp. 5. Fluoroscopic tubes used as simulators.

TEST	FREQUENCY	TOLERANCE
Fluoroscopic image quality	Monthly	Established baseline
Light/radiation field coincidence	Monthly	2 mm or 1 percent
Exposure rate	At intervals not to exceed 12 months	Established baseline
Table top exposure with fluoroscopy	At intervals not to exceed 12 months	Established baseline
kVp and mAs calibration	At intervals not to exceed 12 months	Established baseline
High and low contrast resolution	At intervals not to exceed 12 months	Established baseline

Subp. 6. For computed tomography scanners used as simulators.

TEST	FREQUENCY	TOLERANCE
CT number calibration and noise	Daily	Water: 0 ± 5 CT numbers; Noise: ± 3 standard deviations of the mean of the baseline noise variance measurements
Accuracy of distance	At intervals not to exceed 12 months	± 1 millimeters

measurements	months	
CT dose index	At intervals not to exceed 12 months	± 20 percent from manufacturer's recommendations
CT number dependence on slice thickness	At intervals not to exceed 12 months	Mean ± 3 CT numbers averaged over 100 pixels
Table indexing	At intervals not to exceed six months	± 0.5 millimeter for each increment
Table backlash	At intervals not to exceed six months	± 1.0 millimeter

4733.1075. REQUIREMENTS FOR OPERATORS OF DUAL IMAGING DEVICES

A. Medical dosimetrists may operate a simulation imaging device providing it is an integral part of the therapy procedures for planning or treatment but are prohibited from operating any imaging device for diagnostic purposes unless they have met the requirement found in Minnesota Statutes, 144.121, subdivision 5.

B. Radiation therapeutic technologist may operate a simulation imaging device providing it is an integral part of the therapy procedures for treatment but are prohibited from operating any imaging device for diagnostic purposes unless they have met the requirements found in Minnesota Statutes, 144.121, subdivision 5.

4733.1100. MINIMUM QUALIFICATIONS FOR MEDICAL DOSIMETRIST. Except as indicated in 4733.1110, any individual functioning as a medical dosimetrist in Minnesota must meet the following minimum eligibility requirements:

- A. graduation from high school or its equivalent;
- B. attainment of 18 years of age; and
- C. ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients, other employees or members of the public.

4733.1105. TRAINING AND EXPERIENCE FOR MEDICAL DOSIMETRIST.

Subpart 1. Individuals functioning as medical dosimetrists after the effective date of this rule must:

A. be certified and continue to maintain certification by the Medical Dosimetrist Certification Board (MDCB); or

B. be registered and continue to maintain registration by ARRT in radiology or therapy and have:

(1) 40 hours of training specific to the use of treatment planning computer systems; and

(2) at least one year of full-time practical training and experience involving work in a radiation therapy facility under an individual who meets the qualifications as a certified medical dosimetrist, radiation oncologist, or a qualified medical physicist; or

C. have graduated from with an associate's degree or higher and have:

(1) 40 hours of classroom training in basic radiological physics and including:

(a) therapy simulation equipment;

(b) therapy equipment;

(c) operating and emergency procedures;

(d) quality control or quality management program/testing;

(e) dynamic and static acquisition for image; and

(f) math knowledge for calculations.

(2) 20 hours of training specific to the use of treatment planning computer systems; and

(3) at least one year of full-time practical training and experience involving work in a radiation therapy facility under an individual who meets the qualifications as a certified medical dosimetrist, radiation oncologist, or a qualified medical physicist.

Subp. 2. **Training in computer planning.** Documentation in computer training must be:

A. accomplished by attendance of any course that provides credits acceptable to the ARRT or MDCB;

B. provided by the treatment planning system manufacturer; or

C. verified by attestation of a qualified medical physicist or a certified medical dosimetrist.

Subp. 3. **Variance Request.** A registrant may apply for a variance to this part in accordance with 4733.0125.

Subp. 4. **Records.** Records of training must be maintained according to 4733.0145.

4733.1108. MEDICAL DOSIMETRIST ANNUAL TRAINING.

Subpart 1. **Medical dosimetrist.** An individual functioning as a medical dosimetrist must annually receive the following training:

A. instruction in the health protection problems associated with exposure to radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed:

B. instruction in the quality assurance and quality control required daily tests;

C. instruction in the treatment planning computer systems, verification systems, and therapy responsibilities;

D. review of applicable provisions of this chapter including the responsibility to report promptly to the registrant any condition that may lead to or cause a violation of this chapter or any unnecessary exposure to radiation; and

E. review of appropriate response to warnings made in the event of any unusual occurrence, malfunction, or treatment planning error that may involve exposure to radiation.

Subp. 2. **Records.** Records of training must be maintained according to 4733.0145.

4733.1110. EXCEPTIONS.

The following individuals are exempt from the requirement in 4733.1105:

A. a licensed practitioner of the healing arts who specializes in radiation oncology;

B. individuals who function under the direct supervision of a licensed practitioner of the healing arts specializing in radiation oncology, qualified medical physicist, or qualified radiation therapist; or

C. students enrolled in and participating in an accredited program for radiation therapeutic technology and under the direct supervision of a qualified individual, a school of medicine or school of osteopathy, who have radiation oncology as part of their course of study.

4733.1115. TREATMENT PLAN APPROVAL.

Subpart 1. **Physician approval.** Prior to initial treatment, physician approval must be obtained for all treatment plans prepared by a certified medical dosimetrist who continues to maintain certification by meeting the requirements of the Medical Dosimetry Certification Board (MDCB).

Subp. 2. **Noncertified dosimetrists.** Prior to initial treatment, dosimetrists who are not certified by MDCB must have all treatment plans approved by:

- A the physician; and
- B. a certified medical dosimetrist or a qualified medical physicist.

4733.1150. MINIMUM QUALIFICATIONS FOR RADIATION THERAPEUTIC TECHNOLOGIST.

Subpart 1. **Radiation therapeutic technologist.** Except as indicated in 4733.1155, any individual functioning as a radiation therapeutic technologist in Minnesota must meet the following minimum eligibility requirements:

- A. graduation from high school or its equivalent;
- B. attainment of 18 years of age; and
- C. ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients, other employees or members of the public; and
- D. must be registered and continue to maintain registration by ARRT in radiography or therapy.

Subp. 2. **Variance.** A registrant may apply for a variance to this part in accordance with 4733.0125.

4733.1152. THERAPY TECHNOLOGIST TRAINING.

Subpart 1. **Radiation Therapist required training.** An individual functioning as a radiation therapist must have completed the following training:

- A. Therapy equipment;
- B. Simulation equipment;
- C. Operating and emergency procedures/principles;

- D. Quality control or quality management program tests;
- E. Dynamic and static acquisition; and
- F. Patient care.

Subp. 2. **Radiation Therapist Annual training.** An individual functioning as a radiation therapeutic technologist must annually receive the following training:

- A. instruction in the health protection problems associated with exposure to radiation, in precautions or procedures to minimize exposure and in the purposes and functions of protective devices employed;
- B. instruction in quality assurance and quality control required daily tests;
- C. instruction in treatment planning computer systems, verification systems, and therapy responsibilities;
- D. review of applicable provisions of this chapter including the responsibility to report promptly to the registrant any condition that may lead to or cause a violation of this chapter or any unnecessary exposure to radiation; and
- E. review of appropriate responses to warnings made in the event of any unusual occurrence, malfunction, or treatment planning error that may involve exposure to radiation.

Subp. 3. **Records** of training must be maintained according to 4733.0145.

4733.1155. EXCEPTIONS.

The following individuals are exempt from the requirement in 4733.1150:

- A. a licensed practitioner of the healing arts who specializes in radiation oncology;
 - B. individuals who function under the direct supervision of a licensed practitioner of the healing arts specializing in radiation oncology, qualified medical physicist, or qualified radiation therapist;
 - C. students enrolled in and participating in an accredited program for radiation therapeutic technology and under the direct supervision of a qualified individual, a school of medicine or school of osteopathy, who have radiation oncology as part of their course of study;
- or

D. an individual who is has graduated from an accredited program for radiation therapeutic technology and who is to take the ARRT therapy certification examination within six months.