

Minnesota Rules, Chapter 4733

DRAFT RULES GOVERNING RADIATION THERAPY, 3.0

Summary of Changes

MDH made a number of changes to the Radiation Therapy rule draft based on review and feedback from stakeholders at the April 17, 2018 meeting. Substantive changes to version 2.0 were made in rule parts 4733.0500, 4733.0510, 4733.0520, 4733.0535, 4733.0800, and 4733.0900. Other style and form edits were made throughout the rule draft.

4733.0100 PURPOSE AND SCOPE.

Subpart 1. **Purpose.** The purpose of this chapter is to control and prevent hazards to health and safety from the use of machine-produced radiation therapy equipment and therapy simulation equipment for human and nonhuman use without limiting or interfering with its therapeutic uses.

Subp. 2. **Scope.** This chapter establishes the requirements, for which a registrant is responsible, for using machine-produced radiation therapy equipment and therapy simulation equipment.

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.** "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray.

Subp. 3. **Absorbed dose rate.** "Absorbed dose rate" means absorbed dose per unit time for machines 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 that discharges the resulting particulate or other radiation into a medium at energies usually in excess of one MeV.

Subp. 5. **Air kerma (K).** "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Air 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 unit of kerma is the gray (Gy).

Subp 6. **Annual.** "Annual" means an interval not to exceed 365 days.

Subp. 7. **Authorized physician.** "Authorized physician" means a physician who is certified in:

- A. radiation oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976;
- B. radiation oncology by the American Osteopathic Board of Radiology;
- C. radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
- D. therapeutic radiology by the Canadian Royal College of Physicians and Surgeons;

or

- E. meets the classroom and laboratory instruction, supervised work experience, and supervised clinical experience requirements under part 4733.0430.

Subp. 8. **Beam axis.** "Beam axis" means the axis of rotation of the beam-limiting device for therapy systems.

Subp. 9. **Beam-limiting device.** "Beam-limiting device" means a field-defining collimator integral to the accelerator and capable of restricting the dimensions of the useful beam.

Subp. 10. **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. 11. **Beam-scattering filter or foil.** "Beam-scattering filter" or "foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Subp. 12. **Commissioner.** "Commissioner" means the commissioner of health or the commissioner's designee.

Subp. 13. **Contact therapy system.** "Contact therapy system" means a radiation-therapy machine with a short target-skin distance (TSD) that is on average less than five centimeters.

Subp. 14. **Direct Supervision.** "Direct Supervision" means a qualified medical physicist must be present in the facility and immediately available to furnish assistance and direction throughout the performance of the tests.

Subp. 15. **Dose monitor unit.** "Dose monitor unit" means a unit response from the beam-monitoring system used for calculating the absorbed radiation dose.

Subp. 16. **Electronic brachytherapy.** "Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

Subp. 17. **External beam radiation therapy.** "External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

Subp. 18. **Facility.** "Facility" means a single building or one or more vehicles, registered under at one physical address, or a set of adjoining buildings, that is under one person's responsibility and oversight.

Subp. 19. **Field-flattening filter.** "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field including beam-scattering filter or foil.

Subp. 20. **Filter.** "Filter" means material placed in the useful beam to change beam quality in radiation therapy systems.

Subp. 21. **Gantry.** "Gantry" means that part of the radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

Subp. 22. **High-radiation area.** "High-radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body may result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30

centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

~~Subp. 23. **Intensity modulated radiation therapy or IMRT.**~~

Subp. 24. **Interlock.** "Interlock" means a device preventing the start or continued operation of equipment.

Subp. 25. **Irradiation.** "Irradiation" means the exposure of a living being or matter to ionizing radiation.

Subp. 26. **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. 27. **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 1,000 volts in a vacuum. Current convention is to use kV for photons and KeV for electrons.

Subp. 28. **Leakage radiation.** "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly other than the useful beam.

Subp. 29. **Light field.** "Light field" means the area illuminated by light that simulates the radiation field.

Subp. 30. **Medical event.** "Medical event" means any event, except for an event that results from patient intervention, in which the therapeutic administration of radiation for human use results in:

- A. a total dose delivered that differs from the dose defined in the written order by 20 percent or more;
- B. a delivered dose for a single fraction that is greater than the dose defined in the written order by 50 percent or more;
- C. a dose to the wrong individual or to the wrong treatment site;
- D. treatment with the wrong treatment modality or energy; or
- E. 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 order.

Subp. 31. **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. 32. **Moving beam radiation therapy.** "Moving beam radiation therapy" means radiation therapy in which the useful beam or the patient moves during irradiation. Examples include arc, skip, conformal, intensity modulation, and rotational therapy.

Subp. 33. **Nominal treatment distance.** "Nominal treatment distance" means:

- A. for electron irradiation, the distance from the beam scattering foil, virtual source, or exit window of the useful beam to the entrance surface of the irradiated object along the central axis 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 nonisocentric equipment, the distance specified by the manufacturer.

Subp. 34. **Patient.** "Patient" means an individual or veterinary practice animal subjected to machine-produced beam radiation for therapy.

Subp. 35. **Prescribed dose.** "Prescribed dose" means the total radiation dose and radiation dose per fraction as documented in the written order.

Subp. 36. **Primary beam.**

Subp. 37. **Protective barrier.** Protective barrier" means the material, excluding filters, placed in the useful beam to reduce radiation levels for protection purposes.

Subp. 38. **Qualified medical physicist.** "Qualified medical physicist" means an individual qualified to practice independently in the subfields for therapeutic radiological physics who:

- A. is certified by The American Board of Radiology; or
- B. is certified by The American Board of Medical Physics; or
- C. is certified by The Canadian College of Physicists in Medicine; or
- D. meets the requirements the training and work experience requirements under part 4733.0410, subpart 6.

Subp. 39. **Radiation area.** "Radiation area" means an area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Subp. 40. **Radiation detector.** "Radiation detector" means a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Subp. 41. **Radiation head.** "Radiation head" means the structure from which the useful beam emerges.

Subp. 42. **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. 43. **Registrant.** "Registrant" means a person or facility registered with the commissioner or legally obligated to register with the commissioner according to this chapter.

Subp. 44. **Scattered radiation.** "Scattered radiation" means radiation that, during its passage through a substance, has been changed in direction and may also have been modified by a decrease in energy.

Subp. 45. **Shutter.** "Shutter" means a device attached to the tube housing assembly that can totally intercept the useful beam and has a lead equivalency not less than the tube housing assembly.

Subp. 46. **Stationary beam therapy.** "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Subp. 47. **Stereotactic body radiotherapy.** "Stereotactic body radiotherapy" means a specialized form of radiation therapy that delivers high doses of radiation to a target lesion with high precision in large fraction sizes over a short course of treatment.

Subp. 48. **Stereotactic radiosurgery.** "Stereotactic radiosurgery" means a specialized form of radiation therapy of the brain and spine that delivers high doses of radiation to a target lesion with high precision in large fraction sizes over a short course of treatment.

Subp. 49. **Stray radiation.** "Stray radiation" means the sum of leakage and scattered radiation including x-ray, electron, and neutron.

Subp. 50. **Survey.** "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation.

Subp. 51. **Target.** "Target" means the part of a radiation-producing system used to intercept a beam of accelerated particles and cause emission of other radiation.

Subp. 52. **Target-skin distance .** "Target-skin distance means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source to the surface of the irradiated object or patient.

Subp. 53. **Termination of irradiation.** "Termination of irradiation" means stopping of irradiation until the operating conditions are reset at the control panel.

Subp. 54. **Therapy simulation system.** "Therapy simulation system" means a radiographic, fluoroscopic, stereotactic, cone-beam CT, or CT x-ray system including all applicable software for localizing the volume to be irradiated during radiation therapy and establishing therapeutic irradiation field position and size.

Subp. 55. **Treatment planning.** "Treatment planning" means the process that determines the number, orientation, type, and characteristics of the radiation beams or

electronic brachytherapy used to deliver a large dose of radiation to a patient using software, hardware, and peripheral devices.

Subp. 56. **Useful beam.** "Useful beam" means the radiation that emanates from the activated tube-housing port or radiation head and passes through the aperture of the beam-limiting device.

Subp. 57. **Very high radiation area.** "Very high radiation area" means an area accessible to individuals in which radiation levels from radiation sources external to the body may result in an individual receiving an absorbed dose in excess of 500 rads (5 Gy) in one hour at one meter from a radiation source or 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. 58. **Virtual source.** "Virtual source" means a point from which radiation appears to originate.

Subp. 59. **Wedge filter.** "Wedge filter" means an added filter effecting continuous change in transmission on all or part of the useful beam.

Subp. 60. **Written order.** "Written order" means an authorized physician's written order for the administration of radiation according to part 4733.0435.

REGISTRATION

4733.0107 REGISTRATION.

Subpart 1. **Registration required.** A person must register with the commissioner to acquire, construct, or operate a radiation therapy system, except as provided under subpart 8.

Subp. 2. Application requirements.

- A. A person intending to purchase, construct, or acquire a radiation therapy system must submit an application to the commissioner 60 days before initial construction or installation of a radiation therapy system
- B. An applicant must:
 - (1) submit the application on a form prescribed by the commissioner;
 - (2) submit with the fee required under Minnesota Statutes, section 144.121;
and
 - (3) sign the application.

Subp. 3. Additional information; when required. An applicant must submit additional information the commissioner deems necessary for evaluation of the application for registration.

Subp. 4. Registration issuance.

- A. The commissioner shall issue a registration if the commissioner determines that the applicant has complied with the requirements under subpart 2 and, if applicable, the requirements under subpart 3.
- B. A registration issued under this chapter:
 - (1) authorizes a registrant to acquire, construct, or operate a radiation therapy system; and
 - (2) may contain conditions and limitations that the commissioner deems necessary to protect public health and safety.

Subp. 5. **Additional requirements and conditions after issuance.** After issuing a registration, the commissioner may prescribe additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of a registrant's radiation therapy system to protect public health and safety.

Subp. 6. **Registration not transferrable.** A registration issued by the commissioner under this chapter is not transferrable.

Subp. 7. **Registration expiration.** A registration expires at the end of the day on the expiration date stated in the registration.

Subp. 8. **Exception.** A registrant possessing a radiation therapy system before the effective date of this chapter must submit a new application under subpart 2 to the commissioner no later than 120 days after the effective date of this chapter.

4733.#### REGISTRATION OF SERVICE PROVIDERS.

Each person who is engaged in the business of installing or offering to install radiation therapy equipment or is engaged in servicing radiation therapy equipment must register with the commissioner according to chapter 4732.

4733.0111 AMENDMENTS TO REGISTRATION.

To amend a registration issued under this chapter, a registrant must submit an application under part 4733.0107 that specifies the reason for the requested amendment.

4733.0109 RENEWAL OR TERMINATION OF A REGISTRATION.

Subpart 1. **Intent to renew registration.**

A. A registrant must:

- (1) notify the commissioner in writing of the intent to renew registration at least 30 days before the registration expires; and
- (2) submit an application under part 4733.0107, subpart 2

B. The registration of a registrant who has complied with item A does not expire until the commissioner notifies the registrant in writing that the registration is renewed.

Subp. 2. **Terminating a registration before expiration.** A registrant must notify the commissioner in writing to request termination of a registration before the registrant permanently discontinues activities required under this chapter.

- A. The notice to the commissioner must include the reports and information required under subpart 4, items C and D, and subpart 5; and
- B. A registrant must comply with subparts 4 and 6 until the commissioner terminates the registration.

Subp. 3. **Intent to terminate registration.** At least 30 days before a registration expires, a registrant must notify the commissioner in writing of the registrant's intent to terminate a registration.

Subp.4. **Termination requirements.** When a registrant notifies the commissioner of the registrant's intent to terminate a registration under subpart 3, the registrant must:

- A. discontinue the use of the radiation therapy system by the expiration date of the registration;
- B. submit information describing the disposition of materials to the commissioner required under subpart 6, item B;
- C. submit a radiation survey report under subpart 5 to the commissioner that:
 - (1) confirms the absence of radioactive materials; or
 - (2) establishes the levels of residual radioactive contamination; and
- D. determine residual radioactive contamination level according to subpart 6.
- E. If the commissioner provides written notice to a registrant that a radiation survey report under subpart 5 is not necessary, then the registrant is exempt from submitting a radiation survey report under item D.

Subp. 5. Radiation survey report. A radiation survey report must include:

- A. the radiation levels of:
 - (1) beta and gamma radiation at one centimeter (in units of microrems or microsieverts or in microrads or micrograys per hour);
 - (2) gamma radiation at one meter from surfaces;
 - (3) levels of removable and fixed alpha, beta, and gamma contamination on surfaces (in becquerels or microcuries per 100 square centimeters);
 - (4) concentrations of contamination in soils (in units of picocuries or becquerels per gram) or in water (in units of picocuries or becquerels per liter) where soil and water concentrations are reported; and
- B. the survey instrumentation used to perform these surveys.

Subp. 6. Radioactive contamination level determination.

- A. The commissioner shall notify a registrant in writing that a registration is terminated when:
- (1) the registrant submits certified documentation to the commissioner that no residual radioactive contamination attributable to activities conducted under the registration is detected; and
 - (2) the registrant submits certified documentation to the commissioner that no detectable radioactive contamination attributable to activities conducted under the registration is detected.
- B. If a registrant confirms that detectable levels of residual radioactive contamination attributable to activities conducted under the registration, then the registrant must submit to the commissioner:
- (1) a written request to continue the registration beyond the expiration date;
and
 - (2) a plan for radioactive decontamination.
- C. The commissioner shall allow reasonable time for a registrant to comply with item B.

Subp. 7. Residual radioactive materials; restrictions. A registrant that possesses residual radioactive material under subpart 6, item B must:

- A. limit activities involving the use of radioactive materials to those solely related to:
- (1) decontamination; and

(2) preparation for release for unrestricted use; and

B. control entry to a restricted area until:

(1) the restricted area is deemed suitable for unrestricted use under subpart 8;

and

(2) the commissioner notifies the registrant in writing that the registration is terminated.

Subp. 8. **Unrestricted use determination.** The commissioner shall deem a restricted area suitable for unrestricted use when the level and type of residual radioactive contamination, identified in the radiation survey report, are at or below the threshold established in the registrant's decommissioning plan.

GENERAL ADMINISTRATION

4733.0125 VARIANCES.

The commissioner shall not grant a variance to parts 4733.0108 and 4733.0111. The commissioner shall consider variances for the remaining rule parts according to the procedures and criteria under parts 4717.7000 to 4717.7050.

4733.0135 ENFORCEMENT.

The commissioner shall determine penalties for any violation of this chapter under Minnesota Statutes, sections 144.989 to 144.993.

4733.0140 POSTING WORKER NOTICES.

Subpart 1. **Notice to employees.** A registrant must post a copy of MDH Form 3, "Notice to Employees," or any Form 3 revision provided by the commissioner, within 30 days of receiving the revised notice. A registrant may obtain copies of the Notice to Employees from the Minnesota Department of Health upon request.

Subp. 2. **Posting of notice.** A registrant must:

- A. display the notice in a prominent location where the notice is visible to all workers using radiation therapy or therapy simulation equipment; and
- B. replace notices that are defaced or altered.

REPORTS AND NOTIFICATIONS

4733.0150 DOSE TO MEMBER OF THE PUBLIC NOTIFICATION.

A registrant must notify the commissioner within 24 hours after the discovery of an event where a member of the public receives a dose that exceeds the dose limits under part 4733.0315 involving a registered radiation therapy system.

4733.0160 OCCUPATIONAL EXPOSURE.

Subpart 1. **Notice of exposure that exceeds occupational dose limits.** If a worker receives a dose that exceeds the limits for occupational exposure under part 4733.0305, then a registrant must, within 30 days of discovery, notify:

- A. the commissioner; and

- B. the worker who received a dose that exceeds the limits for occupational exposure by providing the worker with a copy of the notice and the dose report.
- C. The notice and dose report must include:
 - (1) the worker's dose;
 - (2) the date of discovery;
 - (3) the name of the registrant;
 - (4) the name of the worker who received a dose that exceeds the limits for occupational exposure; and
 - (5) The date of the dose report

The notice and the dose report may be sent electronically or in written form.

Subp. 2. **Worker's dose report.** A registrant must provide a dose report to a worker:

- A. annually, if a worker's occupational dose exceeds 100 mrem (1mSv) TEDE; or
- B. if a worker requests a dose report.

A worker's dose report may be sent electronically or in written form.

Subp. 3. **Dose report upon termination.**

- A. Upon written request of a worker who is terminating employment, a registrant must provide a written report containing the radiation dose received by the worker from the registrant's operations involving radiation during the current year or portion of the year.

- B. If the most recent individual monitoring results are not available at the time of termination, a registrant must provide the worker with a written estimate of the dose and include a statement that radiation dose is an estimate.

The dose report may be sent electronically or in written form.

4733.0180 MEDICAL EVENT; NOTIFICATION AND REPORT.

Subpart 1. **Notifying the commissioner of a medical event.** A registrant must notify the commissioner within 24 hours after the discovery of a medical event.

Subp. 2. **Medical event; patient intervention.** A registrant must prepare a medical event report under subpart 3 for a medical event that results from patient intervention where the therapeutic administration of radiation for human use results, or may result, in unintended permanent functional damage to an organ or a physiological system, as determined by an authorized physician.

Subp. 3. **Medical event report; when required.** A registrant must submit a medical event report to the commissioner within 30 days after the discovery of a medical event. A medical event report may be submitted electronically or in written form.

Subp. 4. **Medical event report; contents.**

- A. For purposes of this part, an affected individual means an individual who is the subject of a medical event.
- B. A medical event report must not contain the name of the affected individual or other information that may identify the affected individual.
- C. A medical event report must include:

- (1) the name of the registrant;
- (2) the name of the referring physician;
- (3) the date of the medical event;
- (4) a brief description of the medical event, including why and how it occurred;
- (5) the **medical?** effect, if known, on the affected individual;
- (6) the titles of all individuals involved in the medical event;
- (7) actions taken to prevent recurrence; and
- (8) certification that the registrant notified, or attempted to notify:
 - a) the affected individual; or
 - b) the affected individual's responsible relative or guardian; or
 - c) a written explanation if the registrant did not notify.

Subp. 5. Notice to affected individual and referring physician by a registrant.

- A. Within 24 hours of discovering a medical event, a registrant must notify:
 - (1) the referring physician; and
 - (2) the affected individual.
- B. A registrant is not required to notify an affected individual who is the subject of a medical event under item A if:
 - (1) the authorized physician informs the affected individual of the medical event; or
 - (2) the authorized physician does not inform the affected individual of the medical event, based on the authorized physician's medical judgment.

- C. A registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual who is subject of a medical event cannot be reached within 24 hours, then the registrant must notify the individual as soon as possible thereafter. A registrant must document attempts to notify the referring physician.
- D. A registrant must not delay necessary medical care or remedial care for an affected individual who is the subject of a medical event due to a delay in notification.
- E. If a registrant provides verbal notice of a medical event, then the registrant must inform the individual that a medical event report is required under subpart 3 and available upon request from the registrant.
- F. A registrant must provide a medical event report to the affected individual, or the affected individual's responsible relative or guardian, upon request.

Subp. 6. Individual identification in medical event report. A registrant must:

- A. annotate a copy of the medical event report provided to the commissioner under subpart 3 by adding the name or other identification number of the affected individual who is the subject of the medical event; and
- B. provide a copy of the annotated medical event report under item A to the authorized physician, if other than the registrant, within 30 days of discovery of the medical event.

4733.0210 GENERAL EQUIPMENT OPERATOR REQUIREMENTS.

Subpart 1. **Equipment requirements.** A registrant's radiation therapy equipment and therapy equipment must meet the requirements of:

- A. this chapter;
- B. Code of Federal Regulations, title 21; and
- C. the manufacturer's specifications.

Subp. 2. **Radiation therapy system operation; human use.**

- A. To operate a radiation therapy system for human use, an operator must:
 - (1) be a registered radiation therapy technologist who is both certified and registered with the American Registry of Radiologic Technologists (ARRT); or
 - (2) complete and pass a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology (2001); and
 - (3) complete the initial training under subpart 4.
- B. If an operator has not performed a radiation therapy procedure, a therapy simulation operation, or has not been subject to a performance audit under subpart 5 in the previous 6 months, then the operator may not perform a radiation therapy procedure or a therapy simulation procedure until the operator passes the competency (performance) audit conducted by the radiation safety officer or designee under subpart 5.

- C. For each human use radiation therapy treatment procedure [or therapy simulation operation], an operator and a qualified individual must be present at the console. A qualified individual must be:
- (1) a registered radiation therapy technologist;
 - (2) an authorized physician; or
 - (3) a qualified medical physicist.

Subp. 3. Radiation therapy system operation; veterinary use.

- A. To operate a radiation therapy system for veterinary use, an operator must be:
- (1) a veterinarian who is licensed by the Minnesota Board of Veterinary Medicine; or
 - (2) an individual operating under the direct supervision of a veterinarian who is licensed by the Minnesota Board of Veterinary Medicine.
- B. An individual operating radiation therapy equipment for veterinary use under item A must:
- (1) be 18 years of age or older;
 - (2) meet qualification criteria specified by a veterinarian who is licensed by the Minnesota Board of Veterinary Medicine; and
 - (3) complete initial training under subpart 5.

Subp. 4. Personal monitoring. A registrant must require that all individuals wear a personal monitoring device when entering an area where interlocks are required under part 4733.0255, subpart 4, except when:

- A. a radiation survey demonstrates that radiation levels are below that of a high-radiation area in the area where individual monitoring devices are required; and
- B. the radiation therapy system in the area has:
 - (1) the power locked out; or
 - (2) a beam that cannot be directed to that area.

Subp. 5. Training for operators of a radiation therapy system.

- A. A registrant must provide initial training to an individual before operating radiation therapy equipment. Initial training must be facility-specific and include the following components:
 - (1) radiation therapy system equipment;
 - (2) therapy simulation system equipment, if applicable;
 - (3) operating and emergency procedures;
 - (4) quality control tests;
 - (5) dynamic and static acquisition;
 - (6) quality management program;
 - (7) treatment plan transfer verification; and
 - (8) audit of an operator's performance by the registrant's radiation safety officer or designee during:
 - a) a prescribed patient radiation therapy treatment; and
 - b) a therapy simulation system operation, if applicable.
- B. A registrant must provide an operator of radiation therapy system with annual refresher training. Annual refresher training must include:

- (1) health risks associated with exposure to radiation;
 - (2) precautions and procedures to minimize exposure;
 - (3) purpose and use of personal protective equipment;
 - (4) operating and emergency procedures;
 - (5) medical event identification and reporting requirements; and
 - (6) an audit of the operator's performance by the radiation safety officer or designee during a:
 - a) prescribed patient radiation therapy treatment; and
 - b) therapy simulation system operation, if applicable.
- C. A student who is enrolled and participating in an accredited radiation therapy technology program, or an accredited radiation oncology program at a school of medicine or at a school of osteopathy, is exempt from the annual refresher training requirement under item B.
- D. A registrant must provide initial training to an operator before the operator uses radiation therapy system equipment or therapy simulation system equipment after any modification to:
 - (1) the radiation therapy system equipment;
 - (2) the therapy simulation system equipment;
 - (3) the registrant's quality management program; or
 - (4) the radiation output from new or updated software, modality, technology, or radiation equipment.

4733.0215 RECORDS.

Subpart 1. Record requirements. A registrant must maintain the following records:

- A. documents of receipt, transfer, and disposal of all radiation therapy systems or therapy simulation systems;
- B. operator training documentation under parts 4733.0210, subpart 5, and 4733.0800, subpart 4;
- C. written orders under part 4733.0435;
- D. individual monitoring results under part 4733.0320;
- E. prior occupational dose records according to part 4733.0300;
- F. documentation that demonstrates compliance with dose limits under parts 4733.0305 and 4733.0315, including:
 - (1) shielding plans;
 - (2) modifications; and
 - (3) radiation level verification surveys under part 4733.0265.
- G. radiation safety officer documentation required under part 4733.0405;
- H. procedures for acceptance testing, commissioning, full system calibration, quality control tests, and spot checks under this chapter;
- I. quality management program procedures under part 4733.0425;
- J. radiation protection program audits under part 4733.0420;
- K. calibration and intercomparison records for instruments, survey meters, and electronic equipment including:
 - (1) the date of calibration or intercomparison; and

- (2) the manufacturer, model number, and serial number of the instruments calibrated, intercompared, or compared;
 - (3) the determined correction factors; and
 - (4) the signature or electronic authorization of the individual who performed the calibration, intercomparison, or comparison;
- L. the results of radiation surveys under part 4733.0265, including:
 - (1) the survey date;
 - (2) the manufacturer, model number, and serial number of the instruments used to measure radiation levels;
 - (3) a diagram or sketch of the areas surveyed;
 - (4) the measured dose rate in each area that complies with the dose limits under parts 4733.0300 to 4733.0315;
 - (5) the calculated maximum level of radiation over a period of one year for each restricted area and unrestricted area; and
 - (6) the signature or electronic authorization of the individual who performed the survey;
- M. the equipment performance measurement records for acceptance and commissioning tests, full system calibration, and spot checks, including :
 - (1) the measurement date;
 - (2) the manufacturer, model number, and serial number for the equipment that is tested;

- (3) the manufacturer, model number, and serial number for instruments used to calibrate equipment;
- (4) the numerical results and images, if necessary;
- (5) corrective actions, if necessary; and
- (6) the signature or electronic authorization of the individual who performed the tests.

N. safety checks under this chapter;

O. electronic brachytherapy Institutional Review Board (IRB) documents part 4733.0800, including:

- (1) the IRB approval date;
- (2) the IRB expiration dates; and
- (3) the approved research study application.

Subp. 2. Record format and retention periods. A registrant must:

- A. maintain the records under this part so that they are legible throughout the applicable retention periods;
- B. indicate the units of measurement including rad, roentgen, rem, or equivalent international system of units (SI), on all applicable records.
- C. maintain all records under subpart 1, except items A, D, and E, for three years.
- D. maintain items A, D, and E under subpart 1:
 - (1) for as long as the registration is valid; and
 - (2) for three years after the registration is expired.

SHIELDING AND DESIGN REQUIREMENT

4733.0250 SHIELDING DESIGN REQUIREMENTS.

Subpart 1. **Shielding plan.** A registrant must submit to the commissioner facility design information for a new installation of a radiation therapy system or a therapy simulation system of higher energy into a room not previously approved for that energy before a new installation of the radiation therapy system or therapy simulation system. A registrant may submit the facility design information as part of the registration application under part 4733.0107, or as an amendment under part 4733.0111.

- A. A shielding plan for radiation therapy equipment must be performed by:
 - (1) a qualified medical physicist; or
 - (2) a health physicist certified by the American Board of Health Physics or by the American Board of Medical Physics.
- B. A registrant must document the radiation shielding installed in the registrant's facility. Documentation must include:
 - (1) a blue print or architectural drawing indicating installed shielding;
 - (2) a shielding plan; or
 - (3) a verification radiation survey that complies with part 4733.0265.
- C. A shielding plan for therapy simulation equipment must be performed by:
 - (1) a service provider under chapter 4732;
 - (2) a qualified medical physicist;
 - (3) a diagnostic radiological physicist; or

- (4) a health physicist certified by the American Board of Health Physics or by the American Board of Medical Physics.

Subp. 2. **Barriers.** Except for an electronic brachytherapy system operating at or below 150 kV, a facility with or operating radiation therapy system or a therapy simulation system must be designed with primary and secondary barriers that comply with the dose limits under 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 operates above ten MeV.
- C. For a therapy simulation system, any door that is indicated in the design as a primary barrier must be closed during exposures.

Subp. 3. **Modifications.** When modifications to a radiation therapy area or therapy simulation area alter the output, a registrant must:

- A. perform a radiation survey ensuring the doses to any individuals do not exceed the limits in this chapter;
- B. equip radiation therapy equipment with:
 - (1) beam direction interlocks; or
 - (2) additional shielding to comply with parts 4733.0300 to 4733.0315;
- C. document all modifications; and
- D. document the results of all radiation surveys according to part 4733.0265.

Subp. 4. **Records.** A registrant must maintain records required under this part according to part 4733.0215.

4733.0255 FACILITY DESIGN REQUIREMENTS.

Subpart 1. **Control console.** Except for an electronic brachytherapy operating at or below 150 kV, a radiation therapy system 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 discernible.

Subp. 2. **Warning lights.** An entrance to a radiation therapy room must have warning lights in visible positions near the outside of all access doors to indicate when the useful beam is "ON". This subpart does not apply to an electronic brachytherapy system that operates at or below 150 kV or to a therapy simulation room.

Subp. 3. **Emergency cut-off couch switches.**

- A. An emergency cut-off couch switch must be:
 - (1) located on either side of the useful beam; and
 - (2) clearly identified and discernible in all high-radiation areas.
- B. A cut-off switch must include a manual reset so that a radiation therapy system cannot be restarted from the control console without resetting the cutoff switch.
- C. This subpart does not apply to a therapy simulation system.

Subp. 4. **Interlocks or safety devices.**

- A. An interlock or a safety device must be in place so that all access to the therapy treatment room is blocked before irradiation is initiated or continued.

- B. If the useful beam is interrupted by a door opening or the tripping of a safety device, then it must not be possible to restore the radiation therapy system to operation:

 - (1) without closing the door or resetting the safety device unless the operator closes the door; or
 - (2) without resetting the safety device and manually initiating irradiation at the control console.
- C. Each entrance into a target area or other high-radiation area must have two safety interlocks that shut down the equipment when the barrier is breached.
- D. Breach safety interlock must be on a circuit that allows independent operation of the radiation therapy system.
- E. 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.
- F. This subpart does not apply to electronic brachytherapy below that operates below 150 kV or to a therapy simulation room.

Subp. 5. Patient viewing system.

- A. A registrant must provide a closed-circuit viewing system in a radiation therapy room that allows an operator to observe the patient from the control console at all times during irradiation;
- B. A registrant must provide a closed circuit viewing system in a therapy simulation room that allows an operator to see the patient, other individuals in the room, and all entrances into the room from the control console at all times.

Subp. 6. Audio communication.

- A. A registrant must provide a two-way audio communication system at the control panel that allows the patient and an operator to communicate with each other.
- B. If excessive noise levels or treatment requirements prevent the use of two-way audio communication under item A, then other methods of communication must be used.
- C. This subpart does not apply to veterinary use of a radiation therapy system or a therapy simulation system.

4733.0265 RADIATION SURVEYS.

Subpart 1. Radiation survey; when to perform. A radiation survey must encompass all directions around the equipment and surrounding areas. A radiation survey must be performed:

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

Subp. 2. Radiation survey; performance method.

- A. A radiation survey must cover the radiation levels at the operator position and at pertinent points outside the room during normal operation of the radiation therapy system.
- B. A radiation safety officer or designee must perform the radiation survey with:
 - (1) an instrument that is calibrated according to part 4733.0440;
 - (2) the equipment in a "BEAM-ON" condition;
 - (3) the largest available field; and
 - (4) a scattering phantom in the useful beam of radiation, if applicable.

Subp. 3. **Radiation survey results above dose limits.** If the results of the radiation survey indicate radiation levels above the dose limits under parts 4733.0300 to 4733.0315, then a registrant must:

- A. inactivate and secure the radiation therapy equipment;
- B. notify the commissioner within 24 hours of discovery; and
- C. perform corrective actions.

Subp. 4. **Radiation therapy system equipment inactivated.** A registrant may use radiation therapy system equipment that has been inactivated and secured under subpart 3 if:

- A. the results of a radiation survey indicate that radiation levels do not exceed the dose limits under parts 4733.0300 to 4733.0315;
- B. the radiation safety officer documents that the corrective actions under subpart 3, item C, are complete; and

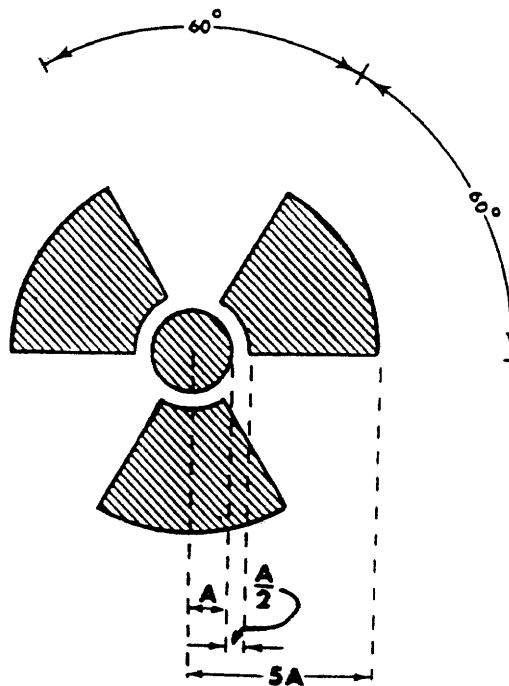
- C. the registrant complies with the dose requirements under parts 4733.0300 to 4733.0315.

Subp. 5. **Records.** A registrant must maintain radiation survey records according to part 4733.0215.

4733.0270 CAUTION SIGNS.

Subpart 1. **Standard radiation symbol and labeling.** Each radiation sign or label must bear:

- A. the standard radiation symbol in this subpart; and
- B. the printed warning, in capital block letters in subpart 4.
- C. The standard symbol for designating any radiation hazard is a circle with three propeller-like blades arranged around it as illustrated:



- (1) the cross-hatched area must be magenta, purple, or black; and

(2) the background must be yellow.

Subp. 2. Additional information on signs and labels. A registrant must provide, on or near the required signs and labels, additional information to make individuals aware of potential radiation exposures.

Subp. 3. Prohibitions on use of symbol. A registrant may not use the standard radiation symbol for any purpose other than designating an area of containing radiation levels.

Subp. 4. Posting and labeling requirements. A registrant must post radiation warning labels and signs at the entrance in areas where a radiation hazard may exist.

- A. The warning "CAUTION RADIATION AREA" or "DANGER RADIATION AREA" must appear on signs in a radiation area.**
- B. The warning "CAUTION HIGH-RADIATION AREA" or "DANGER HIGH-RADIATION AREA" must appear on signs in a high radiation area.**
- C. The warning "CAUTION VERY HIGH-RADIATION AREA" or "DANGER VERY HIGH-RADIATION AREA" must appear on signs in a very high-radiation area.**

4733.0275 WARNING AND CONTROL DEVICES FOR HIGH- AND VERY HIGH-RADIATION AREAS.

- A. Each entrance or access point to a high- or very high-radiation area must be equipped with:**
 - (1) a control device that reduces the level of radiation so that an individual cannot receive a dose in excess of 100 millirems (1.0 mSv) in one hour after entry into the area; or**

- (2) a warning device that uses a visible or audible alarm to alert an individual and other nearby non-occupationally exposed workers entering the high- or very high-radiation area.
- B. A registrant may use a continuous direct surveillance system or an electronic surveillance system that prevents unauthorized entry instead of the controls required under item A.

DOSE REQUIREMENTS

4733.0300 DETERMINATION OF ACCUMULATED OCCUPATIONAL DOSE.

Subpart 1. Determining prior occupational dose. A registrant must determine the occupational dose that an individual received during the current year for each individual in the registrant's facility who:

- A. is likely to receive an occupational dose in a year; and
- B. requires monitoring under part 4733.0320.

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

- A. A registrant may accept a written 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 during the current year; or
- B. A registrant may accept a letter, signed by the individual and countersigned by an official of the individual's most recent employer, for work involving radiation

exposure, or the individual's current employer as the record of cumulative radiation dose, if the individual is not employed by the registrant.

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

- (1) the allowable dose limits for the individual are reduced by 1.25 rem (12.5 mSv) for each quarter for which records are unavailable; and
- (2) the individual was engaged in activities that may have resulted in occupational radiation exposure.

Subp. 3. **Records.** A registrant must maintain occupational dose records according to part 4733.0215.

4733.0305 OCCUPATIONAL DOSE LIMITS FOR ADULTS.

Subpart 1. **Occupational dose control.** A registrant must prevent individual adults from receiving occupational doses that exceed the annual dose limit.

Subp. 2. **Annual dose limit.** The annual dose limit is the lesser 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 equal to 50 rem (0.5 Sv); and
- C. the annual limit to the lens of the eye, to the skin, and to the extremities, all of 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 portion of the body receiving the highest exposure is the assigned deep-dose equivalent and shallow-dose equivalent.

B. The deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent may be assessed from a radiation survey, or other radiation measurements, for complying with the occupational dose limits if:

(1) the individual monitoring device was not in the region of highest potential exposure; or

(2) the results of individual monitoring are unavailable.

Subp. 3. Effective dose equivalent for external radiation. When an individual wears a protective apron or other personal protective equipment while working with radiation-producing equipment and monitoring under part 4733.0320, the effective dose equivalent for external radiation must be determined according to this subpart.

A. When only one individual monitoring device is used and located at the neck or collar outside the protective apron, the reported deep-dose equivalent must be the effective dose equivalent for external radiation;

B. When only one individual monitoring device is used and located at the neck or 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

- C. When more than one individual monitoring devices are worn, under the protective apron at the waist and outside the protective apron at the neck or collar, the effective dose equivalent for external radiation must be assigned the value of:
- (1) 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
 - (2) the deep-dose equivalent reported for the individual monitoring device located at the neck or collar outside the protective apron multiplied by 0.04.
- D. The commissioner must approve any alternative method of determining dose.

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

4733.0310 DOSE EQUIVALENT TO AN EMBRYO OR FETUS.

- A. When a woman declares her pregnancy, in writing, a registrant must prevent the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, from exceeding 0.5 rem (5mSv).
- B. A registrant must avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as not to exceed the limit in item A.

- C. A registrant must limit the occupational dose to the embryo or fetus to 0.05 rem (0.5 mSv) in any one month of pregnancy. The occupational dose does not include the declared pregnant woman's own medical exposure.
- D. If the dose to the embryo or fetus exceeds 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, then a registrant must prevent additional occupational dose equivalent to the embryo or fetus from exceeding 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 (one mSv).
- B. A registrant must conduct operations so that the dose in an unrestricted area does not exceed 0.002 rem (0.02 mSv) in any one-hour period.

4733.0320 INDIVIDUAL MONITORING.

Subpart 1. **Exposure to radiation levels.** A registrant must monitor an individual's exposure to radiation at levels sufficient to comply with the occupational dose limits of this chapter.

Subp. 2. **Requirements for individual monitoring.** A registrant must provide all individuals with monitoring devices and must ensure that personnel to wear the monitoring devices according to this subpart.

- A. An adult likely to receive, in one year, a dose in excess of ten percent of the limits in part 4733.0305;
- B. A minor likely to receive, in one year, a deep dose equivalent in excess of 0.1 rem (1.0 mSv);
- C. A declared pregnant woman 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 apply to the declared pregnant woman as long as the embryo or fetus dose limit is not exceeded; and
- D. An individual entering a high- or very high-radiation area.

Subp. 3. **Required instruction.** A registrant must provide annual training under part 4733.0210, subpart 5 to all individuals who are likely to receive an occupational dose in excess of 0.1 rem (1.0 mSv) in one year.

RADIATION SAFETY

4733.0400 REGISTRANT'S SAFETY RESPONSIBILITIES.

- A. A registrant is responsible for the operation of the registrant's radiation therapy systems, electronic brachytherapy, and therapy simulation systems.
- B. If a registrant is not the radiation safety officer, then the registrant must designate a radiation safety officer who meets the qualifications under part 4733.0405.

4733.0405 RADIATION SAFETY OFFICER.

Subpart 1. **Radiation safety officer training.** A radiation safety officer must be:

- A. an authorized physician;
- B. qualified medical physicist;
- C. certified health physicist; or
- D. an individual who meets the alternate RSO requirements under subpart 2.

Subp. 2. **Alternate RSO requirements.** An individual who does not meet the requirements under subpart 1, items A to C, may perform the duties of a radiation safety officer if the individual:

- A. completes training under subpart 4; and
- B. obtains written attestation from a radiation safety officer or qualified medical physicist stating that the individual satisfactorily completed the requirements in item A and achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for radiation therapy.

Subp. 2. **Implementation of radiation protection program.** A registrant must designate a radiation safety officer who is responsible for implementing the radiation protection program under part 4733.0420.

Subp. 3. **Authority.** A registrant must provide a radiation safety officer sufficient authority, organizational freedom, time, resources, and management prerogative to:

- A. identify radiation safety problems;
- B. initiate or recommend corrective actions;
- C. stop unsafe operations; and
- D. verify the implementation of corrective actions.

Subp. 4. Radiation safety officer responsibilities. A radiation safety officer must:

- A. establish a quality management program;
- B. establish and oversee operating and emergency procedures;
- C. determine the personnel who are subject individual monitoring under part 4733.0320;
- D. investigate each known or suspected case of an individual being exposed to radiation levels that exceed the limits established under this chapter;
- E. assume control of the equipment and institute corrective actions, including shutdown of operations in emergency or unsafe conditions;
- F. design and oversee initial, annual, and other required trainings;
- G. confirm that equipment maintenance is performed according to this chapter;
- H. perform, or arrange to have performed:
 - (1) radiation surveys under part 4733.0265;
 - (2) radiation protection program audits under part 4733.0420;
 - (3) calibrations and equipment performance evaluations;
 - (4) initial and annual operator competency audits; and
- I. review of quality control tests and spot checks;
- J. supervise and review personnel dosimetry.

4733.0410 QUALIFIED MEDICAL PHYSICIST.

Subpart 1. **Qualified medical physicist; required.** A registrant must employ or contract with a qualified medical physicist.

Subp. 2. **Qualified medical physicist; responsibilities.** A qualified medical physicist is responsible for:

- A. full system calibrations and equipment commissionings;
- B. acquiring beam data and transferring beam data for dosimetry;
- C. managing quality assurance, including establishing written procedures and reviewing required quality control and safety checks;
- D. consulting for treatment planning, as needed; and
- E. performing calculations and assessments regarding medical events.
- F. A qualified medical physicist must develop a procedure for verifying the treatment plan before the treatment plan is transferred to the treatment equipment system and before the treatment plan is implemented.

Subp. 3. **Qualified medical physicist; not available.** If a qualified medical physicist is not immediately available, then a registrant must have emergency procedures to address problems, failures, or emergencies related to a registrant's radiation therapy system equipment and therapy simulation equipment.

Subp. 4. **Treatment plan verification.** A qualified medical physicist or qualified medical physicist's designee must verify the treatment plan and treatment plan transfer before:

- A. the first treatment of five or fewer treatment fractions; and

- B. the third fraction for treatments that exceed five fractions.

Subp. 5. **Emergency treatment plan verification.** If a qualified medical physicist is not available for an emergency treatment plan, then an authorized physician may verify and document the treatment plan and the transfer of the emergency treatment plan.

Subp. 6. **Qualified medical physicist; alternate qualifications.** An individual who is not board certified may practice independently in the subfields for therapeutic radiological physics if the individual:

- A. holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
- B. has completed one year of full time training in medical physics; and
- C. has completed one year of full time work experience under the supervision of a board certified qualified medical physicist at a medical institution.
- D. The training and work experience under this subpart must be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy using photons and electrons with energies greater than or equal to one MV/one MeV.

For purposes of this part, board certified means a qualified medical physicist who has met the requirements under part 4733.0105, subpart 36, items A to D.

4733.0420 RADIATION PROTECTION PROGRAM AUDITS.

Subpart 1. **Radiation protection program.** A radiation protection program is a set of written or documented policies or procedures designed to minimize unnecessary radiation exposure to occupational workers, patients and members of the public.

Subp. 2. **Radiation protection program; contents.** A radiation protection program must include:

- A. all aspects of the quality management program under part 4733.0425;
- B. medical events and incidents that may have resulted in a medical event;
- C. required trainings;
- D. operating and emergency procedures;
- E. annual calibrations, periodic spot checks, and other applicable quality control and safety checks;
- F. dosimetry and survey equipment calibrations; and
- G. other items identified by the registrant, radiation safety officer, or qualified medical physicist.

Subp. 3. **Radiation protection program audit; frequency.** A registrant must review the radiation protection program at intervals not to exceed 12 months.

Subp. 4. **Corrective actions.** A registrant must correct any noncompliance issues found during the audit within 30 days.

Subp. 5. **Records.** A registrant must maintain records of radiation protection program audits according to part 4733.0215.

4733.0425 QUALITY MANAGEMENT PROGRAM.

Subpart 1. **Quality management program; when required.** A registrant subject to parts 4733.0500, 4733.0520, or 4733.0800 must implement a site-specific quality management program.

Subp. 2. **Quality management program; program requirements.** A registrant's quality management program must include written procedures for:

- A. a radiation therapy written order and therapy simulation written order under part 4733.0435; and
- B. notification of a medical event under part 4733.0180;

Subp. 3. **Procedures for written orders for radiation therapy and therapy simulation written orders.**

- A. A registrant must develop procedures for a radiation therapy written order and a therapy simulation written order so that each administration of a therapeutic dose to a patient is consistent with the written order.
- B. A registrant must verify that the final plans for radiation therapy treatment and related calculations are consistent with the written order by reviewing:
 - (1) manual calculations and the computer-generated dose calculations to verify they are correct and consistent with the written order; and
 - (2) computer-generated calculations are transferred correctly from the radiation therapy delivery system into the radiation therapy system console.

Subp. 4. **Unintended deviation from a written order.** A registrant is responsible for an unintended deviation from the written order. In the event of an unintended deviation from a written order, a registrant must:

- A. identify and evaluate; and
- B. take appropriate action.

Subp. 5. **Treatment plan approval.** Before a patient receives the first treatment, the treatment plan must be approved and signed by an authorized physician and:

- A. a qualified medical physicist; or
- B. a certified medical dosimetrist who is certified by the Medical Dosimetrist Certification Board (MDCB).

4733.0430 AUTHORIZED PHYSICIAN ALTERNATE QUALIFICATIONS.

Subpart 1. **Therapeutic radiology requirements.** An authorized physician in the active practice of therapeutic radiology who is not board certified must complete:

- A. 200 hours of classroom and laboratory instruction applicable to the use of an external beam radiation therapy unit under subpart 2;
- B. 500 hours of supervised work experience under subpart 3; and
- C. 3 years of supervised clinical experience under subpart 4.

For purposes of this part, board certified means an authorized physician who meets the requirements under part 4733.0105, subpart 6, items A to D.

Subp. 2. **Classroom and laboratory training.** An authorized physician who is not board

certified must complete classroom and laboratory training that includes:

- A. radiation physics and instrumentation;
- B. radiation protection;
- C. mathematics pertaining to the use and measurement of ionizing radiation; and
- D. radiation biology.

Subp. 3. Supervised work experience. An authorized physician who is not board certified must complete supervised work experience under the supervision of a board certified authorized physician and must include:

- A. a review of the full calibration measurements and periodic quality assurance checks;
- B. an evaluation of prepared treatment plan and calculation of treatment times and patient treatment settings;
- C. using administrative controls to prevent medical events;
- D. implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
- E. checking and using radiation survey meters.

Subp. 4. Supervised clinical experience.

- A. An authorized physician who is not board certified must complete supervised clinical experience:
 - (1) for one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American

Osteopathic Association; and

(2) for an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized physician.

B. The supervised clinical experience must include:

(1) examining individuals and reviewing patient case histories to determine suitability for external beam radiation therapy treatment and any limitations or contraindications;

(2) selecting the proper dose and the method of dose administration;

(3) calculating the therapeutic radiation machine doses, collaborating with the authorized physician in the review of patients' progress, and assessing the need to modify originally prescribed doses or treatment plans as warranted by the patients' reaction to radiation; and

(4) post-administration follow-up and review of case histories.

4733.0435 WRITTEN ORDERS.

Subpart 1. Written orders procedures; radiation therapy treatment.

A. The order for a radiation therapy treatment must be made by an authorized physician.

B. The written order for a radiation therapy treatment must be available at the time of the treatment.

C. The written order for a therapeutic procedure must include the:

(1) date;

- (2) patient's identity;
 - (3) identity of the authorized physician who is ordering the treatment, by a signature, an electronic authorization, or equivalent;
 - (4) type and energy of beam;
 - (5) treatment site;
 - (6) total dose;
 - (7) dose per fraction; and
 - (8) total number of fractions and number of fractions per day.
- D. A written order may be revised if the revision to the written order is signed and dated by an authorized physician before the administration of the therapeutic dose or the next fractional dose.

Subp. 2. Written orders procedures; therapy simulation examination.

- A. An order for a therapy simulation examination must be made by an authorized physician.
- B. A written order for a therapy simulation procedure must be available at the time of the examination.
- C. A written order for a therapy simulation procedure must include:
 - (1) the date;
 - (2) the patient's identity;
 - (3) the identity of the authorized physician who is ordering the examination, by a signature, an electronic signature, or equivalent;
 - (4) the intended modality;

- (5) the therapy simulation site;
- (6) patient positioning; and
- (7) immobilization devices and markers.

CALIBRATIONS

4733.0440 RADIATION SURVEY OR MEASUREMENT INSTRUMENTS.

Subpart 1. Requirements.

- A. A facility authorized to operate a radiation therapy system must possess calibrated portable radiation monitoring equipment.
- B. Measurement instruments must be capable of measuring dose rates over the range of 1 mrem per hour to 1000 mrem per hour (10uSv to 10 mSv per hour).
- C. Portable radiation monitoring equipment must be:
 - (1) capable of measuring dose rates over the range of 1 mrem per hour to 1000 mrem per hour (10uSv to 10 mSv per hour);
 - (2) accurate within plus or minus 20 percent over the instrument's applicable range of the instrument;

Subp. 2. Calibration; portable radiation monitoring equipment. A registrant must calibrate portable radiation monitoring equipment:

- A. annually;
- B. after a repair or modification; and
- C. using a radiation source that it is traceable to the National Institute of Standards and Technology (NIST).

Subp. 3. Calibration; portable radiation monitoring equipment with noninvasive kVp meter. A portable radiation monitoring equipment with a noninvasive kVp meter must be calibrated by the manufacturer or by an accredited calibration laboratory.

4733.0445 DOSIMETRY SYSTEM.

Subpart 1. Dosimetry system requirements.

- A.** A registrant must use a dosimetry system that is calibrated for quality control measurements. The system must be calibrated by:

 - (1) the National Institute for Standards and Technology (NIST); or
 - (2) an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL).
- B.** For beams with energies greater than 1.0 MV (1.0 MeV), the dosimetry system must be calibrated for Cobalt-60.
- C.** For beams with energies equal to or less than 1.0 MV (1.0 MeV), the dosimetry system must be calibrated at an energy appropriate for the radiation being measured.

Subp. 2. Dosimetry system calibrations; frequency.

A calibration must be performed:

- A.** every 24 months; and
- B.** after any servicing that may affect dosimetry system calibration.

Subp. 3. Records. A registrant must maintain records under this part according to part 4733.0215.

EQUIPMENT REQUIREMENTS

4733.0500 RADIATION THERAPY SYSTEMS OF LESS THAN 500 kV.

Subpart 1. **Leakage radiation.** A registrant is responsible for the leakage radiation requirements of this subpart.

- A. The leakage air kerma rate must not exceed the value specified at the distance specific to that radiation therapy system's classification when the x-ray tube is operated at its maximum-rated tube current and maximum kV.
- B. A registrant must obtain documentation from the manufacturer for each radiation therapy system indicating that the radiation therapy system allowing for:
 - (1) has been measured under conditions a maximum leakage radiation; or
 - (2) does not exceed the value specified at the distance specified for the classification of that x-ray system.
- C. A registrant's compliance with this subpart is determined by leakage air kerma rate measurements averaged over an area of 100 square centimeters.
- D. Leakage measurement must be performed:
 - (1) at installation;
 - (2) whenever the tube is changed replaced; and
 - (3) every five years.
- E. For contact 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;

- F. For systems at or below 150 kV, the leakage kerma rate measured at any position five centimeters from the tube housing assembly must not exceed 100 mrad (1.0 mGy) in any one hour; and
- G. 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. The air 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.

Subp. 2. Diaphragms, cones, beam-limiting devices, or blocks.

- A. A permanent diaphragms or a cone that is used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.
- B. An adjustable or removable diaphragm, a cone, a beam-limiting device, or a block must not transmit more than five percent of the useful beam for the most penetrating beam used.
- C. When an adjustable beam-limiting device is used, the position and shape of the radiation field must be indicated by a light beam.

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

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

- C. the air kerma rate escaping from the filter slot does not exceed 1.0 rad (1.0 cGy) per hour at one meter under any operating condition; and
- D. each filter is marked as to its material construction and its thickness.

Subp. 4. X-ray tube and tube housing. A registrant is responsible for the requirements of this subpart.

- A. The x-ray tube must be mounted so that it cannot inadvertently turn or slide with respect to the housing aperture.
- B. The tube housing assembly must be capable of being immobilized for stationary portal treatments.
- C. The tube housing assembly must be marked so that it is possible to determine the location of the source to within five millimeters. The marking on the tube housing assembly must be readily accessible during a calibration procedure.
- D. A contact therapy tube housing assembly must have a removable shield equivalent in attenuation to 0.5 millimeters of lead at 100 kV that 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 radiation therapy system must have a timer device that terminates the radiation after a preset time interval has elapsed. The timer device 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) have a cumulative timer that has a "BEAM-ON" indicator to show the instrument is radiating and retains its reading after radiation is interrupted or terminated.
- (4) require resetting the elapsed-time indicator after radiation is terminated and before irradiation can be restarted;
- (5) permit ~~accurate~~ presetting and determination of exposure times as short as one second;
- (6) not permit an exposure if set at zero;
- (7) 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
- (8) be accurate to within 1.0 percent of the selected value or one second, whichever is greater.

B. A control panel must:

- (1) indicate if electrical power is available at the control panel and if activation of the x-ray tube is possible;
- (2) indicate when x-rays are being produced;
- (3) have an indicator for kVp and x-ray tube current;
- (4) be able to terminate an exposure at any time;
- (5) be equipped with a locking device that will prevent unauthorized system use;
and

- (6) for radiation therapy systems manufactured after July 9, 1997, have a positive display of specific filters in the beam.
- C. If a control panel is capable of energizing more than one x-ray tube, then:
 - (1) it must be possible to activate only one x-ray tube at a time;
 - (2) the control panel must have an indicator identifying which x-ray tube is activated; and
 - (3) the tube housing assembly must have an indicator indicating 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 bringing the x-ray output to the prescribed exposure parameters is possible 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. A radiation therapy system that is equipped with a beryllium or other low-filtration window must:
 - (1) be clearly labeled as such on the tube housing assembly; and

- (2) have a permanent warning device on the control panel that activates when no additional filtration is present to indicate that the dose rate is very high.

Subp. 6. Facility design requirements. Except for electronic brachytherapy and in addition to the requirements under parts 4733.0250 to 4733.0255, a treatment room that contains a radiation therapy system capable of operating in a range of 150 kV to 500 kV must meet the following requirements.

- A. All protective barriers must be fixed except for entrance doors or beam interceptors;
- B. The control panel must be located outside the treatment room or in a ~~totally~~ [fully] enclosed booth that has a ceiling inside the room;
- C. Interlocks must be provided so that all entrance doors, including doors to any interior booths, must be closed before treatment is initiated or continues;
- D. if the beam is interrupted by a door opening, it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and
- E. The air kerma rate, at a distance of one meter from the source, must be reduced to less than 100 mrad (1.0 mGy) per hour when a door is opened while the radiation therapy system is activated.
- F. This part does not apply to an electronic brachytherapy system.

4733.0505 OPERATING AND EMERGENCY PROCEDURES FOR THERAPY SYSTEMS OPERATING BELOW 500 kV.

Subpart 1. Operating procedures. A registrant's written operating procedures for therapy systems operating below 500 kV must be maintained at the treatment console and must include:

- A. operation and safety instructions to be used for the radiation therapy and therapy simulation systems;
- B. specify that an operator and one additional qualified individual must be at the therapy control console during the patient setup and during treatment;
- C. procedures for verifying the patient's identity using two forms of identification;
- D. procedures for treatment plan approval and transfer;
- E. procedures for verification of treatment plan accuracy prior to treatment delivery;
- F. procedures for ensuring that the patient is monitored continuously and without obstruction during treatment;
- G. methods for controlling access to restricted areas;
- H. methods and occasions for locking and securing the radiation therapy system;
- I. use of individual monitoring equipment; and
- J. inspections and maintenance of the therapy and therapy simulation systems.
- K. when a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used;

- L. procedures for restricting individuals 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 a protective apron and gloves of not less than 0.5 millimeters lead equivalency at 100 kV; and
- M. procedures that prohibit individuals other than the patient in the treatment room during exposures from radiation therapy systems operating above 150 kV.

Subp. 2. Emergency procedures. A registrant's written emergency procedures for therapy systems operating below 500 kV must be maintained must be maintained at the treatment console and must include:

- A. actions necessary to address equipment failures or patient emergencies;
- B. names and telephone numbers for available individuals to be contacted if the system or console operates abnormally;
- C. notifications if the equipment fails or the patient has an emergency; and
- D. procedures for conducting analysis following any medical event.
- E. notifying the commissioner of a medical event;
- F. A registrant's written emergency procedures must include:
 - (1) actions necessary to address equipment failures or patient emergencies;
 - (2) names and telephone numbers for available individuals to be contacted if the system or console operates abnormally;
 - (3) notifications if the equipment fails or the patient has an emergency; and
 - (4) procedures for conducting analysis following any medical event.

4733.0510 FULL CALIBRATION MEASUREMENTS RADIATION THERAPY SYSTEMS OF LESS THAN 500 kV.

Subpart 1. **Full calibration procedures.** A registrant must establish, document, and implement full calibration procedures that are developed by a qualified medical physicist. The procedures must be:

- A. available for review by the commissioner upon inspection; and
- B. developed according to published protocols accepted by nationally recognized organizations such as the National Council on Radiation Protection and Measurements (NCRP).
- C. A qualified medical physicist may determine that a specific recommendation of the protocol reports under item B is not needed and must document the reasons for this determination.

Subp. 2. **Full system calibration.** Before first medical or clinical use, a full system calibration must be performed by, or under the direct supervision of, a qualified medical physicist. A full system calibration must be performed:

- A. according to the calibration procedures under subpart 1;
- B. following initial installation or reinstallation;
- C. following any change that would alter the calibration or other characteristic of the therapy beam;
- D. 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; and

- E. A registrant may conduct individual elements of a full calibration at different times if all parameters for all energies are completed annually.

Subp. 3. **Exceptions.** Notwithstanding the requirements of this subpart:

- A. A full calibration of a radiation therapy system 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, then a qualified medical physicist must perform a full calibration on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with spot check procedures under part 4733.0510.

Subp. 4. **Records.** A registrant must maintain records under this part according to part 4733.0215.

4733.0515 PERIODIC QUALITY ASSURANCE SPOT CHECKS RADIATION THERAPY SYSTEMS OF LESS THAN 500 kV.

Subpart 1. **Periodic quality assurance spot checks.** A registrant must establish, implement, and document periodic quality assurance spot checks procedures that are developed by a qualified medical physicist for a radiation therapy system capable of operating at 150 kV or greater. Periodic quality assurance spot checks procedures must be:

- A. available for review by the commissioner upon inspection; and

- B. developed according to published protocols accepted by nationally recognized organizations such as the National Council on Radiation Protection and Measurements (NCRP).
- C. A qualified medical physicist may determine that a specific recommendation of the protocol reports under item B is not needed and must document the reasons for this determination.

Subp. 2. **Tolerances.** A qualified medical physicist must investigate and correct the cause of a parameter exceeding a tolerance according to the written procedures under subpart 1 before the therapy system may be used for patient irradiation.

Subp. 3. **Qualified medical physicist review.** A registrant must have a qualified medical physicist review and sign or authorize the results of each radiation output quality control check within 30 days of test completion.

Subp. 4. **Safety check.** An operator trained to perform safety checks must perform safety checks at intervals not to exceed seven days. A safety check must verify the proper operation of:

- A. the electrical interlocks at each external beam radiation therapy room entrance;
- B. the "BEAM-ON", interrupt, and termination switches;
- C. beam condition indicator lights:
 - (1) on the access doors;
 - (2) on control console; and
 - (3) in the radiation therapy room;

- D. viewing and audio systems; and
- E. electrically operated treatment room doors from inside and outside the treatment room, if applicable.

Subp. 5. **Records.** A registrant must maintain records under this part according to part 4733.0215.

4733.0520 PHOTON (500 kV AND ABOVE) AND ELECTRON-PRODUCING SYSTEMS (500 keV AND ABOVE).

Subpart 1. **Leakage radiation; outside the maximum useful beam in photon and electron modes.** Leakage radiation outside the maximum useful beam in photon and electron modes must meet the requirements of this subpart.

- A. 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.
- B. 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.

- C. 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.

Subp. 2. Leakage radiation through beam-limiting devices. Leakage radiation through beam-limiting devices must meet the requirements of this subpart.

- A. All adjustable or interchangeable beam-limiting devices must attenuate the useful beam so that, at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting devices does not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten-centimeter by ten-centimeter radiation field.
- B. All adjustable or interchangeable electron applicators must attenuate the radiation. For example, photon radiation generated by electrons incident to the beam-limiting device and electron applicator and other parts of the radiation head, must be set so that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment does not exceed:
- (1) a maximum of two percent and average of 0.5 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

- (2) 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.

Subp. 3. Measurement of leakage radiation. Measurement of leakage radiation must meet the requirements of this subpart.

- A. Leakage radiation through the beam-limiting devices must be measured 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.
- B. Leakage radiation through the electron applicators must be measured 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.4. Filters and wedges. The filters and wedges must meet the requirements of this subpart.

- A. Each removable wedge filter must be clearly marked with an identification number.

- B. For removable wedge filters, the nominal wedge angle must appear on the wedge or, if the wedge filter is permanently mounted to the tray, then the nominal wedge angle must appear on the wedge tray.
- C. If the wedge or wedge tray is damaged, the wedge transmission factor must be redetermined.
- D. If the absorbed dose rate information required by this subpart is exclusively for operating with a field-flattening or beam-scattering filter in place, then the filter must be removable only by using tools.
- E. For equipment manufactured after July 9, 1997 that uses a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:
 - (1) irradiation must not be possible until a filter is selected or a decision to use "no filter" has been made at the treatment control panel, either manually or automatically;
 - (2) an interlock system must prevent irradiation if the filter selected is not in the correct position;
 - (3) the treatment control panel must have a display that indicates the wedge filters are in use; and
 - (4) an interlock must prevent irradiation if any filter or beam-scattering foil selection operation to be carried out in the treatment room does not agree with the filter or beam-scattering foil selection operation to be carried out at the treatment control panel.

Subp. 5. Beam monitoring.

- A. A registrant must determine during acceptance testing, or obtain from the manufacturer, data sufficient to confirm that stray x-ray 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 complies with this chapter.
- B. All radiation therapy systems operating at 500 kV and above or 500 keV and above must have 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.
- C. Equipment manufactured after July 9, 1997, must have at least two independently powered integrating dose meters.
- D. The detector system and its detector must meet the following requirements
 - (1) each detector must be removable only with tools and, if movable, must be interlocked to prevent incorrect positioning;
 - (2) each detector must form part of a beam-monitoring system from which readings in dose monitoring units of the absorbed dose at a reference point can be calculated;
 - (3) each beam-monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation;
 - (4) the design of the beam-monitoring system must ensure that the:
 - a) malfunctioning of one system does not affect the correct functioning of the other systems; and

- b) failure of either system must terminate irradiation or prevent the initiation of irradiation; and
- E. each beam-monitoring system must have a legible display at the treatment control panel and each display must:
 - (1) retain a reading until intentionally reset;
 - (2) have only one scale and no electrical or mechanical scale multiplying factors;
 - (3) use a design so that the increasing dose is displayed by increasing numbers;
and
 - (4) in the event of a power failure, the required beam-monitoring information displayed at the control panel at the time of failure can be retrieved in at least one system for 20 minutes.

Subp. 6. Beam symmetry.

- A. A bent beam linear accelerator must be provided with auxiliary devices to monitor beam symmetry.
- B. The devices referenced in this subpart must be able to detect field asymmetry greater than ten percent.
- C. The devices must be configured to terminate irradiation if field asymmetry cannot be maintained at ten percent or less.

Subp. 7. Selection and display of dose monitor units.

- A. Irradiation must not be possible until a selection of a number of dose-monitoring units has been made at the treatment console.

- B. The control panel must display the preselected number of dose monitor units until reset manually.
- C. After irradiation is terminated, the dosimeter display must be reset before subsequent treatment may be initiated.
- D. After radiation is terminated, an operator must be required to reset the preselected dose monitor units before starting irradiation.

Subp. 8. **Air kerma rate or absorbed dose rate.** For each radiation therapy system, a registrant must determine, or obtain from the manufacturer, the maximum values for the specified operating conditions.

- A. A radiation therapy system must display readings so that the air kerma rate, or absorbed dose rate, at a reference point may be calculated. A radiation detector under subpart 5 may form part of this system;
- B. The dose monitor unit rate must be selected and displayed at the treatment control panel;
- C. Radiation therapy equipment capable of delivering, under any conditions, an air kerma rate or absorbed dose rate at the nominal treatment distance that is more than twice the maximum value specified by the manufacturer must have a device that terminates irradiation when the air kerma rate, or absorbed dose rate, exceeds a value twice the specified maximum. A registrant must maintain a record of the dose rate at which the irradiation will be terminated;
- D. Radiation therapy equipment that is capable of delivering, under any fault conditions, an air kerma rate or absorbed dose rate at the nominal treatment

distance that is more than ten times the maximum value specified by the manufacturer must have a device that:

- (1) prevents the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value; and
- (2) terminates irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4.0 Gy (400 rad); and

E. A registrant must maintain records of these maximum values at the facility for inspection by the commissioner.

Subp. 9. Termination of irradiation by beam-monitoring system during stationary beam therapy. A registrant's radiation therapy system equipment must allow the operator to terminate the irradiation by the beam-monitoring system during stationary beam radiation therapy and must meet the requirements of this subpart.

- A. Each primary system must terminate irradiation when the beam-monitoring system has detected the preselected number of dose monitor units;
- B. If the radiation therapy system's equipment's original design included a secondary dose-monitoring system, then the secondary dose-monitoring system must terminate irradiation when the secondary system detects radiation of not more than 15 percent, or 40 dose monitor units, above the preselected number of dose monitor units set at the control panel; and
- C. An indicator on the control panel must show which monitoring system has terminated irradiation.

Subp. 10. **Termination of irradiation.** A registrant's radiation therapy system equipment must allow an operator, from the operator's position at the treatment control panel, to terminate irradiation and equipment movement, or move from an interruption condition to termination condition at any time.

Subp. 11. **Interruption of irradiation.**

- A. If a radiation therapy system has an interrupt mode, then interrupting irradiation and equipment movements must be possible from the treatment control panel at any time.
- B. After an interruption, an operator must be able to restart irradiation without reselecting any of the operating conditions.
- C. Irradiation and equipment movements must be automatically terminated if any change of a preselected value is made during an interruption.

Subp. 12. **Timers.** An irradiation control device must terminate the irradiation after a preset time interval. The timer must:

- A. have a display at the treatment control panel;
- B. have a preset time selector and elapsed time indicator;
- C. be a cumulative time that activates with an indication of "BEAM ON" and retains its reading after irradiation is terminated;
- D. require that the elapsed time indicator be reset after irradiation is terminated and before irradiation can be started; and

- E. terminate irradiation when a preselected time has elapsed if the dose-monitoring systems have not previously terminated irradiation.

Subp. 13. Selection of radiation type. Radiation therapy equipment capable of both x-ray and electron therapy must meet the requirements of this subpart.

- A. The radiation type must be selected and displayed at the treatment control panel before and during irradiation; and
- B. an interlock system must:
 - (1) emit only the radiation type that has been selected;
 - (2) prevent x-ray irradiation when electron applicators are fitted, except to obtain a verification image;
 - (3) prevent electron irradiation when accessories specific for x-ray therapy are fitted; and
 - (4) prevent 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. 14. Selection of energy. Equipment capable of generating radiation beams of different energies must meet the requirements of this subpart.

- A. Irradiation must not be possible until energy has been selected at the treatment control panel;
- B. The nominal energy value selected must be displayed at the treatment control panel until the nominal energy value is reset manually for the next irradiation.

After irradiation is terminated, 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 flattening filter or beam scattering foil for the selected energy is in its proper location.

Subp. 15. **Stationary and moving beam radiation therapy.** A radiation therapy system that is capable of both stationary beam radiation therapy and moving beam radiation therapy must meet the requirements of this subpart.

- A. Irradiation must not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been selected at the treatment control panel;
- B. The mode of operation must be displayed at the treatment control panel;
- C. An interlock system must ensure that the equipment can operate only in the mode that has been selected;
- D. An interlock system must 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 terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or 1 cm of linear motion differs by more than 20 percent from the selected value;

- (2) the dose monitor units delivered must differ by less than five percent from the dose monitor unit value selected where angle terminates the irradiation in moving beam radiation therapy;
 - (3) an interlock must prevent motion of more than five degrees or 1 cm beyond the selected limits during moving beam radiation therapy;
 - (4) an interlock must 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. The termination of radiation must comply with subpart 9 where the beam monitoring system terminates the irradiation in moving beam radiation therapy; and
- G. An interlock system must be provided to terminate irradiation if movement:
 - (1) occurs during stationary beam radiation therapy; or
 - (2) does not start or stop during moving beam radiation therapy unless the stop is preplanned.

Subp. 16. Facility design requirements. In addition to shielding that meets the requirements under parts 4733.0250 to 4733.0255, a registrant's facility must meet the requirements of this subpart.

A. The control panel must:

- (1) provide an indicator that shows whether electrical power is available at the control panel and if activation of the radiation is possible;
- (2) indicate when radiation is being produced; and
- (3) have an access control locking device that prevents unauthorized use of the therapy radiation machine.

B. If the shielding material in a protective barrier requires the presence of a beam interceptor to comply with part 4733.0315, then interlocks must prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers.

C. A radiation therapy room must have at least one emergency power cutoff switch on either side of the useful beam that:

- (1) terminates all equipment electrical power, including radiation and mechanical motion.
- (2) is in addition to the termination switch required under subpart 10; and
- (3) must include a manual reset so that the radiation therapy equipment cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

D. Safety interlocks must be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the radiation therapy equipment.

- E. A survey for residual activity must be conducted on all radiation therapy systems that generate photon and electron energies above ten MV before removing or working on radiation therapy system components that may have become activated due to photon-neutron production.

4733.0525 OPERATING AND EMERGENCY PROCEDURES FOR THERAPY SYSTEMS OPERATING AT 500 kV AND ABOVE.

Subpart 1. Operating procedures. A registrant's written operating procedures for therapy systems operating at 500 kV and above must be maintained at the treatment console and must include:

- A. operation and safety instructions to be used for the radiation therapy and therapy simulation systems;
- B. for each machine treating patients on any day of operation, a minimum of one operator and one additional qualified individual must be present at the machine or in the treatment room during patient set up and at the machine during treatment;
- C. procedures for verifying the patient's identity using two forms of identification;
- D. procedures for treatment plan approval and transfer;
- E. procedures for verification of treatment plan accuracy prior to treatment delivery;
- F. procedures for ensuring that the patient is monitored continuously and without obstruction during treatment;

- G. methods for controlling access to restricted areas;
- H. methods and occasions for locking and securing the radiation therapy system;
- I. use of individual monitoring equipment; and
- J. inspections and maintenance of the radiation therapy and therapy simulation systems.
- K. when a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used;
- L. procedures for restricting individuals 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 a protective apron and gloves of not less than 0.5 millimeters lead equivalency at 100 kV; and
- M. procedures that prohibit individuals other than the patient in the treatment room during exposures from radiation therapy systems operating above 150 kV.

Subp. 2. **Emergency procedures.** A registrant's written emergency procedures for therapy systems operating at 500 kV and above must be maintained at the treatment console and must include:

- A. actions necessary to address equipment failures or patient emergencies;
- B. names and telephone numbers for available individuals to be contacted if the system or console operates abnormally;

- C. notifications if the equipment fails or the patient has an emergency; and
- D. procedures for conducting analysis following any medical event.
- E. notifying the commissioner of a medical event;
- F. A registrant's written emergency procedures must include:
 - (5) actions necessary to address equipment failures or patient emergencies;
 - (6) names and telephone numbers for available individuals to be contacted if the system or console operates abnormally;
 - (7) notifications if the equipment fails or the patient has an emergency; and
 - (8) procedures for conducting analysis following any medical event.

4733.0530 FULL CALIBRATION MEASUREMENTS FOR RADIATION THERAPY SYSTEMS OPERATING AT 500 kV AND ABOVE.

Subpart 1. Full calibration procedures.

- A. A registrant must establish, document, and implement full system calibration procedures developed by a qualified medical physicist. The full calibration procedures must be:
 - 1) developed considering all modalities used by the registrant;
 - 2) developed according to published protocols accepted by nationally recognized organizations including AAPM (American Association of Physics in Medicine) or American Society for Radiation Oncology (ASTRO) or. Published protocols include AAPM Report No. 82, AAPM Medical Physics Practice Guideline 8a, AAPM Task Group Guidance TG-21, TG-25, TG-40, TG-51, TG-101, TG-135, TG-142, TG-148, or successor protocols; and

3) available for review by the commissioner upon inspection.

B. A qualified medical physicist may determine that a specific recommendation of the protocol reports under item B is not needed and must document the reasons for this determination.

Subp. 2. Full system calibration.

A. Before first medical or clinical use, a full system calibration must be performed by, or under the direct supervision of, a qualified medical physicist.

B. A full system calibration must be performed annually and:

(1) according to subpart 1;

(2) after installation or reinstallation;

(3) after any change that alters the calibration or other characteristic of the therapy beam; and

(4) whenever quality assurance 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.

C. A registrant may conduct individual elements of a full system calibration at different times if all parameters for all energies are completed at an interval not to exceed 365 days.

Subp. 3. Acceptance testing and commissioning with full calibration.

A. Acceptance testing and commissioning with full calibration of a radiation therapy system required under this part must be performed:

- (1) by, or under the direct supervision of, a qualified medical physicist before first medical or clinical use.
 - (2) following installation or reinstallation of a radiation therapy system; and
 - (3) according to manufacturer specifications and published protocols accepted by nationally recognized associations. Published protocols include AAPM Report No. 82, AAPM Medical Physics Practice Guideline 8a, AAPM Task Group Guidance TG-21, TG-25, TG-40, TG-51, TG-101, TG-135, TG-142, TG-148, or successor protocols.
- B. A qualified medical physicist may determine that a specific recommendation of the report or manufacturer's specifications under item A is not needed and must document the reasons for this determination.

Subp. 4. **Exceptions.** Notwithstanding the requirements of this subpart:

- A. full calibration of a radiation therapy system with multi-energy or multimode capabilities, or both, is required only for those modes or energies that are not within the acceptable range; and
- B. if the repair, replacement, or modification does not affect all modes or energies, then full calibrations must be performed on the affected energy or mode that is clinically used most frequently at the facility. The remaining energies or modes maybe validated with quality control check procedures against the criteria in this part.

Subp. 5. **Records.** A registrant must maintain records under this part according to part 4733.0215.

4733.0535 PERIODIC QUALITY ASSURANCE CHECKS FOR RADIATION THERAPY SYSTEMS OPERATING ABOVE 500 kV.

Subpart 1. **Quality assurance checks and procedures.** A registrant must establish, document, and implement quality assurance checks procedures that are developed by a qualified medical physicist. The procedures must be:

- A. available to for review by the commissioner upon inspection; and
- B. developed according to published protocols accepted by nationally recognized organizations such as American Association of Physics in Medicine (AAPM) and American Society for Radiation Oncology (ASTRO). Published protocols include AAPM Task Group Reports TG-40, TG-101TG-142, TG-148, or ASTRO report on “Quality and Safety Consideration in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy”, or successor protocols.
- C. A qualified medical physicist may determine that a specific recommendation of the reports under item B is not needed and must document the reasons for this determination.
- D. Periodic quality assurance checks must be performed according to procedures under this subpart.

Subp. 2. Tolerances.

- A. A registrant must review the results of each periodic quality assurance check according to this subpart.

- (1) if all quality control check parameters appear to be within their acceptable range, then the registrant or qualified medical physicist must review and sign the quality control check within seven working days;
- (2) if any parameter is not working within its acceptable tolerance, then the registrant and qualified medical physicist must be notified immediately. The radiation therapy system may not be made available for subsequent use until the qualified medical physicist has determined that all parameters are working within their acceptable tolerances;and
- (3) a registrant must promptly repair any system identified in this part that is not operating properly.

Subp. 3. **Qualified medical physicist review.** A registrant must have a qualified medical physicist review and sign or authorize the results of each radiation output quality assurance check within 30 days of test completion.

Subp. 4. **Safety check.** A individual trained to perform safety checks must perform safety checks at intervals not to exceed seven days. A safety check must verify the proper operation of:

- F. the electrical interlocks at each external beam radiation therapy room entrance;
- G. the "BEAM-ON", interrupt, and termination switches;
- H. beam condition indicator lights:
 - (4) on the access doors;
 - (5) on control console; and
 - (6) in the radiation therapy room;

- I. viewing and audio systems; and
- J. electrically-operated treatment room doors from inside and outside the treatment room, if applicable.

Subp. 5. **Emergency cutoff switches.** A registrant must check emergency power cutoff switches for proper operation:

- A. at installation; and
- B. when there is a modification or repair of the emergency switch circuit.

Subp. 6. **Records.** A registrant must maintain records under this part according to part 4733.0215.

4733.0800 ELECTRONIC BRACHYTHERAPY SYSTEMS.

Subpart 1. **Applicability.** A registrant using an electronic brachytherapy system must meet [list the rule parts] and is exempt from parts 4733.0500 to 4733.0515.

- A. A registrant may not use an electronic brachytherapy system for patient use if the electronic brachytherapy system does not meet the requirements of this part .
- B. A registrant may only use an electronic brachytherapy system for human use applications:
 - (1) that are approved by the United States Food and Drug Administration (FDA);
and
 - (2) to participate in a research study that is approved by the registrant's Institutional Review Board (IRB).

Subp. 2. Electronic brachytherapy systems; registrant responsibilities. A registrant must:

- A. monitor individuals according to part 4733.0320, if applicable;
- B. allow only qualified medical personnel trained in safe use of the electronic brachytherapy system, including the manufacturer's device-specific training to deliver the treatment;
- C. possess survey instruments capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1,000 mrem (10 mSv). The survey instruments must be:
 - (1) operable; and
 - (2) calibrated according to part 4733.0440;
- D. maintain a copy of the current operating and emergency procedures at the control console; and
- E. prevent simultaneous operation of more than one radiation therapy system in a treatment room, if applicable.

Subp. 3. Facility design requirements; treatment room. In addition to applicable shielding and facility design requirements under parts 4733.0250 to 4733.0275, the treatment room must meet the design requirements of this subpart.

- A. Access to the treatment room must be controlled by a door at each entrance;
- B. An electronic brachytherapy system must not be used for patient irradiation unless the operator can maintain continuous observation of the patient;

- C. For an electronic brachytherapy systems operating below 150 kV, radiation shielding for the staff in the treatment room must be available as:
 - (1) a portable shield; or
 - (2) localized shielding material around the treatment site;
- D. For an electronic brachytherapy systems operating at greater than 150kV:
 - (1) the control panel must be located outside the treatment room; and
 - (2) the electrical interlocks at all doors must:
 - a) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 - b) cause the x-ray tube to be shielded when an entrance door is opened;
and
 - c) 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. An electronic brachytherapy systems must meet the following requirements for electrical safety:
 - (1) the high voltage transformer must be isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment;
 - (2) the high voltage transformer must be isolated from the operator and the environment by a protective housing that requires special tools to open or with electrical interlocks to prevent operation while open;

- (3) the high voltage transformer must have safety labels warning personnel of potential electrical shock and heat-related injuries; and
 - (4) electrical safety equipment must comply with the most current revision of the following documents from the International Electrotechnical Commission (IEC):
 - 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. a control panel must:
 - (1) indicate whether electrical power is available at the control panel and if activating the electronic brachytherapy x-ray tube is possible;
 - (2) indicate when x-rays are being produced;
 - (3) indicate electronic brachytherapy x-ray tube potential and current;
 - (4) provide a means to terminate an exposure at any time; and
 - (5) include a locking device that prevents unauthorized use of the electronic brachytherapy system;
 - G. An irradiation timer must:
 - (1) terminate the irradiation after a preset time interval or integrated charge on a dosimeter-based monitor;

- (2) be located at the treatment control panel and indicate planned setting and the time elapsed or remaining time;
- (3) operate by 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 restarted, it must be necessary to reset the elapsed time indicator;
- (4) terminate irradiation when a preselected time has elapsed, if any dose-monitoring system has not previously terminated irradiation;
- (5) permit setting of exposure times of 0.1 second;
- (6) not operate if the exposure is 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.** A registrant must permit only trained individuals to operate the electronic brachytherapy system. The registrant must provide instruction for individuals who operate the electronic brachytherapy system initially as relevant to the individual's assigned duties in the operating procedures and must cover:

- A. electronic brachytherapy system-specific radiation safety requirements;
- B. electronic brachytherapy system operation;
- C. clinical uses that are approved by the FDA;
- D. emergency procedures that include an emergency drill; and
- E. a registrant's quality assurance program.

Subp. 5. **Qualified medical physicist support.** A registrant is responsible for using the services of a qualified medical physicist on an electronic brachytherapy system. A qualified medical physicist must:

- A. evaluate the output from the electronic brachytherapy x-ray tube;
- B. generate the necessary dosimetric information;
- C. supervise and review treatment calculations before initially treating any treatment site;
- D. establish the periodic and day-of-use quality assurance checks and review the data from those checks as required under subpart 10;
- E. consult and review with an authorized physician for treatment planning, as needed;
- F. perform calculation and assessments regarding patient treatments that might constitute a medical event; and
- G. be physically present when the treatment is initiated and be available during each patient treatment.

Subp. 6. **Operating procedures.**

- A. A registrant must establish and document operating procedures for electronic brachytherapy activities and keep the procedures at the control console.
- B. If the control console is integral to the electronic brachytherapy system, then a registrant must keep the required procedures where the operator is located during the system operation.

- C. The operating procedures for an electronic brachytherapy system must require that:
- (1) only individuals who are approved by the registrant, radiation safety officer, or qualified medical physicist may be present in the treatment room during treatment;
 - (2) electronic brachytherapy systems may not be made available for use unless the requirements of this chapter have been met;
 - (3) the electronic brachytherapy system is inoperable, either by hardware or password, when the electronic brachytherapy system is unattended by qualified staff or service personnel;
 - (4) an operator of an electronic brachytherapy system must prevent individuals from unshielded exposure by monitoring the position of all individuals who are:
 - a) in the treatment room during operation; and
 - b) entering the treatment room [during operation]; and
 - (5) the use of mechanical supporting or restraining devices when a patient must be held in position during treatment.

Subp. 7. **Emergency procedures.** A registrant must develop, implement, and document emergency procedures at the control console for responding to an abnormal situation.

Emergency procedures must include:

- A. instructions for responding to equipment failures;

- B. the names of the individuals responsible for implementing corrective actions;
- C. contact information for the administration, qualified medical physicist, and the radiation safety officer, all of whom must be contacted if the system or console operates abnormally;
- D. notifying the radiation safety officer and the authorized physician if a patient's radiation exposure results in a medical emergency, injury, or death; and
- E. notifying the manufacturer and the commissioner of the medical emergency, injury, or death under item D.

Subp. 8. Safety precaution requirements.

- A. A qualified medical physicist and an authorized physician must be physically present during the initiation of all patient treatments when all patient treatments occur.
- B. An operator who is trained in the operation and emergency response for the electronic brachytherapy system must be:
 - (1) physically present during the initiation of all patient treatments; and
 - (2) available during patient treatments.
- C. All personnel in the treatment room must remain behind shielding during treatment.
- D. A qualified medical physicist must approve any change from the shielding requirement under item C and must designate alternative radiation safety protocols that provide equivalent protection for all personnel in the treatment room.

E. When shielding is required:

- (1) An operator must use a calibrated survey meter to verify proper placement of the shielding before the initiation of treatment; or
- (2) a qualified medical physicist must designate shielding locations that meet the requirements under parts 4733.0300 to 4733.0315 for any individual in the treatment room, excluding the patient.

4733.0805 FULL CALIBRATION MEASUREMENTS FOR ELECTRONIC BRACHYTHERPY SYSTEMS

Subp. 1. **Full calibration procedures.** A registrant must establish, document, and implement full calibration procedures that are developed by a qualified medical physicist. The procedures must be:

- A. available for review by the commissioner upon inspection; and
- B. developed according to published protocols from a nationally recognized professional body with expertise in electronic brachytherapy. In the absence of a calibration protocol, a registrant is responsible for following the manufacturer's calibration procedures.
- C. A qualified medical physicist may determine that a specific recommendation of the protocol reports under item B is not needed and must document the reasons for this determination.

Subp. 2. **Full system calibration.** Before first medical or clinical use, a full system calibration must be performed by, or under the direct supervision of, a qualified medical physicist. A full system calibration must be performed:

- A. annually;
- B. according to the calibration procedures under subpart 1;
- C. following initial installation or reinstallation;
- D. following any change that would alter the calibration or other characteristic of the therapy beam; and
- E. 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.
- F. A registrant may conduct individual elements of a full calibration at different times if all parameters for all energies are completed at intervals not to exceed 365 days.

Subp. 3. Exceptions. Notwithstanding the requirements of this subpart:

- A. A full calibration of an electronic brachytherapy system 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, then a qualified medical physicist must perform a full calibration 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 under part 4733.0510.

Subp. 4. Records. A registrant must maintain records under this part according to part 4733.0215.

4733.0810 PERIODIC QUALITY ASSURANCE SPOT CHECKS ELECTRONIC BRACHYTHERAPY SYSTEMS

Subpart 1. **Periodic quality assurance checks.** A registrant must establish and document periodic quality assurance checks procedures that are developed by a qualified medical physicist for an electronic brachytherapy system. Periodic quality assurance checks procedures must be:

- A. available for review by the commissioner upon inspection; and
- B. developed according to published protocols from a nationally recognized professional body with expertise in electronic brachytherapy. In the absence of a calibration protocol, a registrant is responsible for following the manufacturer's calibration procedures.
- C. A qualified medical physicist may determine that a specific recommendation of the protocol reports under item B is not needed and must document the reasons for this determination.

Subp. 2. **Tolerances.** A qualified medical physicist must investigate and correct the cause of a parameter exceeding a tolerance according to the written procedures under subpart 1 before the electronic brachytherapy system may be used for patient irradiation.

Subp. 3. **Qualified medical physicist review.** A qualified medical physicist review and sign or authorize the results of each radiation output periodic quality assurance check within one month of test completion.

Subp. 4. **Safety check.** An operator trained to perform safety checks must perform safety checks at intervals not to exceed seven days. A safety check must verify that:

- A. the radiation exposure indicator lights on the electronic brachytherapy system and on the control console are operating as designed;
- B. all radiation monitors are operating as designed;
- C. the condition and integrity of all cables, catheters, or parts of the device that carry high voltages;
- D. the condition and integrity of connecting guide tubes, transfer tubes, transfer-tube applicator interfaces, and treatment spacers;
- E. the viewing system and the intercom system in each electronic brachytherapy facility are operating as designed, if applicable;
- F. the "BEAM-ON", interrupt, and termination switches, are operating as designed, if applicable;
- G. the electrical interlocks at each external beam radiation therapy room entrance are operating as designed, if applicable, and;
- H. the electrically operated treatment room doors from inside and outside the treatment room are operating as designed, if applicable.

Subp. 5. **Records.** A registrant must maintain records under this part according to part 4733.0215.

4733.0815 MOBILE ELECTRONIC BRACHYTHERAPY SERVICE.

A registrant providing mobile electronic brachytherapy service must:

- A. check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive; and

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

4733.0900 THERAPY SIMULATION SYSTEM REQUIREMENTS.

Subpart 1. General.

- A. A registrant's therapy simulation system must meet the same requirements for equipment and mechanical parameters and for accuracy as a radiation therapy system.
- B. The simulator system motions must meet the same requirements for accuracy as a radiation therapy system.
- C. All elements in a simulator system that are required for image quality must be tested, reviewed, and evaluated.

Subp. 2. Therapy simulation system equipment performance evaluation; radiographic and CT simulation systems.

- A. A registrant must establish, document, and implement quality assurance procedures for a radiographic and computed tomography therapy simulation system that are developed by a qualified medical physicist or a service provider who meet the requirements of chapter 4732.
- B. The quality assurance procedures must:
 - (1) include acceptance testing;
 - (2) include periodic verification of system performance; and

- (3) be available for review by the commissioner upon inspection; and
- (4) be developed according to published protocols accepted nationally recognized organizations such as AAPM. Examples of published protocols include AAPM Report No. 46, AAPM task group report TG-40, TG-66.

C. A qualified medical physicist may determine that a specific recommendation of the reports under item A is not needed and must document the reasons for this determination.

D. Quality assurance checks must be performed:

- (1) by a qualified medical physicist; or
- (2) by a service provider who meets the qualifications under chapter 4732; and
- (3) at intervals not to exceed those established under item A.

Subp. 4. **Operator of a therapy simulation system.** A therapy simulation system must be operated by an individual who is:

- A. registered in radiologic technology or radiation therapy with the American Registry of Radiologic Technologists, designated ARRT (R) or ARRT (T);
- B. trained by the manufacturer or equivalent;
- C. trained in positioning and anatomy for applicable procedures; and
- D. trained on the operating procedures for therapy simulation equipment.

Subp. 5. **Records.** A registrant must maintain records under this part according to part 4733.0215.

4733.1100 OPERATORS OF DUAL IMAGING DEVICES.

- A. An operator of therapy simulation equipment may not operate a therapy simulation imaging device except when:
- (1) the operation is an integral part of a radiation therapy procedure for treatment; and
- (2) authorized by an authorized physician.
- B. An operator of therapy simulation equipment must meet the requirements under Minnesota Statutes, section 144.121, subdivision 5, before operating an imaging device for diagnostic purposes.

For purposes of this part, an integral part of the radiation therapy procedure means [...]

REPEALER.

Minnesota Rules, parts **4732.0110** [DEFINITIONS – See specific definitions below],

4732.0900 [GENERAL REQUIREMENTS FOR FACILITIES USING ACCELERATORS], **4732.0925**

[GENERAL REQUIREMENTS FOR THERAPEUTIC EQUIPMENT], **4732.0930** [THERAPEUTIC

RADIATION MACHINES OF LESS THAN 500 KV], **4732.0940** [THERAPEUTIC RADIATION

MACHINES - PHOTON THERAPY SYSTEMS (500 KV AND ABOVE) AND ELECTRON THERAPY

SYSTEMS (500 KEV AND ABOVE], **4732.1120** [THERAPEUTIC EQUIPMENT PERFORMANCE TESTS

AND LIMITS FOR MEASUREMENT EQUIPMENT], and **4732.1130** [EQUIPMENT PERFORMANCE

TESTS FOR EXTERNAL BEAM TELETHERAPY AND SIMULATION SYSTEMS], are repealed.

Definitions to be repealed (from part 4732.0110):

Subp. 3. Absorbed dose rate.

Subp. 13. Attenuation block.

Subp. 20. Beam-scattering filter or foil.

Subp. 21. Bent beam linear accelerator.

Subp. 56. Dose-monitoring system.

Subp. 57. Dose-monitor unit.

Subp. 63. External beam radiation therapy.

Subp. 66. Field flattening filter.

Subp. 71. Gantry.

Subp. 100. Leakage technique factors.

Subp. 111. Megavolt (MV).

Subp. 112. Moving beam radiation therapy.

Subp. 114. Nominal treatment distance.

Subp. 115. Nonstochastic effects.

Subp. 131. Prescribed dose.

Subp. 132. Primary beam.

Subp. 133. Primary dose monitoring system.

Subp. 150. Radiation therapy simulation system.

Subp. 168. Secondary-dose monitoring system.

Subp. 185. Stationary beam therapy.

Subp. 194. Target.

Subp. 198. Termination of irradiation.

Subp. 199. Therapeutic radiation machine.

Subp. 200. Therapeutic radiological physicist.

Subp. 201. Therapeutic-type protective tube housing.

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06/07/2018

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