Minnesota Department of Health

Proposed Permanent Rules Relating to Radiation Therapy

RADIATION THERAPY

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 the therapy equipment that uses radioactive material as found 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 the 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 (D).** "Absorbed dose (D)" means the energy imparted by ionizing radiation per unit mass of irradiated material. The unit of absorbed dose is the rad under the conventional system and the gray (Gy) under the SI system.

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. For purposes of this definition, bent beam linear accelerators, external beam linear accelerators, linear accelerators, particle accelerators, helical tomotherapy systems, and

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

Subp. 5. **Air kerma (K).** "Air kerma (K)" means the kinetic energy released in matter 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. **Beam axis.** "Beam axis" means the axis of rotation of the beam-limiting device for therapy systems.

Subp. 7. **Beam-limiting device.** "Beam-limiting device" means a field-defining collimator integral to the therapeutic radiation machine and capable of restricting the useful beam's dimensions.

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

Subp. 9. **Contact therapy system.** "Contact therapy system" means a radiation-therapy machine with a short target-skin distance (TSD), usually less than five centimeters.

Subp. 10. **Dose monitor unit.** "Dose monitor unit" means a unit response from the beam-monitoring system used for calculating the absorbed radiation dose.

Subp. 11. **Electronic brachytherapy.** "Electronic brachytherapy" means a method of radiation therapy using electrically generated x-rays to deliver a radiation dose:

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

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

Subp. 12. **Field-flattening filter.** "Field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field. For purposes of this definition, beam-scattering filter or foil are included.

Subp. 13. **Filter.** "Filter" means material placed in the useful beam to change beam quality in radiation therapy systems. A filter, exclusive of inherent filtration, could be removed from the useful beam through any electronic, mechanical, or physical process.

Subp. 14. **Gantry.** "Gantry" means that part of the radiation therapy system supporting and allowing movement of the radiation head.

Subp. 15. **Gray or Gy.** "Gray" or "Gy" means the SI unit of absorbed dose, kerma, and specific energy imparted to matter equal to one joule per kilogram. The conventional system equivalent is 100 rad.

Subp. 16. **High-radiation area.** "High-radiation area" means any area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a radiation dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from any source of radiation or 30 centimeters from any surface that the radiation penetrates.

Subp. 17. **Intensity-modulated radiation therapy or IMRT.** "Intensity-modulated radiation therapy" or "IMRT" means a process that enables a more precise conformal radiation dose to be distributed to the target area by allowing control of the radiation-beam intensity within a given area.

Subp. 18. **Interlock.** "Interlock" means a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Subp. 19. **Irradiation.** "Irradiation" means the exposure of matter or a living being to ionizing radiation.

Subp. 20. **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. 21. **Kilovolt (kV) or kilo electron volt (keV).** "Kilovolt (kV)" or "kilo electron volt (keV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000 volts in a vacuum. Current convention is to use kV for photons and keV for electrons.

Subp. 22. **Leakage radiation.** "Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for the useful beam.

Subp. 23. **Licensed practitioner of the healing arts.** "Licensed practitioner of the healing arts" means health professionals for diagnostic or healing treatment of human and animal maladies, who are licensed under Minnesota Statutes, chapter 147 or 156, for the lawful practice of medicine or veterinary medicine.

Subp. 24. **Light field.** "Light field" means the area illuminated by light that simulates the radiation field.

Subp. 25. **Medical event.** "Medical event" means any event for human use, except for an event that results from patient intervention, in which the therapeutic administration of radiation results in:

A. the wrong individual or wrong treatment site;

B. treatment with the wrong treatment modality or energy;

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

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

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

Subp. 26. **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. 27. **Mobile electronic brachytherapy service.** "Mobile electronic brachytherapy service" means transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

Subp. 28. **Moving beam radiation therapy.** "Moving beam radiation therapy" means radiation therapy with relative movement of the useful beam or the patient during irradiation. Examples include arc, skip, conformal, intensity modulation, and rotational therapy.

Subp. 29. **Nominal treatment distance.** "Nominal treatment distance" means:

A. for electron irradiation, distance from the scattering foil, virtual source, or exit window of the useful beam to the entrance surface of the irradiated object along the central access of the useful beam;

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

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

Subp. 30. **Patient.** "Patient" means an individual or veterinary practice animal subjected to machine-produced beam radiation for the purposes of therapy.

Subp. 31. **Physician assistant.** "Physician assistant" means a person licensed under Minnesota Statutes, chapter 147A, who is qualified by academic training, practical training, or both to provide patient services in radiation therapy according to the physician-physician assistant agreement authorized under Minnesota Statutes, section 147A.20.

Subp. 32. **Protective barrier.** "Protective barrier" means the material, excluding filters, placed in the useful beam to reduce radiation levels for protection purposes.

Subp. 33. **Qualified medical physicist.** "Qualified medical physicist" means an individual qualified to practice independently in the subfields for therapeutic radiological physics who:

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

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

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

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

E. holds a bachelor of science degree in radiological sciences, or an equivalent field involving further study in physics applied to the application of radiation to humans or veterinary practice animals from an accredited college or university and has at least ten years of full-time practical training and experience involving work in a radiation therapy facility under an individual who meets the qualifications in item A, B, or C, through a written attestation.

Subp. 34. **Radiation area.** "Radiation area" means an area accessible to individuals where radiation levels could result in an individual receiving a dose equivalent in excess

of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Subp. 35. **Radiation detector.** "Radiation detector" means a device that detects the presence of ionizing radiation. The detector must measure the type of radiation being measured. Some radiation detectors also identify the characteristics of the radiation.

Subp. 36. **Radiation head.** "Radiation head" means the structure from which the useful beam emerges.

Subp. 37. **Radiation therapist or radiation therapy technologist.** "Radiation therapist" or "radiation therapy technologist" means a person, other than a licensed practitioner of the healing arts, who:

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

B. is a member of the radiation oncology team who sees the patient on the treatment day and is responsible for delivering treatment and reviewing the patient's tolerance to treatment; and

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

D. following the effective date of this chapter, has satisfactorily completed a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology or is a registered American Registry of Radiologic Technologists ARRT (T).

Subp. 38. **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. 39. **Registrant.** "Registrant" means a person having administrative control of any radiation therapy system or therapy simulation system and who is legally obligated to register with the commissioner according to this chapter.

Subp. 40. **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. 41. **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. 42. **Sievert (Sv).** "Sievert (Sv)" means the international system of units (SI) dose equivalent. The conventional system of dose equivalent is 100 rem.

Subp. 43. **Stereotactic body radiation therapy or SBRT.** "Stereotactic body radiation therapy" or "SBRT" means a specialized form of radiation therapy of the body, other than intracranial or spinal lesions, which uses a known three-dimensional reference system to localize and deliver high doses of radiation to a target lesion with high precision in large fraction sizes over a short course, which is typically five or fewer fractions, of treatment.

Subp. 44. **Stereotactic radiosurgery or SRS.** "Stereotactic radiosurgery" or "SRS" means a specialized form of radiation therapy of the brain and spine, and which uses a known three-dimensional reference system to localize and deliver high doses of radiation to a target lesion with high precision in large fraction sizes over a short course of treatment.

Subp. 45. **Stray radiation.** "Stray radiation" means the sum of leakage and scattered radiation.

Subp. 46. **Supervising physician.** "Supervising physician" means a Minnesota-licensed physician who accepts full medical responsibility for the performance, practice, and activities of a registered radiologist assistant, radiology practitioner assistant, or physician assistant according to Minnesota Statutes, section 147A.20.

Subp. 47. **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. 48. **Target-skin distance (TSD).** "Target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the target or electron virtual source to the surface of the irradiated object or patient.

Subp. 49. **Termination of irradiation.** "Termination of irradiation" means stopping of irradiation until the operating conditions are reset at the control panel.

Subp. 50. **Therapeutic-type protective tube housing.** "Therapeutic-type protective tube housing" means:

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

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

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

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:

A. localizing the volume to be irradiated during radiation therapy; and

B. 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 in order to control or cure a cancerous tumor or other problem. The radiation treatment planning (RTP) system consists of a software package, hardware platform, and associated peripheral devices.

Subp. 53. **Useful beam.** "Useful beam" means the radiation emanating from the tube-housing port or the radiation head and passes through the aperture of the beam-limiting device when the exposure controls are in a mode that causes the radiation therapy system to produce radiation.

Subp. 54. **Very high radiation area.** "Very high radiation area" means an area accessible to individuals where radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rad (5 Gy) in one hour at one meter from any surface that the radiation penetrates.

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

Subp. 56. **Written order.** "Written order" means an order either in writing or electronically for the administration of radiation according to part 4733.0435.

REGISTRATION REQUIREMENTS

4733.0108 REGISTRATION REQUIREMENTS FOR RADIATION THERAPY FACILITIES.

Subpart 1. **Registration.** The person having administrative control of a radiation therapy system, electronic brachytherapy system, or therapy simulation system must complete the registration and submit the applicable fee in addition to the registration requirements found in chapter 4732. The registrant must keep the registration information current.

A. Registration of the facility is not transferable as part of an ownership change.

B. All communications and reports concerning the regulations, applications, and violations filed thereunder must be addressed to the Minnesota Department of Health, Radiation Control.

C. No one may refer in advertisements to the fact that the ionizing radiation-producing equipment is registered with the commissioner or state, or imply that the commissioner has approved any activity under the registration.

Subp. 2. **Notifications.** The registrant must notify the commissioner within 30 days of any of the following:

A. the administrator changes;

B. the radiation safety officer or other personnel identified on the registration changes;

C. the equipment or any related registered equipment is relocated permanently within the facility or otherwise disposed of;

D. the radiation-producing equipment's ownership status changes, including sale, lease, or transfer; or

E. the facility's physical plan changes affect radiation exposure such as remodeling by changing or removing shielded walls or barriers.

4733.0109 REGISTRATION FEES.

The registrant must submit the fee specified in Minnesota Statutes, section 144.121, subdivision 1a, with the initial registration application or renewal for registration of radiation-producing therapy and simulation equipment required under chapter 4732. The registration fee is nonrefundable.

GENERAL ADMINISTRATION

4733.0110 DATA PRIVACY.

Collection, security, and dissemination of information gathered for registration is governed by Minnesota Statutes, chapter 13.

4733.0115 EMPLOYEE PROTECTION.

Employee protection and employment discrimination issues are governed by Minnesota Statutes, sections 181.931 to 181.937.

4733.0120 DELIBERATE MISCONDUCT.

For purposes of this chapter, "deliberate misconduct" means a registrant, employee of a registrant, or service provider who knowingly:

A. commits intentional acts that cause or would have caused, if not detected, a registrant to be in violation of this chapter; or

B. intentionally submits to the commissioner or the registrant information that the submitting person knows to be incomplete or inaccurate.

4733.0125 VARIANCES.

Except for parts 4733.0108 and 4733.0109, the commissioner may grant a variance to this chapter according to the variance procedures and criteria in parts 4717.7000 to 4717.7050.

4733.0130 INSPECTIONS.

The registrant must allow the commissioner, or commissioner's designee, at all reasonable times, the opportunity to inspect facilities, premises, equipment, and records for compliance with this chapter and Minnesota Statutes, sections 144.989 to 144.993.

4733.0135 ENFORCEMENT.

The commissioner may assess 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.** Each registrant must prominently post an MDH Form 3, "Notice to Employees," provided by the commissioner. A copy of any revision of the Notice to Employees must be posted within 30 days of receiving the revised notice from the commissioner. Copies of the Notice to Employees may be obtained upon request from the Minnesota Department of Health.

Subp. 2. **Posting locations.** The registrant must:

A. post these notices in a prominent location to be viewed by all workers using radiation therapy or simulation equipment; and

B. replace postings if they become illegible, defaced, or altered in any way.

REPORTS AND NOTIFICATIONS

4733.0160 EXPOSURE NOTIFICATIONS AND REPORTS.

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

A. include the individual's dose;

B. be in writing or electronic mail; and

C. include the date of discovery, name of the registrant, name of the exposed individual worker, and date of the dose report.

Subp. 2. **Individual's dose report.** The registrant must provide, in writing or electronic mail, dose information to individual workers:

A. annually if the individual's occupational dose exceeds 100 mrem (1mSv) TEDE; or

B. if the individual requests a report.

Subp. 3. **Report upon termination.** When a worker who is terminating employment makes a written request of the worker's radiation dose, the registrant must furnish a radiation dose report. The report must:

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

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

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

4733.0180 REPORTS OF MEDICAL EVENTS.

Subpart 1. **Notification within 24 hours.** A registrant must notify the commissioner within 24 hours of discovering any medical event as defined in part 4733.0105, subpart 25.

Subp. 2. **Written report information.** In addition to any notification required by subpart 1, the registrant must submit within 30 days a written report to the commissioner signed by the facility administrator and the individual who completed the analysis of the medical event. The report must include:

A. the registrant's name;

B. the name of the prescribing physician;

C. a brief description of the event;

D. the root cause of the event;

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

F. the titles of individuals involved in the event;

G. what corrective or planned actions have been taken to prevent reoccurrence, and the dates of the corrective or planned actions;

H. the estimates of the patient's dose; and

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

Subp. 3. **Notification of referring physician.**

A. The registrant must notify the referring physician no later than 24 hours after discovery of a medical event.

B. The registrant must provide the referring physician, if other than the registrant, a copy of the report, including the information in subpart 2, no later than 30 days after discovery of the medical event.

GENERAL REQUIREMENTS

4733.0210 GENERAL REQUIREMENTS FOR RADIATION THERAPY FACILITIES.

Subpart 1. **Equipment.**

A. Radiation therapy and therapy simulator equipment must meet the requirements of:

(1) nationally recognized standards such as Code of Federal Regulations, title 21;

(2) the manufacturer's specifications; and

(3) this chapter.

B. When an operating parameter has been exceeded and if the parameter cannot be corrected immediately, the radiation therapy or simulation system may be used if the radiation safety officer and qualified medical physicist:

(1) establishes written procedures, that may be used for no more than 14 days, to ensure the safe use until corrective actions have been implemented; and

(2) verifies the corrective actions have resolved the out-of-limits parameters.

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

A. A registrant must not permit an individual to operate a radiation therapy system for human use until the individual:

(1) meets the qualifications in part 4733.0105, subpart 37; and

(2) has completed the initial training required in subpart 5.

B. If an operator has not participated in a radiation therapy or therapy simulation operation for more than six months since the operator's last competency audit, the

radiation safety officer or designee must observe and record the operator's performance the next time the individual operates a radiation therapy system or therapy simulation system.

C. Radiation therapy for veterinary applications must be by, or under the supervision of, a currently licensed veterinarian licensed by the Minnesota Board of Veterinary Medicine. Individuals operating radiation therapy for veterinary use must:

(1) be at least 18 years of age;

(2) meet qualification criteria specified by a supervising radiation therapy veterinarian as qualified in this item; and

(3) have completed the initial training required in subpart 5.

Subp. 3. **Individual monitoring.** In addition to the requirements of part 4733.0320, the registrant must require that all individuals entering any area where interlocks are necessary wear individual monitoring devices unless:

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

B. power to a radiation therapy system cannot be activated or a beam cannot be directed to that area.

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

A. The registrant must secure radiation therapy systems that are not in operation to prevent unauthorized use.

B. The registrant must check all safety and warning devices, including interlocks, for proper operation according to the following schedule:

(1) emergency cutoff switches must be tested before initial use and after any component in the emergency switch circuit is modified or repaired;

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

(3) warning devices must be tested at intervals not to exceed one month.

C. The registrant's written operating procedures must include:

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

(2) procedures to ensure that two qualified individuals, therapists, radiation oncologists, or medical physicists are at the therapy control console during the patient setup and during treatment;

(3) procedures for verifying the patient's identity using two forms of identification;

(4) procedures for treatment plan approval and transfer;

(5) procedures for verification of treatment plan accuracy prior to treatment delivery;

(6) procedures for ensuring that the patient is monitored continuously and without obstruction during treatment;

(7) methods for controlling access to restricted areas;

(8) methods and occasions for locking and securing the radiation therapy system;

(9) use of individual monitoring equipment; and

(10) inspections and maintenance of the therapy and simulation systems.

D. The 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.

E. The registrant must keep a copy of the current written operating and emergency procedures at the radiation therapy and simulation system control area.

Subp. 5. **Training for operating radiation therapy equipment.**

A. Initial training for individuals operating radiation therapy equipment after the effective date of this chapter must include completion of the following facility-specific training prior to operating radiation therapy equipment:

(1) therapy equipment;

(2) simulation equipment;

(3) operating and emergency procedures;

(4) relevant quality control tests;

(5) dynamic and static acquisition;

(6) quality management program;

(7) relevant treatment planning and plan transfer; and

(8) an audit of the operator's performance by the registrant's radiation safety officer or designee during a prescribed patient radiation therapy and therapy simulation system operation.

B. Annual training for operators must include:

(1) health risks associated with exposure to radiation, precautions or procedures to minimize exposure, and the purpose and use of protective devices;

(2) operating and emergency procedures;

(3) required daily quality control tests and safety checks;

(4) treatment planning systems, verification systems, and operator responsibilities;

(5) appropriate responses to warnings made in the event of any unusual occurrence, malfunction, or treatment planning error;

(6) applicable provisions of this chapter, including the reporting requirements of any condition that would violate this chapter or cause unnecessary radiation exposure; and

(7) an audit of the operator's performance by the registrant's radiation safety officer or designee during a prescribed patient radiation therapy and therapy simulation system operation.

C. The following individuals are exempt from the annual training requirement in item B:

(1) a licensed practitioner of the healing arts; or

(2) students enrolled in and participating in an accredited program for radiation therapy technology, a school of medicine, or school of osteopathy who have radiation oncology as part of a course of study.

D. The registrant must conduct initial training following program or equipment modifications for radiation therapy or a simulation system following changes to:

(1) the quality management program; or

(2) the radiation output from new software, modality, technology, or radiation equipment.

4733.0215 RECORDS.

Subpart 1. **Requirements.** The registrant must maintain the following records according to this chapter:

A. receipt, transfer, and disposal of all radiation therapy or simulation systems;

B. registrant's information;

C. employee training documentation, including training content, dates, and attendees as required in part 4733.0210, subpart 5, and electronic brachytherapy training as required in part 4733.0800, subpart 4;

D. written orders;

E. individual monitoring results, including accidents or emergencies;

F. manufacturer's specifications for any new therapy or simulation equipment installed after the effective date of this chapter;

G. shielding plans, modifications, and associated radiation level verification surveys sufficient to demonstrate compliance with the dose limits for occupational workers, according to part 4733.0305, and members of the public, according to part 4733.0315;

H. radiation safety officer training, delegation agreement, and radiation safety officer responsibilities according to part 4733.0405;

I. dated acceptance testing, commissioning, full calibration, quality control tests, and spot check procedures as developed by a qualified medical physicist, as required by this chapter;

J. quality management program as defined in part 4733.0425 and radiation safety program audits according to part 4733.0420;

K. calibrations and intercomparisons for instruments, survey meters, and electronic equipment to include:

(1) the date;

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

(3) the correction factors determined; and

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

L. results of radiation surveys to include:

(1) the date;

(2) the purpose of the survey;

(3) the manufacturer, model number, and serial number of the instruments used to measure radiation levels;

(4) a diagram or sketch of the areas surveyed;

(5) the measured dose rate at locations in each area to show compliance with the dose limits in parts 4733.0300 to 4733.0320;

(6) the calculated maximum level of radiation over a period of one year for each restricted and unrestricted area; and

(7) the signature or electronic signature of the individual who performed the tests;

M. equipment performance measurements during full calibration and spot checks to include:

(1) the 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 signature of the individual who performed the tests;

N. acceptance and commissioning tests performed at the time of installation;

O. daily, weekly, or monthly equipment performance tests;

P. electronic brachytherapy Institutional Review Board (IRB) documents including:

(1) IRB approval date;

(2) IRB expiration dates; and

(3) other records as described in this chapter; and

Q. other records as described in this chapter.

Subp. 2. **Format and retention.**

A. Required records must be maintained so they remain legible throughout the specified retention period.

B. Appropriate units, rad, roentgen, rem, or equivalent international system of units (SI), must be clearly indicated on applicable records.

C. Records such as letters, drawings, or specifications must include all supporting data such as stamps, initials, and signatures.

D. All required records listed in subpart 1, except items A, E, and G, must be maintained for three years.

Records required in subpart 1, items A, E, and G, must be maintained as long as the registration is active and for three years following.

4733.0220 OTHER USE OF ELECTRONICALLY PRODUCED RADIATION TO DELIVER THERAPEUTIC RADIATION DOSAGE.

A. No one may use a radiation therapy not specifically covered elsewhere in this chapter without first submitting a completed registration application to the commissioner.

B. The applicant or registrant must submit the following information:

(1) a detailed description of the system and its intended application;

(2) facility requirements for design, shielding, and access control;

(3) written documentation for:

(a) initial training for the radiation oncologist, licensed practitioner of the healing arts, qualified medical physicist, and radiation therapist;

(b) methodology for measuring doses to be administered to patients;

(c) calibration, maintenance, and repair of the device, including instruments and equipment necessary for radiation safety;

(d) radiation safety precautions and instructions; and

(e) other information required by the commissioner for reviewing the application for registration and use.

C. The applicant or registrant must receive written approval from the commissioner to use the device according to:

(1) any applicable regulations; and

(2) all specific conditions identified by the commissioner.

SHIELDING AND DESIGN REQUIREMENTS

4733.0250 SHIELDING DESIGN REQUIREMENTS.

Subpart 1. **Shielding plan.** Facility design information for a new installation of radiation therapy or simulation systems of higher energy into a room not previously submitted for that energy must be submitted to the commissioner prior to actual installation of the system.

A. The registrant must document the radiation shielding installed in the registrant's facility. Acceptable documentation is:

(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.

B. A shielding plan for simulation equipment must be completed by a service provider qualified according to chapter 4732, qualified medical physicist, diagnostic radiological physicist, health physicist certified in x-ray installation, or a health physicist certified in therapy installations.

C. A shielding plan for radiation therapy equipment must be completed by a qualified medical physicist or health physicist certified in therapy equipment installations.

Subp. 2. **Barriers.** Except for electronic brachytherapy below 150 kV, facilities that have radiation therapy or simulation systems must be designed with primary and secondary barriers to comply with the dose limits in 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 can operate above ten MeV.

For simulation systems, any door that is indicated in the design as a primary barrier must be closed during exposures.

4733.0255 FACILITY DESIGN REQUIREMENTS.

Subpart 1. **Control console.** Except for electronic brachytherapy below 150 kV, the 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.** Except for electronic brachytherapy below 150 kV and simulation rooms, radiation therapy room entrances must have warning lights in readily visible positions near the outside of all access doors to indicate when the useful beam is "ON."

Subp. 3. **Emergency cutoff couch switches.** Except for simulation systems, an emergency cutoff couch switch must be located on either side of the primary beam and easily identifiable in all high-radiation areas. The cutoff switch must include a manual reset so that the therapy system cannot be restarted from the therapy system control console without resetting the cutoff switch.

Subp. 4. **Interlocks.** Except for electronic brachytherapy below 150 kV and simulation rooms, interlocks or safety devices must be in place so all access to the room is blocked before irradiation is initiated or continued. If the useful radiation beam is interrupted by any door opening or tripping of the safety device, restoring the system to operation without closing the door or resetting the safety device must not be possible unless the operator closes the door or resets the safety device and manually reinitiates irradiation at the control console. In addition:

A. 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;

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

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

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

A. For radiation therapy rooms, a closed-circuit television, or an equivalent system, must be provided to permit continuous observation of the patient during irradiation and located so the operator can see the patient from the control console at all times.

B. For simulation rooms, the viewing system must be designed so that the operator at the control panel may directly observe the patient, any other individual in the room, and any doorway into the room.

Subp. 6. **Audio communication.** Except for veterinary use, two-way audio communication between the patient and the operator must be provided at the control panel. When excessive noise levels or treatment requirements make audio communication impractical, other methods of communication must be used.

4733.0260 MODIFICATION.

When modifications to the radiation therapy area or simulation area are made, the registrant must:

A. perform a verification radiation survey ensuring the doses to any individuals do not exceed the limits in this chapter;

B. equip therapy equipment with beam direction interlocks or add additional shielding to comply with parts 4733.0250 to 4733.0275; and

C. document modifications made and the results of all radiation surveys according to part 4733.0265.

4733.0265 RADIATION SURVEYS.

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

A. before the first use;

B. after making any change in the shielding;

C. after installing or relocating the accelerator or simulation equipment; and

D. before using the equipment in a manner that could result in increased radiation levels in areas outside the shielded area.

Subp. 2. **Performance method.** The radiation survey must cover the radiation levels at the operator position and at pertinent points outside the room during normal operation. The radiation safety officer or designee must perform the radiation survey with the equipment in a "BEAM-ON" condition, with the largest available field and with a scattering phantom in the useful beam of radiation, if applicable, to ensure that radiation levels in restricted areas are not likely to expose the personnel in excess of the limits of this chapter.

Subp. 3. **Notification.** If the results of the radiation survey indicate levels above dose limits in parts 4733.0300 to 4733.0320, the registrant must:

A. inactivate and secure the equipment;

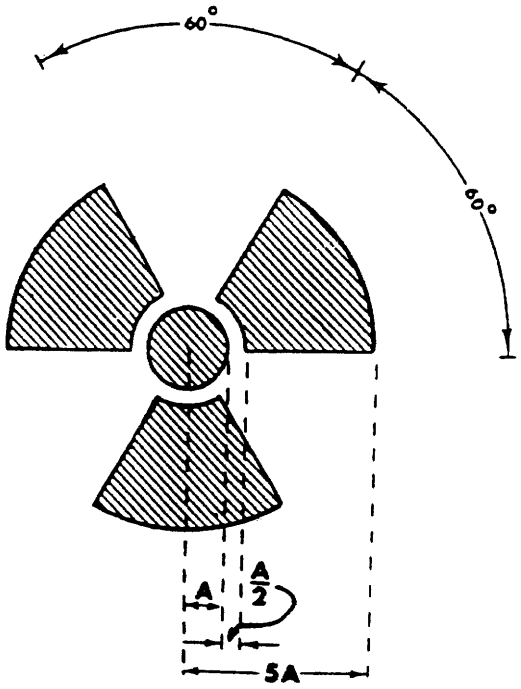
B. notify the commissioner within 24 hours of discovery; and

C. perform corrective actions.

When the radiation survey results document that the corrective actions have been completed and the registrant has complied with the dose requirements in parts 4733.0300 to 4733.0320, the registrant may begin to use the equipment.

4733.0270 CAUTION SIGNS.

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



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

B. the background must be yellow.

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

Subp. 3. **Prohibitions on use of symbol.** The registrant may not use the specified radiation symbol for any purpose other than designating or referring to an area of applicable radiation levels.

Subp. 4. **Posting and labeling requirements.** The registrant must post conspicuous radiation warning labels in areas where a radiation hazard might exist.

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

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

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

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:

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

B. In place of the controls required under item A, a registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

DOSE REQUIREMENTS

4733.0300 DETERMINATION OF ACCUMULATED OCCUPATIONAL DOSE.

Subpart 1. **Determination of prior occupational dose.** The registrant must determine the occupational dose an individual received during the current year for each individual who is likely to receive an occupational dose in a year requiring monitoring according to part 4733.0305.

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

A. A registrant may:

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

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

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

C. If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant must assume the allowable dose limits for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

4733.0305 OCCUPATIONAL DOSE LIMITS FOR ADULTS.

Subpart 1. **Occupational dose control.** The registrant must prevent individual adults from receiving occupational doses that exceed the following annual dose limit, which 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 limits to the lens of the eye, to the skin, and to the extremities, which are:

(1) a lens dose equivalent of 15 rem (0.15 Sv); and

(2) a shallow-dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

Subp. 2. **Dose equivalent.**

A. The 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 demonstrating compliance with the occupational dose limits if the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable.

C. When an individual wears a protective apron while working with radiation-producing equipment and monitoring as specified in part 4733.0320, the effective dose equivalent for external radiation must be determined as follows:

(1) when only one individual monitoring device is used 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. Any alternative method of determining dose must be approved by the commissioner.

Subp. 3. **Reduction of dose.** The registrant must reduce the dose that an individual 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.

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

4733.0310 DOSE EQUIVALENT TO AN EMBRYO OR FETUS.

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

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

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

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

4733.0315 RADIATION DOSE LIMITS FOR THE PUBLIC.

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

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

4733.0320 INDIVIDUAL MONITORING.

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

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

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

B. minors likely to receive, in one year, 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 worker 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.** The registrant must ensure that all individuals who are likely to receive an occupational dose in excess of 100 millirems (1 mSv) in a year receive annual training as required by part 4733.0210, subpart 5.

RADIATION SAFETY

4733.0400 REGISTRANT'S SAFETY RESPONSIBILITIES.

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

B. If the registrant is not the radiation safety officer, the registrant must appoint a radiation safety officer who meets the qualifications in part 4733.0405.

4733.0405 RADIATION SAFETY OFFICER (RSO).

Subpart 1. **Radiation safety officer training.** The radiation safety officer must be either a licensed practitioner of the healing arts, qualified medical physicist, or an individual who:

A. has completed training according to the responsibilities in 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.** The registrant must appoint a radiation safety officer, who agrees in writing, to be responsible for implementing the radiation protection program.

Subp. 3. **Authority.** The registrant must provide the 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. **RSO responsibilities.** The 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 according to part 4733.0320;

D. investigate each known or suspected case of an individual being exposed to radiation levels in excess of limits established by this chapter;

E. assume control and institute corrective actions, including shutdown of operations in emergency or unsafe conditions;

F. design and oversee initial, annual, and other required trainings;

G. ensure equipment maintenance is performed according to this chapter;

H. perform or arrange to have performed:

(1) radiation surveys;

(2) radiation safety program audits according to 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 SUPPORT.

Subpart 1. **Physicist responsibilities.** The registrant must employ or contract with a qualified medical physicist. The qualified medical physicist is responsible for:

A. full calibrations and radiation protection surveys required by this chapter;

B. supervising and reviewing dosimetry;

C. acquiring beam data, transferring it for computerized dosimetry, and supervising its use;

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

E. consulting for treatment planning, as needed; and

F. performing calculations and assessments regarding medical events.

Subp. 2. **Availability.** The registrant must have emergency procedures in place to address the specific actions that must be taken if problems, failures, or emergencies occur and the qualified medical physicist is not immediately available.

Subp. 3. **Verification.** The 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. The qualified medical physicist must verify the treatment plan and plan transfer before:

A. the first treatment of five or less treatment fractions; and

B. the third fraction for treatments over five fractions.

Subp. 4. **Alternative verification.** If a qualified medical physicist is not available for an emergency treatment plan, the radiation oncologist may verify and document the treatment plan and the plan transfer.

4733.0420 RADIATION PROGRAM AUDITS.

Subpart 1. **Program review.** A registrant must review at intervals not to exceed 12 months:

A. all aspects of the quality management program;

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.

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

QUALITY MANAGEMENT PROGRAM

4733.0425 QUALITY MANAGEMENT PROGRAM.

A registrant subject to part 4733.0500, 4733.0520, or 4733.0800 must implement a site-specific quality management program. The program must include at a minimum:

A. therapy and simulation procedure written orders according to part 4733.0435;

B. notification procedures for medical events in accordance with part 4733.0180;

C. procedures to ensure that:

(1) each administration is in accordance with the written order;

(2) radiation therapy final plans of treatment and related calculations are in accordance with the written order by:

(a) checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written order; and

(b) verifying that any computer-generated calculations are correctly transferred into the therapy system consoles; and

(3) any unintended deviation from the written order is identified and evaluated and appropriate action is taken.

4733.0435 ORDERING THERAPY OR SIMULATION PROCEDURES.

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

A. The order for radiation therapy treatments must be made by:

(1) a licensed practitioner of the healing arts; or

(2) a physician assistant supervised by a therapeutic radiologist or a radiation oncologist if the ordering of therapeutic procedures is designated in the physician-physician assistant agreement authorized under Minnesota Statutes, section 147A.20.

B. The written order for radiation therapy treatments 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 individual who is ordering the treatment, by a signature, an electronic signature, or equivalent procedure;

(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 provided that the revision is dated and signed by a radiation oncologist prior to the administration of the therapeutic dose or the next fractional dose.

Subp. 2. **Therapy simulator system procedure orders.**

A. The order for a simulation examination must be made only by:

(1) a licensed practitioner of the healing arts;

(2) an advanced practice nurse;

(3) a certified nurse practitioner; or

(4) a physician assistant supervised by a therapeutic radiologist or a radiation oncologist if the ordering of therapeutic procedures is designated in the physician-physician assistant agreement authorized under Minnesota Statutes, section 147A.20.

B. The written order for simulation procedures must be available at the time of the examination.

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

(1) date;

(2) patient's identity;

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

(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.** Each facility authorized to operate a radiation therapy system in accordance with parts 4733.0500, 4733.0520, and 4733.0800 must possess calibrated portable radiation monitoring equipment.

Subp. 2. **Calibration.** The registrant must ensure the correct response to radiation by calibrating each radiation instrument at intervals not to exceed 12 months, and after any repair. The instrument must:

A. meet energy levels over a range appropriate for the use;

B. be accurate within plus or minus 20 percent over the instrument's applicable range of the instrument;

C. be traceable to its calibration standard at the National Institute of Standards and Technology (NIST); and

D. for noninvasive kVp meters, be calibrated by the manufacturer or an accredited calibration laboratory.

4733.0445 DOSIMETRY SYSTEM.

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

A. For beams with energies greater than 1.0 MV (1.0 MeV), the dosimetry system must be calibrated for Cobalt-60.

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

Subp. 2. **Calibrations.** Calibration must be performed by, or under the direct supervision of a qualified medical physicist.

A. The calibration must be performed:

(1) at least every 24 months; and

(2) after any servicing that might have affected system calibration.

B. Instead of calibrating the system every 24 months as in item A, the registrant may use an intercompared system that has been calibrated within the previous 48 months. Each calibrated system used must have been calibrated within the past 24 months.

Subp. 3. **Intercomparison.**

A. The intercomparison results must show that the system's calibration factor has not changed by more than two percent. The intercomparison result cannot be used to change the calibration factor.

B. When intercompared dose-monitoring systems are used for calibrating radiation therapy systems, the units must be compatible with the therapy system.

4733.0455 TREATMENT PLAN APPROVAL.

Subpart 1. **Approval.** Prior to a patient's first treatment, plan approval must be completed and signed by a radiation oncologist and:

A. a qualified medical physicist; or

B. a certified medical dosimetrist.

Subp. 2. **Noncertified dosimetrists.** If the treatment plan has been prepared by a dosimetrist who is not certified by the Medical Dosimetrist Certification Board (MDCB), the radiation oncologist and either a certified medical dosimetrist or a qualified medical physicist must review and approve the treatment plan before a patient's first treatment.

EQUIPMENT REQUIREMENTS

4733.0500 RADIATION THERAPY SYSTEMS OF LESS THAN 500 kV.

Subpart 1. **Leakage radiation.**

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

B. The registrant must obtain documentation from the manufacturer for each radiation therapy system indicating the radiation system:

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

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

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

D. The registrant must ensure that a leakage measurement is performed at installation and whenever the tube is changed. The registrant must also ensure that leakage measurements are performed at least once every five years specifically:

(1) 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;

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

(3) for systems greater than 150 kVp and less than 500 kV, the leakage kerma rate measured at a distance of one meter from the target in any direction must not exceed 1.0 rad (1.0 cGy) in any one hour. 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. Permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.

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

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

A. filters cannot be accidentally displaced at any possible tube orientation;

B. an interlock system must prevent irradiation if the proper filter is not in place;

C. the 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 conditions; and

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

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

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

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

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

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

A. A system must have a control device that terminates the radiation after a preset time interval has elapsed and must:

(1) have a display at the treatment control panel;

(2) have a preset time selector and an elapsed time or time remaining indicator;

(3) 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. The panel must require resetting the elapsed-time indicator after radiation is terminated and before irradiation can be restarted;

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

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

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

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

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

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

(2) an indicator for whether x-rays are being produced;

(3) an indicator for kVp and x-ray tube current;

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

(5) a locking device that will prevent unauthorized system use; and

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

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

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

(2) the control panel must have an indicator identifying which x-ray tube is activated; and

(3) the tube housing assembly must have an indicator showing 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. Each radiation therapy system equipped with a beryllium or other low-filtration window must be clearly labeled as such on the tube housing assembly and must 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, in addition to the requirements in parts 4733.0250 to 4733.0260, treatment rooms that contain 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 enclosed booth which 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 can be initiated or continued;

D. if the beam is interrupted by any 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. when a door is opened while the radiation therapy system is activated, 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.

4733.0505 OPERATING AND EMERGENCY PROCEDURES FOR RADIATION THERAPY SYSTEMS OF LESS THAN 500 kV.

Subpart 1. **Operating procedures.** In addition to the requirements in part 4733.0210, subpart 4, item C, the procedures must include:

A. when a patient must be held in position for radiation therapy, the mechanical supporting or restraining devices that will be used;

B. 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

C. 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.** In addition to the requirements in part 4733.0210, subpart 4, item D, the procedures must include notifying the manufacturer and the commissioner of a 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. 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. 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.** The registrant must establish, document, and implement full calibration procedures developed by a qualified medical physicist. Full calibrations must be performed at intervals within the tolerances not to exceed those specified in either "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy;

AAPM report No. 46," prepared by Committee Task Group 40 or "Task Group 142 report: Quality assurance of medical accelerators" unless the qualified medical physicist determines and documents that a specific recommendation of these reports is not warranted.

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

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

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

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

Subpart 1. **Periodic quality spot checks.** Periodic quality spot checks must be performed on radiation therapy systems capable of operation at 150 kV or greater. Quality spot checks must:

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

B. 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.** The cause for a parameter exceeding a tolerance set in the written procedures established by the qualified medical physicist must be investigated and corrected before the therapy system is used for patient irradiation.

Subp. 3. **Qualified medical physicist review.** The registrant must have the qualified medical physicist review and sign the results of each radiation output quality control check within one month of test completion.

Subp. 4. **Frequency.** The registrant must ensure that periodic quality spot checks are performed at intervals not to exceed one month.

Subp. 5. **Safety checks.** Safety checks must be performed at intervals not to exceed one month and 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.

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

Subpart 1. **Leakage radiation.**

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

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

Measurements must be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

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

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

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

(1) 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.

(2) 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:

(a) 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

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

C. Measurement of leakage radiation must meet the following requirements:

(1) 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.

(2) 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. 2. **Filters and wedges.** Filters and wedges must meet the requirements in items A to E.

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, 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, the filter must be removable only by using tools.

E. For equipment manufactured after July 9, 1997, which 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 shows 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. 3. **Beam monitoring.**

A. For equipment manufactured after July 9, 1997, the registrant must determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure 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.

(1) Equipment manufactured on or before July 9, 1997, must have at least one radiation detector that is incorporated into a useful beam-monitoring system.

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

(3) The detector system and its detector must meet the following requirements:

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

(b) 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;

(c) each beam-monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation;

(d) for equipment manufactured after July 9, 1997, the design of the beam-monitoring system must ensure that the:

i. malfunctioning of one system does not affect the correct functioning of the other systems; and

ii. 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. For equipment manufactured after July 9, 1997, each display must:

i. retain a reading until intentionally reset;

ii. have only one scale and no electrical or mechanical scale multiplying factors;

iii. use a design so that the increasing dose is displayed by increasing numbers; and

iv. 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. 4. **Beam symmetry.**

A. Bent-beam linear accelerators 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. 5. **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 can be initiated.

D. For equipment manufactured after July 9, 1997, after radiation is terminated, the operator must be required to reset the preselected dose monitor units before starting irradiation.

Subp. 6. **Air kerma rate or absorbed dose rate.** For equipment manufactured after July 9, 1997, a system must display readings so that the air kerma rate or absorbed dose

rate at a reference point can be calculated. The radiation detectors specified in subpart 3 may form part of this system. In addition:

A. the dose monitor unit rate must be selected and displayed at the treatment control panel;

B. if the equipment can deliver under any condition, an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, the system must have a device that terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The registrant must maintain a record of the dose rate at which the irradiation will be terminated;

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

D. for each radiation therapy system, the registrant must determine, or obtain from the manufacturer, the maximum values in this subpart for the specified operating conditions. The registrant must maintain records of these maximum values at the facility for inspection by the commissioner.

Subp. 7. **Termination of irradiation by beam-monitoring system during stationary beam therapy.** The equipment must allow the operator to terminate the irradiation by the beam-monitoring system or systems during stationary beam radiation therapy, which requires:

A. each primary system must terminate irradiation when the system has detected the preselected number of dose monitor units;

B. if the equipment's original design included a secondary dose-monitoring system, that 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. for equipment manufactured after July 9, 1997, an indicator on the control panel must show which monitoring system has terminated irradiation.

Subp. 8. **Termination of irradiation.** Equipment must allow the operator to terminate irradiation and equipment movement, or move from an interruption condition to termination condition, from the operator's position at the treatment control panel at any time.

Subp. 9. **Interruption of irradiation.** If a radiation therapy system has an interrupt mode, interrupting irradiation and equipment movements must be possible from the treatment control panel at any time. After an interruption, restarting irradiation by operator action without any reselection of operating conditions must be possible. Irradiation and equipment movements must be automatically terminated if any change of a preselected value is made during an interruption.

Subp. 10. **Timers.** An irradiation control device must terminate the irradiation after a preset time interval.

A. The system must have a timer with a display at the treatment control panel. The timer must have a preset time selector and an elapsed time indicator.

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

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

Subp. 11. **Selection of radiation type.** Equipment capable of both x-ray and electron therapy must meet the following additional requirements:

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

B. an interlock system must ensure:

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

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

(3) electron irradiation is prevented when accessories specific for x-ray therapy are fitted; and

(4) irradiation is prevented 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. 12. **Selection of energy.** Equipment capable of generating radiation beams of different energies must meet the following requirements:

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 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 appropriate flattening filter or scattering foil for the selected energy is in its proper location.

Subp. 13. **Stationary and moving beam radiation therapy.** Radiation therapy systems capable of both stationary beam radiation therapy and moving beam radiation therapy must meet the following requirements:

A. irradiation must not be possible until a selection of stationary beam radiation therapy or 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) where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than five percent from the dose monitor unit value selected;

(3) an interlock must 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. where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of radiation must comply with subpart 7; and

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

(1) occurs during stationary beam radiation therapy; or

(2) does not start or stop during moving beam radiation therapy unless the stop is preplanned.

Subp. 14. **Facility design requirements.** In addition to shielding adequately to meet the requirements in parts 4733.0250 to 4733.0260, the facility must have the following provisions.

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 whether 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 any protective barrier requires the presence of a beam interceptor to comply with part 4733.0315, 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. The radiation therapy room must have at least one emergency power cutoff switch on either side of the primary beam and must terminate all equipment electrical power, including radiation and mechanical motion. This switch is in addition to the termination switch required by subpart 8. Emergency power cutoff switches must include a manual reset so that the 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 therapy equipment.

E. Surveys for residual activity must be conducted on all radiation therapy systems that can 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.

In addition to the requirements in part 4733.0210, subpart 4, the procedures must specify:

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

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

C. if a patient is immobilized during treatment, that mechanical supporting or restraining devices must be used.

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

Subpart 1. **Frequency.** 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. 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. **Acceptance testing, commissioning, and full calibration.**

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

B. Before the first use following installation or reinstallation of the radiation therapy system, acceptance testing and commissioning must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45 and the manufacturer's specifications, unless a qualified medical physicist determines and documents that a specific recommendation of these reports is not warranted.

C. The registrant must establish, document, and implement full calibration procedures developed by a qualified medical physicist. Full calibration must include 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 must be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45 unless a qualified medical physicist determines and documents that a specific recommendation of these reports is not warranted.

D. For radiation therapy systems that include asymmetric jaws, multileaf collimation, or dynamic/virtual wedges, a qualified medical physicist must establish, document, and implement a calibration protocol. Protocol must include recommendations listed in "Quality Assurance of Medical Accelerators," prepared by AAPM Task Group 142 unless a qualified medical physicist determines and documents that a specific recommendation of this report is not warranted.

E. For linear accelerator-based robotic stereotactic radiosurgery systems, a qualified medical physicist must establish, document, and implement a calibration protocol. Protocol must include current recommendations listed in "Quality Assurance for robotic radiosurgery" prepared by AAPM Task Group 135 unless a qualified medical physicist determines and documents that a specific recommendation of this report is not warranted.

F. For tomotherapy systems a qualified medical physicist must establish, document, and implement a calibration protocol. Protocol must include current recommendations listed in "Quality Assurance of helical tomotherapy," prepared by AAPM Task Group 148 unless a qualified medical physicist determines and documents that a specific recommendation of this report is not warranted.

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

A. full calibration of radiation therapy systems 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, 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 may be validated with quality control check procedures against the criteria in this part.

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

Subpart 1. **Spot checks.**

A. The registrant must establish, document, and implement spot check procedures developed by a qualified medical physicist. Spot checks must be performed at intervals and within the tolerances not to exceed those specified in either "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy; AAPM report No. 46," prepared by Committee Task Group 40 or "Task Group 142 report: Quality Assurance of medical accelerators" unless a qualified medical physicist determines and documents that a specific recommendation of these reports is not warranted.

B. Registrants using IMRT:

(1) must establish, document, and implement spot check procedures developed by a qualified medical physicist in accordance with "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) must 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) must also be in accordance with the manufacturer's contractual specifications.

C. Registrants using linear accelerator-based robotic stereotactic radiosurgery, must establish, document, and implement spot check procedures developed by a qualified medical physicist in accordance with "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 checks must also be in accordance with the manufacturer's contractual specifications.

D. Registrants using helical tomotherapy must establish, document, and implement spot check procedures developed by a qualified medical physicist in accordance with "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 checks must also be in accordance with the manufacturer's contractual specifications.

Subp. 2. **Tolerances.**

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

(1) the registrant and qualified medical physicist must be immediately notified if any parameter is not within its acceptable tolerance. The radiation therapy system may 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 quality control check parameters appear to be within their acceptable range, the quality control check must be reviewed and signed by either the registrant or qualified medical physicist within seven working days; and

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

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

Subp. 3. **Safety checks.** To satisfy the requirement of this subpart, safety checks performed at intervals not to exceed one week, must ensure 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 the access doors, control console, and in the radiation therapy room;

D. viewing and audio systems; and

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

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

4733.0600 STEREOTACTIC RADIOSURGERY/STEREOTACTIC BODY RADIOTHERAPY.

In addition to the requirements in parts 4731.0520 to 4731.0535, registrants performing stereotactic radiosurgery or stereotactic body radiotherapy must follow the safety and quality assurance guidelines in AAPM Task Group 101 Report and the American Society for Radiation Oncology (ASTRO) report on "Quality and Safety

Consideration in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy," unless the qualified medical physicist determines and documents that a specific recommendation of these reports is not warranted.

4733.0800 ELECTRONIC BRACHYTHERAPY SYSTEMS.

Subpart 1. **Applicability.** Electronic brachytherapy systems are subject to the requirements of applicable parts of this chapter and are exempt from parts 4733.0500 to 4733.0510.

A. An electronic brachytherapy device that does not meet the requirements of part 4733.0800 must not be used for patient use.

B. An electronic brachytherapy device must only be utilized for human use applications specifically approved by the United States Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

Subp. 2. **Registrant's responsibilities for electronic brachytherapy systems.** In addition to the requirements in subpart 1, the 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 operable and 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.** In addition to applicable shielding and facility design requirements in parts 4733.0250 to 4733.0275, the treatment room must meet the following design requirements:

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

B. the electronic brachytherapy system must not be used for patient irradiation unless the operator can maintain continuous observation of the patient;

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

D. for electronic brachytherapy systems operating at greater than 150 kV:

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

(2) 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. electrical safety for electronic brachytherapy systems must meet the following conditions:

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

(2) the high voltage transformer must be isolated from 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 appropriate safety labels warning personnel of potential electrical shock and heat-related injuries; and

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

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

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

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

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

F. the control panel, in addition to the displays required by other provisions in this part, 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 whether 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 will prevent 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 as short as 0.1 second;

(6) not operate if the exposure is set at zero; and

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

Subp. 4. **Training.** The 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. system-specific radiation safety requirements;

B. system operation;

C. clinical uses approved by the FDA;

D. emergency procedures, including an emergency drill; and

E. the registrant's quality assurance program.

Subp. 5. **Qualified medical physicist support.** The registrant must provide the services of a qualified medical physicist in facilities having electronic brachytherapy systems. The qualified medical physicist is responsible for the electronic brachytherapy and 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 appropriate periodic and day-of-use spot checks and review the data from those checks as required in subpart 10;

E. consult and review with the radiation oncologist or a licensed practitioner of the healing arts for the treatment planning, as needed;

F. perform calculation and assessments regarding patient treatments that 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.** The registrant must establish written operating procedures for brachytherapy activities that are located at the control console. If the control console is integral to the electronic brachytherapy system, the registrant must keep the required procedures where the operator is located during the system operation. The procedures must require that:

A. only individuals approved by the registrant, radiation safety officer, or qualified medical physicist may be present in the treatment room during treatment;

B. electronic brachytherapy systems may not be made available for use unless the requirements of this chapter have been met;

C. the electronic brachytherapy system is inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

D. the electronic brachytherapy system operator must prevent individuals from unshielded exposure by monitoring the position of all individuals in the treatment room during operation and all individuals entering the treatment room; and

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

Subp. 7. **Emergency procedures.** The registrant must develop, implement, and keep written emergency procedures at the control console for responding to an abnormal situation. These procedures must include:

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

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

C. instructions for notifying the radiation safety officer and physician if the patient's radiation exposure results in a medical emergency, injury, or death and instructions for informing the manufacturer and the commissioner of the event.

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

A. A qualified medical physicist and either a radiation oncologist or licensed practitioner of the healing arts who are trained in the operation and emergency response for the electronic brachytherapy system, must be physically present when all patient treatments occur.

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

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

D. When shielding is required, the registrant must use a survey meter to verify proper placement of the shielding before the initiation of treatment. Alternatively, a qualified medical physicist must designate shielding locations sufficient to meet the requirements of parts 4733.0300 to 4733.0315 for any individual, other than the patient, in the treatment room.

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 done for each electronic brachytherapy system:

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

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

C. Calibrating of the 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 recognized national professional association with expertise in electronic brachytherapy. In the absence of such a calibration protocol, the registrant must follow the manufacturer's calibration procedures.

E. The 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 responsible for performing the calibration.

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

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

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

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

(3) after each x-ray tube installation.

B. The registrant must perform required periodic spot checks according to procedures established by a qualified medical physicist.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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;

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

(5) for radiation output spot checks:

(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. The registrant must perform acceptance testing on the treatment planning system of electronic brachytherapy related computer systems in accordance with the current published recommendations from a recognized national professional association with expertise in electronic brachytherapy, when available. In the absence of acceptance testing protocol published by a national association, the manufacturer's acceptance testing protocol must be followed.

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

(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, as appropriate, at the time of commissioning.

D. Prior to each patient treatment regimen, the parameters for the treatment must be evaluated and approved by the licensed practitioner of the healing arts and the qualified medical physicist for correctness through means independent of those used for the determination of the parameters.

4733.0805 MOBILE ELECTRONIC BRACHYTHERAPY SERVICE.

In addition to other applicable parts of this chapter, the 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;

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

C. perform, at each location on each day of use, all of the required spot checks in this part to ensure proper operation of the system.

4733.0900 SIMULATION SYSTEM REQUIREMENTS.

Subpart 1. **Generally.** Equipment and mechanical parameters of any simulation system are subject to the same rigorous quality control checks as the treatment unit. The various simulator system motions should be as accurate as those of the radiation therapy system. In addition, all the elements in the simulator system needed for good image quality must be tested, reviewed, and evaluated.

Subp. 2. **Equipment performance evaluations.**

A. The registrant must establish, document, and implement equipment performance procedures, including acceptance testing and periodic verification of system performance developed by a service provider qualified according to chapter 4732 or a qualified medical physicist; and

B. for a radiographic simulation system, be performed, at intervals not to exceed 24 months, in accordance with "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy; AAPM report No. 46," prepared by Committee Task Group 40 unless a qualified service provider determines and documents that a specific recommendation of these reports is not warranted; or

C. for a computed tomography simulation system, be performed, at intervals not to exceed 12 months, in accordance with "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" unless a qualified medical physicist determines and documents that a specific recommendation of these reports is not warranted. A dose index (CTDI) must be completed using a CT dosimetry phantom.

Subp. 3. **Operators.** The simulation system must only be operated by a qualified individual who:

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

B. has been trained by the manufacturer or equivalent;

C. has been trained in appropriate positioning and anatomy for applicable procedures; and

D. has received training regarding the operating and emergency procedures for the simulation equipment.

Subp. 4. **Operating procedures.** In addition to the requirements in part 4733.0210, subpart 4, item C, the procedures must include:

A. a current protocol or technique that specifies the conditions of operation and the number of images or scans per examination;

B. procedures for personal protective garment use if individuals 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.

Simulation equipment operators may operate a simulation imaging device only if it is an integral part of the therapy procedures for treatment but are prohibited from operating any imaging device for diagnostic purposes unless they have met the requirements in Minnesota Statutes, section 144.121, subdivision 5.