DEPARTMENT OF HEALTH

# Minnesota Rules, Chapter 4733

DRAFT RULES GOVERNING RADIATION THERAPY, 1.0

## PURPOSE, SCOPE, AND DEFINITIONS

## 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 and simulation equipment for human and nonhuman use without limiting or interfering with its therapeutic uses. This chapter does not include radiation therapy equipment that uses radioactive material in chapter 4731 or the use of diagnostic or industrial x-ray equipment found in chapter 4732.

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

Subp. 7. **Beam axis.** "Beam axis" means the axis of rotation of the beam-limiting device for therapy systems.

Subp. 8. **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. 9. **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. 10. **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. 11. **Commissioner.** "Commissioner" means the commissioner of health or the commissioner's designee.

Subp. 12. **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. 13. **Dose monitor unit.** "Dose monitor unit" means a unit response from the beam-monitoring system used for calculating the absorbed radiation dose.

Subp. 14. **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. 15. **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. 16. **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. 17. **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. 18. **Filter.** "Filter" means material placed in the useful beam to change beam quality in radiation therapy systems.

Subp. 19. **Gantry.** "Gantry" means that part of the radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

Subp. 20. **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. 21. **Intensity-modulated radiation therapy or IMRT.** "Intensity-modulated radiation therapy" or "IMRT" means a process that allows a precise conformal radiation dose to be distributed to the target area by controlling the radiation-beam intensity within a given area.

Subp. 22. **Interlock.** "Interlock" means a device preventing the start or continued operation of equipment.

Subp. 23. **Irradiation.** "Irradiation" means the exposure of a living being or matter to ionizing radiation.

Subp. 24. **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. 25. **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.

Subp. 26. **Leakage radiation.** "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly other than the useful beam.

Subp. 27. **Light field.** "Light field" means the area illuminated by light that simulates the radiation field.

Subp. 28. **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 prescribed dose defined in the written order by 20 percent or more;

B. the calculated weekly dose delivered that differs from the weekly prescribed dose by 30% or more;

C. dose to the wrong individual or to the wrong treatment site;

D. treatment with the wrong treatment modality or energy; or

E. 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. 29. **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. 30. **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. 31. **Nominal treatment distance.** "Nominal treatment distance" means:

A. for electron irradiation, the distance from the 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. 32. **Patient.** "Patient" means an individual or veterinary practice animal subjected to machine-produced beam radiation for therapy.

Subp. 33. **Prescribed dose.** "Prescribed dose" means the total radiation dose and radiation dose per fraction as documented in the written order.

Subp. 34. **Primary beam.** "Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation-producing equipment housing.

Subp. 35. **Protective barrier.** Protective barrier" means the material, excluding filters, placed in the useful beam to reduce radiation levels for protection purposes.

Subp. 36. **Qualified medical physicist.** "Qualified medical physicist" means an individual qualified to practice independently in the subfields for therapeutic radiological physics according to part 4733.0410, subpart 1.

Subp. 37. **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. 38. **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. 39. **Radiation head.** "Radiation head" means the structure from which the useful beam emerges.

Subp. 40. **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. 41. **Registrant.** "Registrant" means a person or facility registered with the commissioner or legally obligated to register with the commissioner according to this chapter.

Subp. 42. **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. 43. **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. 44. **Stationary beam therapy.** "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Subp. 45. **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. 46. **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. 47. **Stray radiation.** "Stray radiation" means the sum of leakage and scattered radiation including x-ray, electron, and neutron.

Subp. 48. **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. 49. **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 and/or electron virtual source to the surface of the irradiated object or patient.

Subp. 50. **Termination of irradiation.** "Termination of irradiation" means stopping of irradiation until the operating conditions are reset at the control panel.

Subp. 51. **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. 52. **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. 53. **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.

Supb. 54. **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. 55. **Virtual source.** "Virtual source" means a point from which radiation appears to originate.

Subp. 56. **Wedge filter.** "Wedge filter" means an added filter effecting continuous change in transmission on all or part of the useful beam.

Subp. 57. **Written order.** "Written order" means an authorized physician's written order for the administration of radiation according to part 4733.0435.

# REGISTRATION

## 4733.0107 NOTIFICATION AND REGISTRATION REQUIREMENTS.

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 5.

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 [90] days before initial construction or installation of a radiation therapy system

B. An application must be:

(1) submitted on a form prescribed by the commissioner;

(2) accompanied with the fee required under Minnesota Statutes, section 144.121; and

(3) signed by the applicant or the applicant's designee.

Subp. 3. **Additional information; when required.** An applicant must submit additional information when requested by the commissioner to determine if the commissioner shall approve or deny the application or the registration will be modified or revoked.

Subp. 4. **Registration not transferrable.** A registration issued under this chapter is not transferrable.

Subp. 5. **Exception.** A registrant possessing a radiation therapy system before the effective date of this chapter may continue to operate that radiation therapy system if the registrant submits an application to the commissioner no later than 120 days after the effective date of this chapter.

## 4733.0108 ISSUANCE OF REGISTRATION.

Subpart 1**. Registration.** The commissioner shall issue a registration under part 4733.0107 if the commissioner determines that the applicant has complied with the requirements of this chapter. A registration:

A. authorizes the applicant to acquire, construct, or operate a radiation therapy system; and

B. contains the conditions and limitations to the registration that the commissioner deems necessary to protect public health and safety .

Subp. 2. **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.

## 4733.0109 EXPIRATION AND TERMINATION OF A REGISTRATION.

Subpart 1. **Registration expiration.** Except under part 4733.0110 and subject to subpart 4, item D, sub-item (2), a registration expires seven years from the date of issuance.

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 renew or terminate registration.** At least 30 days before a registration expires, a registrant must:

A. submit a registration renewal application under part 4733.0110; or

B. notify the commissioner in writing of the registrant's intent to terminate a registration.

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

A. discontinue the use of the radiation therapy system by the expiration date;

B. dispose of incidental radioactive material generated by the operation of the accelerator under part 4733.####; and

C. submit information describing the disposition of materials to the commissioner required under part 4733.####;

D. 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

E. determine residual radioactive contamination level according to subpart 6.

F. 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 if:

(1) the registrant submits certified documentation 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 the 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.

## 4733.0110 REGISTRATION RENEWAL.

Subpart 1. **Registration renewal required.** A registrant must apply for registration renewal according to part 4733.0107.

Subp. 2. **Intent to renew registration.** When a registrant submits an intent to renew under part 4733.0109, subpart 3 to the commissioner at least 30 days before registration expires, then the registrant's current registration does not expire until the commissioner notifies the registrant in writing that the registration is renewed.

## 4733.0111 AMENDMENTS TO REGISTRATION.

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

# 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 may be obtained 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 simulation equipment; and

B. replace notices that are defaced or altered.

# REPORTS AND NOTIFICATIONS

## 4733.0150 NON-MEDICAL EVENT NOTIFICATION.

A registrant must notify the commissioner within 24 hours after the discovery of any of the following events involving a registered radiation therapy system:

A. an event where equipment is disabled or fails to function as designed when:

(1) the equipment is required by rule or registration condition to prevent exposure to the public that exceeds the dose limit in this chapter;

(2) the equipment is required to be available and operable; and

(3) no redundant equipment is available and operable to perform the required safety function;

B. an event where a member of the public receives a dose that exceeds the dose limit in this chapter; or

C. an event that damages the integrity of the registered device, console, or shielding of a registered facility.

## 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 of and dose report must include the:

(1) worker's dose;

(2) date of discovery;

(3) name of the registrant;

(4) name of the worker who received a dose that exceeds the limits for occupational exposure; and

(5) 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. **Report upon termination.** At the request of a worker who is terminating employment with the registrant who was involved in radiation during the current calendar quarter or the current year, a registrant must provide at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

## 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 medical event report must not contain the affected individual's name or other information that may identify the affected individual. The medical event report must include:

A. the name of the registrant;

B. the name of the authorized physician;

C. the date of the medical event;

D. a brief description of the medical event, including when [why] and how it occurred;

E. the [medical] effect, if known, on the affected individual;

F. the titles of all individuals involved in the medical event;

G. actions taken to prevent recurrence; and

H. certification that the registrant notified, or attempted to notify:

(1) the affected individual; or

(2) the affected individual's responsible relative or guardian; or

(3) a written explanation if the registrant did not notify.

For purposes of this part, an affected individual means an individual who is the subject of a medical event.

Subp. 4. **Notice to affected individual and authorized physician by a registrant.**

A. Within 24 hours of discovering a medical event , a registrant must notify:

(1) the authorized 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 the authorized physician:

(1) informs the affected individual; or

(2) does not inform the affected individual, 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, 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 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 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. 5. **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 this chapter and:

A. Code of Federal Regulations, title 10, part 21; and

B. the manufacturer's specifications.

Subp. 2. **Radiation therapy systems; human use; veterinary use.**

A. To operate a radiation therapy system for human use, an operator must:

(1) be ARRT Registered Radiation Therapy Technologists; or

(2) submit that they have satisfactorily completed 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.

C. If an operator has not performed a radiation therapy procedure or a simulation operation, or has not been subject to a competency audit under subpart 4 in the previous 6 months, then the radiation safety officer or designee must perform an competency audit according subpart 4 during the operator's next radiation therapy or simulation procedure.

D. For human use for each treatment an operator and one additional qualified individual must be present at the console. A qualified individual may be a radiation therapist, an authorized physician, or a qualified medical physicist;

E. Veterinary radiation therapy procedures must be performed by:

(1) a veterinarian who is licensed by the Minnesota Board of Veterinary Medicine; or

(2) an individual under the supervision of a licensed veterinarian.

D. An individual operating radiation therapy for veterinary use must:

(1) be 18 years of age or older;

(2) meet qualification criteria specified by a supervising radiation therapy veterinarian; and,

(3) complete initial training under subpart 4.

Subp. 3. **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. 4. **Training for radiation therapy system operators.**

A. A registrant must provide training to an individual before operating radiation therapy equipment. Initial training must be facility-specific and include the following components:

(1) therapy equipment;

(2) simulation 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) therapy simulation system operation, if applicable.

B. A registrant must provide an operator of radiation therapy equipment with annual refresher training. Annual refresher training must include:

(1) health risks associated with exposure to radiation;

(2) precautions or procedures to minimize exposure;

(3) purpose and use of personal protective devices 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 enrolled in and participating in an accredited radiation therapy technology program or an accredited radiation oncology program at a school of medicine, or 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 equipment or simulation equipment after modifications to:

(1) the radiation therapy system equipment;

(2) the simulation system equipment;

(3) the registrant’s quality management program; or

(4) the radiation output from new 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 simulation systems;

B. operator training documentation required under parts 4733.0210, subpart 4, 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 calibration, quality control tests, and spot checks as required by this chapter;

I. quality management program procedures required 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) date of calibration or intercomparison; and

(2) manufacturer, model number, and serial number of the instruments calibrated, intercompared, or compared;

(3) determined correction factors; and

(4) signature or electronic signature of the individual who performed the calibration, intercomparison, or comparison;

L. 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 dose limits under parts 4733.0300 to 4733.0320;

(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. equipment performance measurement records for acceptance and commissioning tests, full calibration, and spot checks, including :

(1) the measurement date;

(2) the manufacturer, model number, and serial number for equipment being 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. daily, weekly, and monthly equipment performance tests approved by the commissioner under part 4733.0108;

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

(1) IRB approval date;

(2) IRB expiration dates; and

(3) approved research study application.

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

A. maintain the records under this part so that they remain legible throughout the applicable retention period;

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) as long as the registration is active; and

(2) for three years after the registration is inactive.

# 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 simulation system of higher energy into a room not previously approved for that energy before installation of the radiation therapy system or 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 in therapy equipment installations.

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 simulation equipment must be completed by:

(1) a qualified service provider under chapter 4732;

(2) a qualified medical physicist;

(3) diagnostic radiological physicist;

(4) health physicist certified in x-ray installation; or

(5) a health physicist certified in radiation therapy installation.

D. A registrant must maintain records required under this part according to part 4733.0215.

Subp. 2. **Barriers.** Except for electronic brachytherapy below 150 kV, a facility that has radiation therapy system or a simulation system must be designed with primary and secondary barriers that comply with the dose limits under parts 4733.0300 to 4733.0320. 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.

For a 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 simulation area impact/alter the [energy] output , a registrant must:

A. perform a radiation protection 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 4733.0250 to 4733.0275; and

C. document all modifications; and

D. Document the results of all radiation protection surveys according to part 4733.0265.

# 4733.0255 FACILITY DESIGN REQUIREMENTS.

Subpart 1. **Control console.** Except for electronic brachytherapy below 150 kV, a radiation therapy console must be located outside the high-radiation area. Instrumentation, readouts, and controls on the radiation therapy system control console must be clearly identified and easily discernible.

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

This subpart does not apply to a 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 treatment room is blocked before irradiation is initiated or continued.

B. If the useful beam is interrupted by a door opening or 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 it to operate independently of the therapy system; and

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.

This subpart does not apply to electronic brachytherapy below that operates below 150 kV or to a simulation room.

Subp. 5. **Patient viewing system.**

A. A registrant must provide a closed-circuit television, or comparable 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 television, or comparable system, in a 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.

This subpart does not apply to veterinary use of a radiation therapy system or a simulation system.

## 4733.0265 RADIATION SURVEYS.

Subpart 1. **Radiation survey.** 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 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. **Performance method.** 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. A radiation safety officer, or the RSO's designee, must perform the radiation survey with:

A. an instrument that is calibrated according to part 4733.0440;

B. the equipment in a "BEAM-ON" condition;

C. the largest available field; and

D. 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 levels above the dose limits under parts 4733.0300 to 4733.0320, 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. 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 4733.0320;

B. the radiation safety officer documents that the corrective actions are complete; and

C. the registrant complies with the dose requirements under parts 4733.0300 to 4733.0320.

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

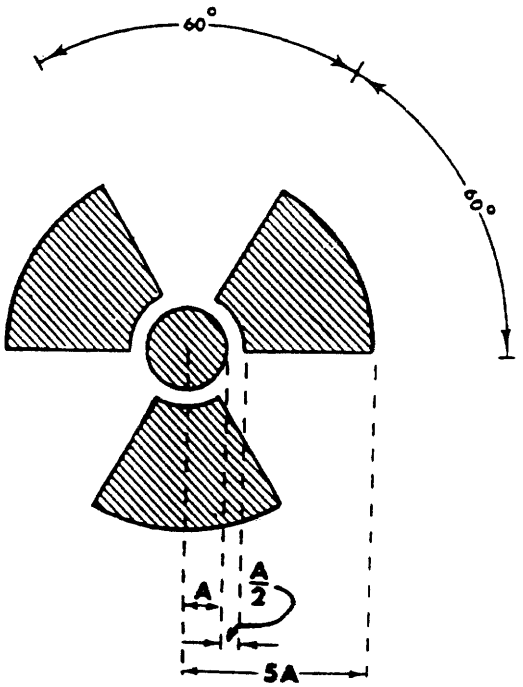
# 4733.0270 CAUTION SIGNS.

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 substitute continuous direct surveillance or electronic surveillance 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 an individual received during the current year for each individual **in the registrant's facility** who is likely to receive an occupational dose in a year requiring monitoring under part 4733.0320.

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

A. A registrant may accept a written signed statement from the individual or from the individual's most recent employer for work involving radiation exposure that discloses the nature and amount of any occupational dose that the individual received as a record of the occupational dose that the individualreceived during the current year; or

B. A registrant may accept a form (or vletter), 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 theindividual 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.

D. 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.

C. 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 as follows:

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

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

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

the deep-dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

D. 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 (5 mSv).

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 levels.** A registrant must monitor exposures 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 is responsible for the registrant's personnel to wear the monitoring devices:

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

B. minors likely to receive, in one year, a deep dose equivalent in excess of 0.1 rem (1.0 mSv);

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

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

Subp. 3. **Required instruction.** A registrant is responsible for providing annual training under part 4733.0210, subpart 4 to all individuals who are likely to receive an occupational dose in excess of 0.1 rem (1.0 mSv) in a 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 appoint 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 either an authorized physician, qualified medical physicist, or an individual who:

A. has completed training under subpart 4; and

B. has obtained written attestation, signed by a qualified medical physicist, that the individual has satisfactorily completed the requirements in item A and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for radiation therapy.

Subp. 2. **Agreement.** A registrant must appoint a radiation safety officer who is responsible for implementing the radiation protection program.

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, recommend, or provide 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 personnel required to have 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;

(2) radiation protection program audits under part 4733.0420;

(3) calibrations and equipment performance evaluations;

(4) review of quality control tests and spot checks; and

(5) initial and annual operator competency audits.

## 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 calibrations and equipment commissionings;

B. radiation surveys under part 4733.0265;

C. supervising and reviewing personnel dosimetry;

D. acquiring beam data and transferring beam data for dosimetry;

E. managing the quality assurance, including establishing written procedures and reviewing required quality control and safety checks;

F. consulting for treatment planning, as needed; and

G. performing calculations and assessments regarding medical events.

Subp. 3. **Availability.** If a qualified medical physicist is not immediately available, then a registrant must have emergency procedures in place to address equipment problems, failures, or emergencies.

Subp. 4. **Treatment plan verification.** A qualified medical physicist must develop a procedure for verifying the treatment plan before it is transferred to the treatment equipment system and before it is implemented. A qualified medical physicist 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. **Alternative 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 plan transfer.

## 4733.0420 RADIATION PROTECTION PROGRAM AUDITS.

Subpart 1. **Program review.** A registrant must review the radiation protection program at intervals not to exceed 12 months. For purposes of this subpart, a radiation protection program means written or documented policies or procedures designed to minimize unnecessary radiation exposure to occupational workers, patients and members of the public and includes […].

A. all aspects of the quality management program under part 4733.0425;

B. medical events and incidents that could 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.

A registrant must maintain radiation protection program audits according to part 4733.0215.

Subp. 2. **Corrective actions.** A registrant must correct any noncompliance issues found during the audit within 30 days.

## 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 simulation written order under part 4733.0435; and

B. notification of a medical event under part 4733.0180;

Subp. 3. **Radiation therapy and simulation written order procedures.**

A. A registrant must develop procedures for a radiation therapy written order and a simulation written order so that each therapeutic] 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 consoles.

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 written order, a registrant must:

A. identify and evaluated **what?** [does this reach level of medical event?]; and

B. take appropriate action is taken.

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).

## 4733.0435 ORDERING THERAPY OR SIMULATION PROCEDURES.

Subpart 1. **Therapy procedure written orders.**

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 signature, 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. **Therapy simulator system procedure orders.**

A. An order for a simulation examination must be made only by an authorized physician.

B. A written order for a simulation procedure must be available at the time of the examination.

C. An order for a simulation procedure must include the:

(1) date;

(2) patient's identity;

(3) identity of the authorized physician who is ordering the examination, by a signature, an electronic signature, or equivalent;

(4) intended modality;

(5) 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. at intervals not to exceed 12 month;

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 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 RADIATION THERAPY SYSTEMS OF LESS THAN 500 kV.

Subpart 1. **Operating procedures.** A registrant's written operating procedures must maintained at the treatment console and must include:

A. operation and safety instructions to be used for the radiation therapy and simulation systems;

B. specify that an operator and one additional qualified individual must 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 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 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 manufacturer [of a medical event];

F. notifying the commissioner of a medical event;

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

A. following initial installation or reinstallation;

B. following any change that would alter the calibration or other characteristic of the therapy beam;

C. 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

D. at intervals not to exceed 12 months. The registrant may conduct individual elements of a full calibration at different times provided all parameters for all energies are completed at intervals not to exceed 12 months.

Subp. 2. **Full calibration procedures.** A registrant is responsible for the requirements of this subpart.

A. A qualified medical physicist must establish, document, and implement procedures for a full calibration.

B. A full calibration must be performed at intervals within the tolerances not to exceed those specified in "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10keV to 50 MeV, NCRP Report No. 69;

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.

Subp. 3. **Exception.** 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, 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, subpart 1, item C.

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

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

Subpart 1. **Periodic quality assurance checks.** A registrant is responsible for the periodic quality assurance checks on a radiation therapy system capable of operating at 150 kV or greater. A periodic quality spot check must:

A. be performed according to written procedures established by a qualified medical physicist;

B. be performed at intervals not to exceed one month; and

C. follow written procedures that specify:

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

(2) that the quality control check is performed during full calibrations.

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, item A. 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 the results of each radiation output quality control check within one month of test completion.

Subp. 4. **Safety check.** A registrant is responsible for having a safety check performed at intervals not to exceed one month. A safety check must ensure proper operation of:

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

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

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

D. viewing and audio systems; and

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

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) ~~to~~ 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 ~~or systems~~ 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 ad 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 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 primary 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 THERAPEUTIC SYSTEMS OPERATING ABOVE 500 kV.

The operating and emergency procedures for therapeutic systems operating above 500 kV must be maintained at the treatment console and must include:

A. prohibit all individuals, other than the patient, from being in the treatment room during treatment or during any irradiation for testing or calibration purposes;

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

C. require that mechanical supporting devices or restraining devices be used when a patient is immobilized during treatment.

Subp. 2. **Emergency procedures.** A registrant's written emergency procedures 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 manufacturer of a medical event; and

F. notifying the commissioner of a medical event.

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

Subpart 1. **Full system calibration .** Full system calibration must be performed by, or under the direct supervision of, a qualified medical physicist. Before use, full system calibration must be performed:

A. following installation or reinstallation;

B. following any change that would alter the calibration or other characteristic of the therapy beam;

C. 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

D. at intervals not to exceed 12 months. 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 12 months.

Subp. 2. **Acceptance testing, commissioning, and full calibration.** Acceptance testing, commissioning, and full calibration of a radiation therapy system required under this part must be performed by, or under the direct supervision of, a qualified medical physicist.

A. Before use following installation or reinstallation of a radiation therapy system, **acceptance testing and commissioning** must be performed according to:

(1) "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45; and

(2) the manufacturer's specifications;

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.

C. A registrant must establish, document, and implement full calibration procedures that are developed by a qualified medical physicist. Full calibration procedures must be performed according to:

(1) measurement of all applicable elements required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy; AAPM report No. 46," prepared by Committee Task Group 40; and;

(2) Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45.

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

E. For a radiation therapy system that include asymmetric jaws, multileaf collimation, or dynamic/virtual wedges, a qualified medical physicist must establish, document, and implement a calibration protocol. The calibration protocol must include recommendations listed in "Quality Assurance of Medical Accelerators," prepared by AAPM Task Group 142

F. unless a qualified medical physicist determines and documents that a specific recommendation of this report is not warranted.

G. For a linear accelerator-based robotic stereotactic radiosurgery system, a qualified medical physicist must establish, document, and implement a calibration protocol. The calibration protocol must include current recommendations listed in "Quality Assurance for robotic radiosurgery" prepared by AAPM Task Group 135

H. unless a qualified medical physicist determines and documents that a specific recommendation of this report is not warranted.

I. For a tomotherapy system, a qualified medical physicist must establish, document, and implement a calibration protocol. The calibration protocol must include current recommendations listed in "Quality Assurance of helical tomotherapy," prepared by AAPM Task Group 148

J. unless a qualified medical physicist determines and documents that a specific recommendation of this report is notwarranted.

Subp. 3. **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. 3. **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.** A registrant is responsible for the requirements of this part.

A. A qualified medical physicist must establish, document, and implement procedures for quality assurance checks.

B. Quality assurance checks must be performed at intervals and within the tolerances not to exceed those specified in:

(1) "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy; AAPM report No. 46," prepared by Committee Task Group 40; or

(2) "Task Group 142 report: Quality Assurance of medical accelerators".

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. A registrant using IMRT must:

(1) establish, document, and implement spot check procedures developed by a qualified medical physicist according to "Guidance document on delivery, treatment, planning, and clinical implementation for IMRT: Report of IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No.

82," unless a qualified medical physicist determines and documents that a specific recommendation of this report is not warranted;

(2) include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans; and

(3) follow the manufacturer's contractual specifications.

E. A registrants using linear accelerator-based robotic stereotactic radiosurgery must establish, document, and implement spot check procedures developed by a qualified medical physicist according to "Report of AAPM TG 135: Quality assurance for robotic radiosurgery" unless a qualified medical physicist determines and documents that a specific recommendation of this report is not warranted. Spot check procedures must be developed according to the manufacturer's contractual specifications.

F. A registrant using helical tomotherapy must establish, document, and implement spot check procedures developed by a qualified medical physicist according to "Quality assurance for tomotherapy: Report of the AAPM Task Group 148" unless a qualified medical physicist determines and documents that a specific recommendation of this report is not warranted. Spot check procedures must be developed according to the manufacturer's contractual specifications.

Subp. 2. **Tolerances.**

A. A registrant must review the results of each periodic radiation output check according to this subpart.

(1) if any parameter is not working within its acceptable tolerance, then the registrant and qualified medical physicist must be immediately notified. 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;

(2) 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;and

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

A. A registrant must promptly repair any system identified in this part that is not operating properly.

Subp. 4. **Safety checks.** A registrant is responsible for the requirements of this subpart. A [QMP, operator?] must perform safety checks at intervals not to exceed one week to verify proper operation of:

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

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

C. beam condition indicator lights on:

(1) on the access doors;

(2) on the 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. 4. **Emergency cutoff switches.**. A [QMP/registrant responsibility]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.

## 4733.0600 STEREOTACTIC RADIOSURGERY AND STEREOTACTIC BODY RADIOTHERAPY.

A registrant performing stereotactic radiosurgery or stereotactic body radiotherapy must follow:

A. the safety and quality assurance guidelines in AAPM Task Group 101 Report; and

B. the American Society for Radiation Oncology (ASTRO) report on "Quality and Safety Consideration in Stereotactic Radiosurgery and Stereotactic Body RadiationTherapy."

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

## 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 DrugAdministration (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 µSv) 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 150 kV:

(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] or [electronic brachytherapy system] 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 [of the selected value ?], 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 electronic brachytherapy system operator 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 ~~written~~ 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; and

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 [in the treatment room] when all patient treatments occur.

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

C. All personnel in the treatment room must remain behind shielding during treatment. A qualified medical physicist must approve any change from this requirement and must designate alternative radiation safety protocols that provide equivalent protection.

D. When shielding is required:

(1) a registrant must use a 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.

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

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

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

(1) after any repair affecting the x-ray beam generation; or

(2) when indicated by the electronic brachytherapy x-ray tube spotchecks.

C. Calibrating an electronic brachytherapy x-ray tube output must include, as applicable, determining:

(1) the output within two percent of the expected value, if applicable, or determining the output if there is no expected value;

(2) timer accuracy and linearity over the typical range of use;

(3) backup exposure control devices are operating properly;

(4) the relative dose distribution about the x-ray tube to within five percent of that expected; and

(5) the x-ray tube positioning accuracy to within one millimeter within the applicator.

D. Calibrating the x-ray tube output required in items A to C must meet current published recommendations from a nationally recognized professional association with expertise in electronic brachytherapy. In the absence of a calibration protocol, a registrant is responsible for following the manufacturer's calibration procedures.

E. A registrant must maintain a record of each calibration in an auditable form for three years. The record must include the:

(1) calibration date;

(2) unique identifier for the corresponding electronic brachytherapy source;

(3) manufacturer, model number, and serial number for the electronic brachytherapy system;

(4) model numbers and serial numbers of the instruments used to calibrate the electronic brachytherapy system; and

(5) name and signature of the qualified medical physicist who performed the calibration.

Subp. 10. **Periodic quality assurance checks and day-of-use spot checks.**

A. [A QMP] must perform periodic spot checks on each electronic brachytherapy system:

(1) at the beginning of each day of use;

(2) each time the system is moved to a new room or site; and

(3) after each x-ray tube installation.

B. A registrant is responsible for periodic spot checks according to procedures established by a qualified medical physicist.

C. Radiation output spot checks must :

(1) verify that the output of the electronic brachytherapy x-ray tube falls within three percent of expected values by the output as a function of time or the setting on a monitor chamber;

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

(3) validate the positioning methods so that the treatment dose exposes the intended location within one millimeter.

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

(1) Notifying the authorized physician and the qualified medical physicist if any parameter is not within its acceptable tolerance. The electronic brachytherapy system must not be made available for subsequent use until the qualified medical physicist has determined that all parameters are within their acceptable tolerances;

(2) if all radiation output quality control check parameters are within their acceptable range, then the quality control check must be reviewed and signed by either authorized physician or qualified medical physicist within two working days; and

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

E. A safety system spot check must verify that:

(1) the radiation exposure indicator lights on the electronic brachytherapy system and on the control console are operating as designed;

(2) the viewing system and intercom system in each electronic brachytherapy facility are operating as designed, if applicable;

(3) that all radiation monitors are operating as designed;

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

(5) the integrity of connecting guide tubes, transfer tubes, transfer-tube applicator interfaces, and treatment spacers.

F. If the results of the safety system spot checks ~~required by this part~~ indicate the malfunction of any system, then a registrant must:

(1) secure the control console in the "OFF" position; and

(2) not use the electronic brachytherapy system except as necessary to repair, replace, or check the malfunctioning system.

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

(1) the date of the quality control check;

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

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

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

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

a) the unique identifier for the electronic brachytherapy x-ray tube and the manufacturer's name; and

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

Subp. 11. **Acceptance testing for electronic brachytherapy systems**.

A. A registrant must perform acceptance testing on the treatment planning system of electronic brachytherapy related computer systems according to recommendations from a nationally recognized professional association with expertise in electronic brachytherapy. In the absence of acceptance testing protocol published by a nationally recognized professional association, a

registrant is responsible for following the manufacturer's acceptance testing protocol.

B. Acceptance testing must be performed by, or under the direct supervision of, a qualified medical physicist and, as applicable, must verify:

(1) the source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays;

(4) the accuracy of the software used to determine radiation source positions from radiographic images; and

(5) the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system if the treatment planning system is different from the treatment delivery system.

C. The position indicators in the applicator must be compared to the actual position of the source or planned dwell positions, at the time of commissioning.

D. Before each patient treatment regimen, an authorized physician and a qualified medical physicist must evaluate and approve the parameters for the treatment for accuracy by using independent methods of those used for the [initial or original] determination of the parameters.

## 4733.0805 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 SIMULATION SYSTEM REQUIREMENTS.

Subpart 1. **General.** A registrant's simulation system must meet the same requirements for equipment and mechanical parameters and for accuracy as a [radiation therapy system] treatment unit.

A. The equipment and mechanical parameters of a registrant's simulation system must meet the same quality control checks as a [radiation therapy system] treatment unit.

B. The simulator system motions must meet the same requirements for accuracy as a radiation therapy system [treatment unit].

C. All elements in a simulator system that are required for image quality must be tested, reviewed, and evaluated.

*A qualified medical physicist must test, review, and evaluate all elements in a simulator system that are required to produce [acceptable] image quality.*

Subp. 2. **Equipment performance evaluations; radiographic and CT simulation systems**. A registrant is responsible for establishing, documenting and implementing equipment performance evaluation procedures for a simulation system according to this subpart.

A. An equipment performance evaluation must:

(1) include acceptance testing;

(2) include periodic verification of system performance; and

(3) be developed [and performed] by a qualified service provider who meets the requirements of chapter 4732 or a qualified medical physicist.

B. An equipment performance evaluation for a radiographic simulation system must be performed at intervals not to exceed 24 months according to "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy; AAPM report No. 46," prepared by Committee Task Group 40.

C. An equipment performance evaluation for a computed tomography simulation system must be:

(1) performed at intervals not to exceed 12 months;

(2) performed according to “Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy committee Task Group No. 66: AAPM Report No. 83"; and

(3) a dose index (CTDI) must be completed using a CT dosimetry phantom.

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

Subp. 3. **Operator of a simulation system.** A simulation system must be operated by a qualified individual who is:

A. registered in radiologic technology or radiation therapy with the American Registry of Radiologic Technologists, designated ARRT (R) orARRT (T);

B. trained by the manufacturer or equivalent;

C. trained in positioning and anatomy for applicable procedures; and

D. trained on the operating and emergency proceduresfor simulation equipment.

Subp. 4. **Operating procedures.** Operating procedures for simulation equipment must include:

A. a protocol or technique that specifies:

(1) the conditions of operation; and

(2) the number of images or scans per examination;

B. personal protective equipment use when individuals [other than the patient?] remain in the simulation room during exposure; and

C. instructions for using the dosimetry or image quality phantoms, including the allowable variations for the indicated parameters.

## 4733.1100 OPERATORS OF DUAL IMAGING DEVICES.

A. A simulation equipment operator may operate a simulation imaging device only when doing so is an integral part of the [radiation] therapy procedures for treatment.

B. A simulation equipment operator must meet the requirements under Minnesota Statutes, section 144.121, subdivision 5 before the operator may operate an imaging device for diagnostic purposes.

# REPEALER.

Minnesota Rules, parts 4732.### are repealed.

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