Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 42
"Registration and Safety Requirements for Therapeutic Use of Radiation Machines, Particle Accelerators for Nonhuman Use, and Analytical X-Ray Equipment"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 136C.3, 136C.4, 136C.5, 136C.10, and 136C.14

State or federal law(s) implemented by the rulemaking: Iowa Code sections 136C.3, 136C.4, 136C.5, 136C.10, and 136C.14

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 4, 2025 10 to 10:30 a.m.	Microsoft Teams Meeting ID: 256 572 060 444 0 Passcode: SG2Vc96j

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed chapter is one of eight rule chapters pertaining to radiologic health matters regulated by the Department. This proposed chapter and the seven others underwent a fulsome review as a part of the Red Tape Review process laid out in Executive Order 10. As a result of this review, restrictive terms were removed, areas that were duplicative were combined or eliminated, and editorial updates were made to reflect current policies and procedures. This proposed chapter establishes the requirements of registrants, or people seeking to be certified, for the use of therapeutic radiation machines.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

There are not any expected costs for this proposed rulemaking beyond administrative costs for the Department.

- **Classes of persons that will benefit from the proposed rulemaking:**

Those seeking to be certified to use therapeutic radiation machines will benefit from clarified rules.

2. **Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:**

- **Quantitative description of impact:**

No quantitative impact is expected.

- **Qualitative description of impact:**

Persons seeking to be certified for use of therapeutic radiation machines will benefit from clarified and updated rules.

3. **Costs to the State:**

- **Implementation and enforcement costs borne by the agency or any other agency:**

Enforcement costs are incurred by the Department as a part of its administrative purview as required by the Iowa Code.

- **Anticipated effect on State revenues:**

This rulemaking is not expected to have any impact on State revenues.

4. **Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:**

Certification for the use of therapeutic radiation machines is required by Iowa Code chapter 136.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

Not applicable.

6. **Alternative methods considered by the agency:**

- **Description of any alternative methods that were seriously considered by the agency:**

Not applicable.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

Not applicable.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

This proposed rulemaking is not expected to have an impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 42 and adopt the following **new** chapter in lieu thereof:

CHAPTER 42
REGISTRATION AND SAFETY REQUIREMENTS FOR THERAPEUTIC USE OF RADIATION MACHINES, PARTICLE ACCELERATORS FOR NONHUMAN USE, AND ANALYTICAL X-RAY EQUIPMENT

641—42.1(136C) General provisions. The provisions of this chapter establish the requirements of a registrant for the use of therapeutic radiation machines.

42.1(1) The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training and experience criteria established by rule 641—42.5(136C).

42.1(2) Unless otherwise specified in rule 641—41.3(136C), all registrants are subject to the applicable requirements of 641—Chapters 37 through 40.

641—42.2(136C) Definitions. The definitions provided in 641—Chapters 37 and 40 may also apply to the provisions of this chapter. Additionally, the following definitions set forth below are specific to this chapter.

"Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Added filtration" means any filtration that is in addition to the inherent filtration.

"Analytical X-ray equipment" means equipment used for X-ray diffraction or fluorescence analysis.

"Analytical X-ray system" means a group of components utilizing X-rays or gamma rays to determine the elemental composition or to examine the microstructure of materials.

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

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

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

"Cold pasteurization" means the process of using radiation for destroying disease-causing microorganisms in commercial products.

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

"Dose monitor unit" or *"DMU"* means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

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

"Fail-safe characteristics" means a design feature that causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

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

"Filter" means material placed in the useful beam to change beam quality or its intensity profile in therapeutic radiation machines.

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Iowa approved" means recognized or accepted by the department as meeting the training and experience requirements established by the Mammography Quality Standards Act as amended to August 1, 2025, CFR, or any additional criteria set forth by the department. This may include but is not limited to formal approval by the department based on documentation of education, training, certification, and clinical experience.

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

"Local components" means part of an analytical X-ray system and includes X-ray areas that are struck by X-rays, such as radiation source housings, port and shutter assemblies, collimators,

sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

"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 one million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

"Monitor unit" or *"MU"* means the same as "dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy, intensity modulation, and rotational therapy.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For X-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"Normal operating procedures" means step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures, which are related to radiation safety.

"Open-beam configuration" means an analytical X-ray system in which an individual could accidentally place some part of the individual's body in the primary beam path during normal operation.

"Periodic quality assurance check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73-109, Jan/Feb 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Agency on Radiation Units and Measurements, September 15, 1984.

"Primary beam" means radiation that passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

"Radiation field" means the same as "useful beam."

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

"Radiation therapy physicist" means an individual qualified in accordance with 641—subrule 41.5(3).

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Self-shielded particle accelerator" means a particle accelerator with the accelerator installed in an enclosure independent of the existing architectural structures, except the floor on which it may be placed. The enclosure must have been evaluated by a qualified expert and that evaluation approved by an appropriate regulatory authority through a device evaluation. The self-shielded accelerator is intended to contain at least that portion of material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. A particle accelerator used within a shielded part of a building, or which may temporarily or occasionally incorporate portable shielding, is not a self-shielded particle accelerator.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Shielded facility" means an accelerator facility where shielding is required to be constructed on site in order to assure compliance with the requirements of 641—Chapter 40 or where shielding supplied with the accelerator has been evaluated by qualified experts and that evaluation approved by an appropriate regulatory authority through a device evaluation.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Target" means that part of an X-ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Tenth-value layer" or *"TVL"* means the thickness of a specified material that attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

"Therapeutic radiation machine" means X-ray or electron-producing equipment designed and used for external beam radiation therapy.

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

641—42.3(136C) Registration or license requirements. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines, except as authorized by a registration issued in accordance with rule 641—37.8(136C). Each therapeutic radiation machine shall be registered in accordance with the requirements of 641—subrule 37.8(2).

641—42.4(136C) General administrative requirements for facilities using therapeutic radiation machines.

42.4(1) Administrative controls.

a. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the department.

b. The registrant or the registrant's agent shall ensure that the requirements of this chapter are met in the operation of the therapeutic radiation machine(s).

42.4(2) A therapeutic radiation machine that does not meet the provisions of these regulations cannot be used for irradiation of patients unless authorized by the department.

641—42.5(136C) Training for external beam radiation therapy authorized users.

42.5(1) The registrant for any therapeutic radiation machine subject to rules 641—42.15(136C) and 641—42.16(136C) shall require the authorized user to be a physician who:

a. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology";

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology and has completed all of the following:

(1) 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit;

(2) 500 hours of supervised work experience;

(3) A minimum of three years of supervised clinical experience.

42.5(2) To satisfy the requirement for instruction in paragraphs 42.5(1)*"a"* and *"b,"* the classroom and laboratory training shall include all of the following:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of ionization radiation; and

d. Radiation biology.

42.5(3) To satisfy the requirement for supervised work experience in subparagraph 42.5(1) *"b"*(2), training shall be under the supervision of an authorized user and shall include all of the following:

a. Reviewing the full calibration measurements and periodic quality assurance checks;

b. Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;

c. Using administrative controls to prevent a reportable radiation incident as described in 641—subrule 37.13(3);

d. Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console;

e. Checking and using radiation survey meters.

42.5(4) To satisfy the requirement for a period of supervised clinical experience, training shall include all of the following:

a. One year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association;

b. An additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress as well as consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation;

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

42.5(5) Notwithstanding the requirements of rule 641—42.5(136C), the registrant for any therapeutic radiation machine subject to rules 641—42.15(136C) and 641—42.16(136C) may also submit the training of the prospective authorized user physician for department review.

42.5(6) A physician cannot act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the registrant.

641—42.6(136C) Training for radiation therapy physicist. The registrant for any therapeutic radiation machine subject to rules 641—42.15(136C) and 641—42.16(136C) shall require the radiation therapy physicist to:

42.6(1) Be Iowa approved as defined in this chapter.

a. Medical physicists that are Iowa approved for radiation therapy may perform only radiation therapy services in the area of calibration and compliance surveys of external beam radiation therapy units or additional radiation therapy services as deemed appropriate by the department;

b. Medical physicists wishing to perform services other than those outlined in rule 641—42.3(136C) must be registered with the department under the provisions of rule 641—37.8(136C) as a radiation machine service provider, whether as an individual, as part of a corporation, or as any other entity included in the definition of "person" under 641—Chapter 37.

c. A medical physicist cannot perform any services unless such services are specifically listed on the Iowa approval or radiation machine provider notice issued by the department.

42.6(2) Be certified by the American Board of Radiology in, at a minimum, one of the following:

a. Therapeutic radiological physics;

b. Roentgen-ray and gamma-ray physics;

c. X-ray and radium physics;

d. Radiological physics; or

e. Therapeutic medical physics.

42.6(3) Be certified by the American Board of Medical Physics in radiation oncology physics; or

42.6(4) Be certified by the Canadian College of Physicists in Medicine; or

42.6(5) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics and have completed one year of:

a. Full-time training in therapeutic radiological physics;

b. Full-time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in rule 641—42.14(136C) under the supervision of a radiation therapy physicist during the year of work experience.

641—42.7(136C) Qualifications of operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and hold a current permit to practice in radiation therapy as a radiation therapist under the provisions of 641—Chapter 38.

42.7(1) The permit holder shall make the permit available at the individual's place of employment.

42.7(2) If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

641—42.8(136C) Written safety procedures and rules. Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

42.8(1) The operator shall be able to demonstrate familiarity with these rules.

42.8(2) All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

641—42.9(136C) Exposure to the useful beam. Individuals cannot be exposed to the useful beam, except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing arts purposes.

641—42.10(136C) Records of visiting authorized users. Notwithstanding the provisions of rule 641—42.5(136C), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under all of the following conditions:

42.10(1) The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

42.10(2) The visiting authorized user meets the requirements of rule 641—42.5(136C);

42.10(3) The registrant maintains copies of all records for five years from the date of the last visit.

641—42.11(136C) Information and maintenance record and associated information. The registrant shall maintain all the following information in a separate file or package for each therapeutic radiation machine for inspection by the department:

42.11(1) Report of acceptance testing.

42.11(2) Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by rule 641—37.12(136C), as well as the name(s) of person(s) who performed such activities.

42.11(3) Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services.

42.11(4) Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

42.11(5) Records of training specified in rule 641—42.5(136C).

641—42.12(136C) Record retention. All records required by rule 641—42.5(136C) shall be retained until disposal is authorized by the department unless another retention period is specifically authorized.

42.12(1) All required records shall be retained in an active file from at least the time of generation until the next department inspection.

42.12(2) Any required record generated before the last department inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the department authorizes final disposal.

641—42.13(136C) Written directives. Each registrant shall meet all of the following.

42.13(1) *Written directive.* A written directive must be dated and signed by an authorized user prior to the administration of radiation.

a. If, because of the patient's condition, a delay in the order to provide a written revision to an existing directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision.

b. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the external beam dose or the next fractional dose.

d. The registrant shall retain a copy of the written directive for three years.

42.13(2) *Procedures for administration.* The registrant shall have written procedures that provide all of the following information:

a. Prior to the administration of each course of radiation treatment, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

b. Each administration is in accordance with the written directive;

c. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives by completing all of the following:

(1) Checking both manual and computer-generated dose calculations to verify that they are correct and in accordance with the written directive;

(2) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

d. Any unintended deviation from the written directive is identified and evaluated and appropriate action is taken;

e. The registrant retains a copy of the procedures for administrations for the duration of the registration.

641—42.14(136C) General technical requirements for facilities using therapeutic radiation machines.

42.14(1) *Protection surveys.*

a. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months.

b. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist.

c. The survey shall be performed with the therapeutic radiation machine in a "BEAM-ON" condition using the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation. The survey must verify all of the following:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 37.11(3);

(2) Radiation levels in unrestricted areas do not exceed the limits specified in 641—subrule 37.11(11). In addition to the requirements of subrule 42.14(1), a radiation protection survey shall also be performed prior to any subsequent medical use and at the following frequencies:

1. After making any change in the treatment room shielding;

2. After making any change in the location of the therapeutic radiation machine within the treatment room;

3. After relocating the therapeutic radiation machine;

4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

d. The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations.

e. The survey record shall also include all of the following:

(1) The date of the measurements;

(2) The reason the survey is required;

(3) The manufacturer's name, model number, and serial number of the therapeutic radiation machine;

(4) The instrument(s) used to measure radiation levels;

(5) A plan of the areas surrounding the treatment room that were surveyed;

(6) The measured dose rate at several points in each area, expressed in microsieverts or millirems per hour;

(7) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area;

(8) The signature of the individual responsible for conducting the survey.

f. If the results of the surveys required by subrule 42.14(1) indicate any radiation levels in excess of the respective limit specified in 641—subrule 37.11(3), the registrant shall lock the control in the "OFF" position and not use the unit, except under either of the following conditions:

(1) If operation is necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding;

(2) Until the registrant has received a specific exemption in writing from the department.

42.14(2) *Modification of radiation therapy unit or room before beginning a treatment program.*

a. Survey radiation levels. If the survey required by subrule 42.14(1) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—subrule 37.11(11) before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—subrule 37.11(11);

(2) Perform the survey required by 641—paragraph 37.11(12)*"a"* again; and

(3) Include in the report the results of the initial survey a description of the modifications made and the results of the second survey; or

(4) Request and receive written authorization from the department that authorizes radiation levels in unrestricted areas greater than those permitted by 641—subrule 37.11(11).

b. Dosimetry equipment. The registrant shall have a calibrated dosimetry system available for use.

(1) The system shall have been 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).

(2) The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

c. Calibration. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60.

(1) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements.

1. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph 42.14(2)*"b."*

2. This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration.

3. The quality assurance check system may be the same system used to meet the requirement in paragraph 42.14(2)*"b."*

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the following:

1. The date;

2. The model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraph 42.14(2)*"b"*;

3. The correction factors that were determined;

4. The names of the individuals who performed the calibration, intercomparison, or comparison and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to rule 641—42.3(136C) shall furnish a copy of the records required in subrules 42.11(1) and 42.11(2) to the department within 30 days following completion of the action that initiated the record requirement.

641—42.15(136C) Therapeutic radiation machines of less than 500 kV.

42.15(1) *Equipment requirements.*

a. Leakage radiation. When the X-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate cannot exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

(1) 5-50 kV systems. The leakage air kerma rate measured at any position five centimeters from the tube housing assembly cannot exceed 100 mrad (one mGy) in any one hour.

(2) >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction cannot exceed one rad (one cGy) in any one hour.

1. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters.

2. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly cannot exceed 30 rad (30 cGy) per hour.

(3) For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in subrule 42.15(1) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility and made available for inspection by the department.

b. Permanent beam-limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

c. Adjustable or removable beam-limiting devices. All adjustable or removable beam-limiting devices, diaphragms, cones, or blocks cannot transmit more than 5 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 shall be indicated by a light beam.

d. Filter system. The filter system shall be so designed to meet all of the following:

(1) Filters cannot be accidentally displaced at any possible tube orientation;

(2) For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

(3) The air kerma rate escaping from the filter slot cannot exceed one rad (one cGy) per hour at one meter under any operating conditions; and

(4) Each filter shall be marked as to its material of construction and its thickness.

e. Tube immobilization.

(1) The X-ray tube shall be mounted in a manner that it cannot accidentally turn or slide with respect to the housing aperture.

(2) The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

f. Source marking. The tube housing assembly shall be marked in a manner that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

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

h. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

(1) A timer that has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

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

(3) The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation;

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

(5) The timer cannot permit an exposure if set at zero;

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

(7) Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

i. Control panel functions. The control panel, in addition to the displays required by other provisions in paragraph 42.15(2)*"i,"* shall have:

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

(2) An indication of whether X-rays are being produced;

(3) Means for indicating X-ray tube potential and current;

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

(5) A locking device that will prevent unauthorized use of the therapeutic radiation machine; and

(6) For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

j. Multiple tubes. When a control panel may energize more than one X-ray tube:

(1) It shall be possible to activate only one X-ray tube at any time;

(2) There shall be an indication at the control panel identifying which X-ray tube is activated;

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

k. Target-to-skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

l. Shutters. Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds after the X-ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly.

(1) In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel.

(2) An indication of shutter position shall appear at the control panel.

m. Low filtration X-ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present to indicate that the dose rate is very high.

42.15(2) *Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV.* In addition to shielding adequate to meet requirements of rule 641—42.17(136C), the treatment room shall meet the following design requirements.

a. Aural communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel.

b. Viewing systems. Provision shall be made to permit continuous observation of the patient during irradiation, and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine cannot be used for patient irradiation unless at least one viewing system is operational.

c. Additional requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

(1) All protective barriers shall be fixed, except for entrance doors or beam interceptors;

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

(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it cannot be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel;

(4) When any door referred to in subparagraph 42.15(2)*"c"*(3) is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one mGy (100 mrad) per hour.

d. Full calibration measurements. Full calibration of a therapeutic radiation machine subject to subrule 42.15(2) shall be performed by, or under the direct supervision of, a radiation therapy physicist.

e. Initial use. The first medical use following installation or reinstallation of the therapeutic radiation machine must be:

(1) At intervals not exceeding one year; and

(2) Before medical use under the following conditions:

1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled;

2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

f. Calibration. Notwithstanding the requirements of paragraph 42.15(2)*"d"*:

(1) Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and

(2) If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in paragraph 42.15(2)*"c."*

(3) To satisfy the requirements of paragraph 42.15(2)*"d,"* full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(4) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include all of the following:

1. The date of the calibration;
2. The manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X-ray tube;
3. The model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and
4. The signature of the radiation therapy physicist responsible for performing the calibration.

g. Periodic quality assurance checks. Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to this rule, that are capable of operation at greater than or equal to 50 kV.

(1) To satisfy the requirement of paragraph 42.15(2)*"g,"* quality assurance checks shall meet all of the following requirements:

1. The quality assurance checks shall be performed by the registrant in accordance with written procedures established by the radiation therapy physicist;
2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed.
3. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in subparagraph 42.15(2)*"f"*(1).
4. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in subparagraph 42.15(2)*"f"*(1), shall be stated.

(2) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

1. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in subparagraph 42.15(2)*"f"*(1);
2. The registrant shall use the dosimetry system described in subparagraph 42.14(2)*"c"*(2) to make the quality assurance check required in paragraph 42.15(2)*"g"*;
3. The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;
4. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to this rule are performed at intervals not to exceed one month;
5. Notwithstanding the requirements of numbered paragraphs 42.15(2)*"g"*(2)"3" and "4," the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required have been performed within the 30 days prior to administration.

(3) To satisfy the requirement of numbered paragraph 42.15(2)*"g"*(2)"4," safety quality assurance checks shall ensure proper operation of the following:

1. Electrical interlocks at each external beam radiation therapy room entrance;
2. The "BEAM-ON" and termination switches;

3. Beam condition indicator lights on the access door(s), on the control console, and in the radiation therapy room;

4. Viewing systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(4) The registrant shall maintain a record of each quality assurance check for three years. The record shall include all of the following:

1. The date of the quality assurance check;

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

3. The manufacturer's name, model number, and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine;

4. The signature of the individual who performed the periodic quality assurance check.

h. Operating procedures.

(1) Therapeutic radiation machines cannot be left unattended unless secured by means identified in paragraph 42.15(1)*"i"*;

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly cannot be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console;

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—subrule 37.11(11).

(6) The therapeutic radiation machine cannot be used for irradiation of patients unless the requirements of paragraph 42.15(2)*"d"* have been met.

i. Possession of survey instrument(s).

(1) Each facility location authorized to use a therapeutic radiation machine in accordance with rule this rule shall have at its disposal appropriately calibrated portable monitoring equipment.

(2) As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1,000 mrem (10 mSv) per hour.

(3) The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

641—42.16(136C) Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

42.16(1) *Equipment requirements;*

a. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters that is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), cannot 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. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

b. Except for the area defined in paragraph 42.16(1)*"a"* 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 cannot exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance.

c. Measurements shall be averaged over an area not exceeding 100 square centimeters.

d. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 as amended to August 1, 2025.

e. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraph 42.16(1)*"a"* for the specified operating conditions. Records of leakage radiation measurements shall be maintained and made available for inspection by the department.

42.16(2) *Leakage radiation through beam-limiting devices.*

a. Photon radiation. All adjustable or interchangeable beam-limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting device(s) cannot exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten-centimeter by ten-centimeter radiation field;

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

(1) A maximum of 2 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 shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(2) A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

42.16(3) *Measurement of leakage radiation.*

a. Photon radiation. Measurements of leakage radiation through the beam-limiting devices shall be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenth value layers of suitable absorbing material.

(1) In the case of overlapping beam-limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose.

(2) Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters.

b. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made:

(1) With the electron beam directed into the air and using a radiation detector that has an area up to but not exceeding one square centimeter and that is suitably protected against radiation that has been scattered from material beyond the radiation detector.

(2) Using one centimeter of water equivalent buildup material.

c. Filters/wedges. Each wedge filter that is removable from the system shall be clearly marked with an identification number.

(1) For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray).

(2) If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.

(3) If the absorbed dose rate information required by paragraph 42.16(3)*"h"* relates exclusively to operation with a field-flattening filter or beam-scattering foil in place, such filter or foil shall be removable only by the use of tools.

(4) For equipment manufactured after July 9, 1997, that utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam-scattering foils:

1. Irradiation cannot be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

2. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

3. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field-flattening filter(s), and interchangeable beam-scattering foil(s) in use;

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

d. Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X-ray stray radiation in the useful electron beam, absorbed dose at the surface during X-ray irradiation and stray neutron radiation in the useful X-ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601-2-1 as amended to August 1, 2025.

e. Beam monitors. All therapeutic radiation machines subject to this rule shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

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

(2) Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system.

(3) The detector and the system into which that detector is incorporated shall meet the following requirements:

1. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

2. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

3. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

(4) For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that:

1. The malfunctioning of one system cannot affect the correct functioning of the other system(s); and

2. The failure of any element common to both systems that could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

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

1. Maintain a reading until intentionally reset;

2. Have only one scale and no electrical or mechanical scale multiplying factors;

3. Utilize a design such that increasing dose is displayed by increasing numbers;

4. In the event of power failure, the beam monitoring information at the time of failure required in this paragraph is retrievable in at least one system for a 20-minute period of time.

f. Beam symmetry.

(1) Bent-beam linear accelerators with beam-flattening filter(s) subject to subrule 42.16(1) shall be provided with auxiliary device(s) to monitor beam symmetry;

(2) The device(s) referenced in paragraph 42.16(3)*"f"* shall be able to detect field asymmetry greater than 10 percent and shall be configured to terminate irradiation if field asymmetry cannot be maintained at 10 percent or less.

g. Selection and display of dose monitor units. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

(1) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

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

(3) Irradiation cannot be possible until a new selection of a number of dose monitor units has been made at the treatment control panel.

h. Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in paragraph 42.16(3)*"e"* may form part of this system.) In addition:

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

(2) If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided that terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

(3) If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent 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 (four Gy); and

(4) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in paragraph 42.16(3)*"g"* for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the department.

i. Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

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

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

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

k. Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel.

(1) Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions.

(2) If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

l. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

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

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

(3) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

m. Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation cannot be possible until a selection of radiation type (X-rays or electrons) has been made at the treatment control panel;

(2) The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

(3) An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

(4) An interlock system shall be provided to prevent irradiation with X-rays, except to obtain a verification image, when electron applicators are fitted;

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X-ray therapy are fitted; and

(6) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

n. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(1) Irradiation cannot be possible until a selection of energy has been made at the treatment control panel;

(2) The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

(3) Irradiation cannot be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(4) For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 as amended to August 1, 2025.

o. Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(1) Irradiation cannot be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(2) The mode of operation shall be displayed at the treatment control panel;

(3) An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;

(4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(5) Moving beam radiation therapy shall 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 shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation or one centimeter 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 shall differ by less than 5 percent from the dose monitor unit value selected.

3. An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy.

4. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units that are capable of both clockwise and counterclockwise moving beam radiation therapy.

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

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by paragraph 42.16(3)*"i"*;

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

A. Occurs during stationary beam radiation therapy; or

B. Does not start or stop during moving beam radiation therapy unless such stoppage is a preplanned function.

p. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of rule 641—42.17(136C), the following design requirements are made.

(1) All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) In addition to other requirements specified in 641—paragraph 40.4(19)*"c,"* the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and whether activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced;

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

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

r. Aural communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine cannot be used for irradiation of patients unless continuous two-way aural communication is possible.

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

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

u. Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraph 37.11(11)*"a,"* interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

v. Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power, including radiation and mechanical motion.

(1) This switch is in addition to the termination switch required by paragraph 42.16(3)*"j."*

(2) All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

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

x. Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above ten MV prior to machining, removing, or working on therapeutic radiation machine components that may have become activated due to photoneutron production.

y. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with rule 641—42.16(136C) shall have at its disposal appropriately calibrated portable monitoring equipment.

(1) As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range one mrem (ten μSv) per hour to 1,000 mrem (ten mSv) per hour.

(2) The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

z. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by subparagraph 42.16(3)*"bb"*(1) and protection surveys required by subrule 42.16(1).
2. Supervision and review of dosimetry.
3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use.
4. Quality assurance, including quality assurance check review required by paragraph 42.15(2)*"g."*
5. Consultation with the authorized user in treatment planning as needed.
6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by paragraph 42.15(2)*"e"* shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

aa. Operating procedures. No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes.

(1) Therapeutic radiation machines cannot be made available for medical use unless the requirements of this chapter have been met;

(2) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(3) When adjustable beam-limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(4) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

(5) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

bb. Acceptance testing, commissioning, and full calibration measurements. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to rule this rule shall be performed by, or under the direct supervision of, a radiation therapy physicist.

(1) Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45 as amended to August 1, 2025, and the manufacturer's contractual specifications and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(2) Full calibration shall include measurement of all parameters listed in Appendix A of 641—Chapter 41 and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47" as amended to August 1, 2025, prepared by Radiation Therapy Task Group 45. Although it cannot be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this department.

(3) The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits at the following frequencies:

1. Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multienergy or multimode capabilities or both shall only require measurements for those modes or energies that are not within their acceptable range; and

2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement, or modification does not affect all modes or energies, measurements shall be performed on the affected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in paragraph 42.16(3)*"z."*

(4) The registrant shall use the dosimetry system described in paragraph 42.14(2)*"b"* to measure the radiation output for one set of exposure conditions.

(5) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include all of the following:

1. The date of the calibration;

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

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

4. The signature of the radiation therapy physicist responsible for performing the calibration.

cc. Periodic quality assurance checks. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to these rules at intervals as specified in Appendix A of this chapter.

(1) To satisfy the requirement of paragraph 42.14(2)*"g,"* quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix A. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months.

(2) The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system to make the periodic quality assurance checks required in paragraph 42.14(2)*"g."*

(3) The registrant shall perform periodic quality assurance checks in accordance with procedures established by the radiation therapy physicist.

(4) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine cannot be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days;

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

(5) Therapeutic radiation machines subject to this rule shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week or at longer intervals as recommended by the manufacturer.

(6) Safety quality assurance checks shall ensure proper operation of all of the following:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the "BEAM-ON," interrupt and termination switches;

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

4. Viewing systems;

5. Aural systems;

6. Electrically operated treatment room door(s) from inside and outside the treatment room;

7. At least one emergency power cutoff switch.

A. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis.

B. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

(7) The registrant shall promptly repair any system that is not operating properly.

(8) The registrant shall maintain a record of each quality assurance check for three years. The record shall include all of the following:

1. The date of the quality assurance check;

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

3. The manufacturer's name, model number, and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine;

4. The signature of the individual who performed the periodic quality assurance check.

641—42.17(136C) Shielding and safety design requirements.

42.17(1) Each therapeutic radiation machine subject to shall be provided with such primary or secondary barriers as are necessary to ensure compliance with rule 641—37.11(136C).

42.17(2) Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for department approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix B of this chapter.

641—42.18(136C) Calibration of survey instruments.

42.18(1) The registrant shall ensure that the survey instruments used to show compliance with rule 641—42.16(136C) have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

42.18(2) To satisfy the requirements of this rule, the registrant shall:

a. Calibrate all required scale readings up to 1,000 mrem (ten mSv) per hour with an appropriate radiation source that is traceable to the NIST;

b. Calibrate at least two points on each scale to be calibrated. These points should be at approximately 1/3 and 2/3 of full scale;

c. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent;

d. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

42.18(3) The registrant shall retain a record of each calibration required in this rule for three years. The record shall include the following:

a. A description of the calibration procedure;

b. A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

42.18(4) The registrant may obtain the services of individuals licensed by this department, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required in rule this rule shall be maintained by the registrant.

641—42.19(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use.

1. This rule establishes procedures for the registration or licensing and the use of particle accelerators.

2. Unless specifically required otherwise, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 through 40.

42.19(1) *Registration or license requirements.* No person shall receive, possess, use, transfer, own, or acquire a particle accelerator, except as authorized in a registration or license issued by the department and unless the following requirements are met:

a. Each accelerator shall be registered in accordance with the requirements of 641—subrule 37.8(2).

b. Accelerator facilities whose operations result in nuclear transformations that produce, or are likely to produce, radioactive material more than the exempt quantities and concentrations listed in Appendices C and D of 641—Chapter 39 are authorized by the issuance of a radioactive material license. Accelerator facilities that produce or are likely to produce radioactive material less than the exempt quantities and concentrations shall be authorized by registration.

c. For accelerator facilities required to be licensed, those operations that would require personnel monitoring due to the presence of radioactive material shall be performed only by a specific licensee. Such operations would normally include installation, testing and maintenance, and routine operations.

42.19(2) *General requirements for the issuance of a registration or license for particle accelerators.* Along with the requirements of this chapter, an application for use of a particle accelerator will be approved only if the department determines all of the following:

a. The applicant is qualified to use the accelerator in question for the purpose requested and in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the registration or license will not be detrimental to the health and safety of the public;

d. The applicant satisfies any applicable requirements set forth in this chapter;

e. The applicant has appointed a radiation safety officer responsible for the day-to-day operation of the radiation safety program;

f. The applicant and the applicant's staff have experience in the use of particle accelerators and training sufficient for application to its intended uses;

g. The applicant has an adequate training program for operators of particle accelerators.

42.19(3) *Personnel monitoring.* In addition to the requirements of 641—subrule 40.4(13) personnel monitoring shall be provided to and used by all individuals entering any area for which interlocks are required unless a survey of the area has determined that radiation levels are below that of a high radiation area and at least one of the following conditions is met:

a. Power to an accelerator cannot be activated; or

b. An accelerated beam cannot be directed to the area.

42.19(4) *Operations.*

a. No registrant shall permit any individual to act as an operator of a particle accelerator until all of the following conditions have been met:

(1) The individual has been instructed in radiation safety and has demonstrated an understanding of that instruction;

(2) The individual has received copies of, and instruction in, this rule, the applicable requirements of the pertinent registration, and the registrant's operating and emergency procedures and has demonstrated understanding of that instruction;

(3) The individual has demonstrated competence to use the particle accelerator, related equipment, and survey instruments that will be employed.

b. The radiation safety officer or radiation safety committee, if applicable, shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

c. Along with the audit required in 641—paragraph 37.11(2)*"c,"* each operator's performance during an actual accelerator operation shall be audited by the radiation safety officer or designee at intervals not to exceed six months.

(1) If an operator has not participated in an accelerator operation for more than six months since the last audit, the individual's performance shall be observed and recorded at the first opportunity the individual participates in an accelerator operation.

(2) Records of the audits shall be maintained by the registrant and made available for inspection by the department for three years from the date of the audit.

d. Operators of particle accelerators used for industrial radiography shall meet the requirements of subrule 42.19(2).

42.19(5) *Shielding and safety design requirements.* A department-qualified expert shall be consulted in the design of a particle accelerator installation and shall perform a radiation survey when the accelerator is first capable of producing radiation.

a. Each particle accelerator installation shall be provided with the primary and secondary barriers necessary to ensure compliance with 641—subrules 37.11(3) and 37.11(11).

b. In addition to the requirements of this chapter, shielded facilities or self-shielded particle accelerators shall meet all of the following requirements:

(1) Authorization, through issuance of a construction permit, shall be granted following review of the initial application, including the shielding design, physical plant and site specifications, and the applicant's proposed equipment, uses, and workloads;

(2) For a shielded facility, the applicant shall submit an evaluation of the shielding design completed by a qualified expert. For a self-shielded particle accelerator, submission of an evaluation of a shielding design is not required if an evaluation has been performed by an appropriate regulatory authority. In such cases, the applicant may reference that evaluation. A copy of any shielding design evaluation shall be maintained by the applicant and made available to the department upon request;

(3) Authorization for installation and testing of an accelerator shall be given only after a determination of adequacy of testing protocols, testing safety procedures, staff training, and radiation detection instrumentation has been made;

(4) Operational use of an accelerator shall be authorized only after the department determines that all criteria specified in subrule 42.19(2) have been met.

42.19(6) *Particle accelerator controls and interlock systems.* Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified, easily discernible, and located outside the high radiation area.

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

b. Each safety interlock shall be on a circuit that allows it to operate independently of all other safety interlocks.

c. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

d. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, subsequently, at the main control console.

e. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

42.19(7) *Warning devices.* Each location designated as a high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate only when radiation is being produced.

a. Each high radiation area shall have an audible warning device that shall be activated for 15 seconds prior to the possible creation of high radiation in the area. Such warning device shall be clearly discernible in all high radiation areas.

b. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 641—subrule 37.11(20).

42.19(8) *Operating and emergency procedures.*

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

b. The safety interlock system shall not be used to turn off the accelerator beam, except in an emergency.

c. All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three months. Records of such tests shall be maintained at the accelerator facility and made available for inspection by the department for three years.

d. All incidents in which the interlock system fails to operate properly or where the operation is terminated by the interlock system shall be investigated and reported to the radiation safety officer or the radiation safety committee, if applicable. Documentation shall be maintained and made available for inspection by the department for three years.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) Authorized by the radiation safety officer and the radiation safety committee, if applicable;

(2) Recorded in a permanent log and a notice posted at the accelerator control console; and

(3) Terminated as soon as possible.

f. The registrant's operating and emergency procedures shall include all of the following:

(1) Operation and safety instructions on the accelerator(s) to be used;

(2) Methods for controlling access to restricted areas;

(3) Methods and occasions for locking and securing sources of radiation;

(4) Use of personnel monitoring equipment;

(5) The procedure for notifying proper personnel in the event of an accident;

(6) Maintenance of records;

(7) Inspections and maintenance of the accelerator;

(8) Steps to be taken in the case of an emergency.

g. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

42.19(9) *Radiation monitoring requirements.* A radiation protection survey shall be performed and documented by a qualified expert when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

a. Accelerator facilities shall survey with a radiation detection instrument at intervals not to exceed every 12 months. Records of this survey shall be maintained and made available for inspection by the department for three years.

b. Accelerator facilities registered or licensed pursuant to this chapter shall survey for removable contamination at intervals not to exceed six months.

c. Each time removable shields on self-shielded particle accelerators are opened, a visual survey of the shielding must be performed to observe physical damage.

(1) In addition, when these shields are returned to the closed position, a physical radiation survey shall be conducted upon initial reactivating of the accelerator.

(2) Records of this survey shall be maintained and made available for inspection by the department review for three years.

d. Accelerator facilities registered or licensed pursuant to this chapter shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation areas.

e. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

f. Upon installation, all area monitoring equipment shall be tested to ensure proper operation under operating conditions of the particle accelerator. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

g. Whenever applicable, accelerator facilities registered or licensed pursuant to this chapter shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

h. All surveys shall be made in accordance with the written procedures established by the radiation safety officer or a qualified expert.

i. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for and made available for inspection by the department.

42.19(10) *Radiation safety officer (RSO).*

a. Each registrant shall appoint a radiation safety officer who meets the following requirements:

(1) Possesses a high school diploma or a certificate of high school equivalency based on the GED test;

(2) Documents at least two years of radiation protection experience.

b. The specific duties of the RSO include but are not limited to the following:

(1) Establishing, reviewing, and overseeing operating, emergency, and ALARA procedures to ensure that the procedures are current and are in compliance with these rules;

(2) Overseeing and approving all phases of the training program for accelerator operators to ensure appropriate and effective radiation protection practices are taught;

(3) Ensuring that required radiation surveys are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

(4) Ensuring that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by rules 641—37.11(136C) and 641—37.14(136C);

(5) Ensuring that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

(6) Investigating and reporting to the department each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules; additionally, investigating and reporting each theft or loss of source(s) of radiation to determine the cause of such events and to take steps to prevent its recurrence;

(7) Ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures, including adequate training and experience as required by this chapter.

(8) Assuming control and having the authority to institute corrective actions, including shutdown of operations when necessary, in emergency situations or unsafe conditions;

(9) Maintaining records as required by this chapter;

(10) Ensuring the proper storing, labeling, and use of the accelerator;

(11) Ensuring that proper inspection and maintenance programs are performed as required by this chapter;

(12) Ensuring that personnel are complying with these rules as well as the operating and emergency procedures.

641—42.20(136C) Radiation safety requirements for analytical X-ray equipment. This rule provides special requirements for analytical X-ray equipment. The requirements of these rules are in addition to, and not in substitution for, 641—Chapters 37, 38, 39, and 40.

1. No person shall receive, possess, use, transfer, own, or acquire an analytical X-ray device except as authorized by a registration issued in accordance with rule 641—37.8(136C).

2. Each analytical X-ray device shall be registered in accordance with the requirements of 641—subrule 37.8(2).

42.20(1) *Equipment requirements.*

a. Safety device. A device that prevents the entry of any portion of an individual's body into the primary X-ray beam path or that causes the beam to be shut off upon entry into its path are required on all open-beam configurations. A registrant or licensee may apply to the department for an exemption from the requirement of a safety device. Such application shall include all of the following:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used;

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to ensure that operators and others in the area will be informed of the absence of safety devices.

b. Warning devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of the following:

1. X-ray tube "on-off" status located near the radiation source housing if the primary beam is controlled in this manner; or

2. Shutter "open-closed" status located near each port on the radiation source housing if the primary beam is controlled in this manner.

(2) An easily visible warning light labeled with the words "X-RAY ON" or words having a similar intent shall be located:

1. Near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized; or

2. In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after [the effective date of these rules], warning devices shall have fail-safe characteristics.

c. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

d. Labeling. All analytical X-ray equipment shall be labeled with a readily discernible sign(s) bearing the radiation symbol and the words:

(1) "CAUTION—HIGH INTENSITY X-RAY BEAM" or words having a similar intent on the X-ray source housing; and

(2) "CAUTION—RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent near any switch that energizes an X-ray tube if the radiation source is an X-ray tube; or

(3) "CAUTION—RADIOACTIVE MATERIAL" or words having a similar intent on the source housing if the radiation source is a radionuclide.

e. Shutters. On open-beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

f. Radiation source housing. Each radiation source housing shall be subject to the following requirements:

(1) Each X-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled;

(2) Each radioactive source housing or port cover, or each X-ray tube housing, shall be constructed so that with all shutters closed the radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing X- ray tubes, this limit shall be met at any specified tube rating.

g. Generator cabinet. Each X-ray generator shall be supplied with a protective cabinet that limits leakage radiation measured at a distance of five centimeters from its surface so that it is not capable of producing a dose in excess of 0.25 millirem (2.5 mSv) in one hour.

42.20(2) *Area requirements.*

a. Radiation levels. The local components of an analytical X-ray system shall be located and arranged, and shall include sufficient shielding or access control, so that no radiation levels exist in any area surrounding the local component group that could result in a dose to an individual present in excess of acceptable dose limits. For systems utilizing X-ray tubes, these levels shall be met at any specified tube rating.

b. Surveys. Radiation surveys of all analytical X-ray systems shall be performed at all of the following frequencies:

(1) Upon installation of the equipment and at least once every 12 months thereafter;

(2) Following any change in the initial arrangement, number, or type of local components in the system;

(3) Following any maintenance requiring the disassembly or removal of a local component in the system;

(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed;

(5) Any time a visual inspection of the local components in the system reveals an abnormal condition;

(6) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the allowable limits.

c. Compliance. Radiation survey measurements may not be required if a registrant or licensee can demonstrate compliance to the satisfaction of the department.

d. Posting. Each area or room containing analytical X-ray equipment shall be conspicuously posted with a sign(s) bearing the radiation symbol and the words "CAUTION—X-RAY EQUIPMENT" or words having a similar intent.

42.20(3) *Operating requirements.*

a. Procedures. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless that individual has obtained written approval of the radiation safety officer.

b. Bypassing. No individual shall bypass a safety device or interlock unless that individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period

of time. When a safety device or interlock has been bypassed, a readily displayed sign bearing the words "SAFETY DEVICE NOT WORKING" or words having a similar intent shall be placed on the radiation source housing.

c. Repair or modification of X-ray tube systems. Except as specified in paragraph 42.20(5)*"b,"* no operation involving removal of covers, shielding materials, or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

d. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

42.20(4) *Personnel requirements.*

a. Instruction. No individual shall be permitted to operate or maintain analytical X-ray equipment unless such individual has received instruction in, and demonstrated competence as to, all of the following:

(1) Identification of radiation hazards associated with the use of the equipment;

(2) Significance of the various radiation warnings, safety devices, and interlocks incorporated into the equipment or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) Proper operating procedures for the equipment;

(4) Recognition of symptoms of an acute localized exposure;

(5) Proper procedures for reporting an actual or suspected exposure.

b. Personnel monitoring.

(1) Finger or wrist dosimetry devices shall be provided to, and used by, the following:

1. Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

2. Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 641—subrule 40.2(1) unless evaluated by a qualified expert.

These rules are intended to implement Iowa Code chapter 136C.

CHAPTER 42—APPENDIX A

QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	Safety	
	Door interlocks	functional
	Audiovisual monitors	functional
Monthly	Dosimetry	
	X-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2mm @ therapeutic depth
	X-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	X-ray and electron symmetry	3%
	Safety Interlocks	
	Wedge, electron cone interlocks	functional
	Mechanical	
	Light/radiation field coincidence	2mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 degree
	Wedge position	2mm (or 2% change in transmission factor)
	Tray position	2mm
	Applicator position	2mm
	Field size indicators	2mm
	Cross-hair centering	2mm diameter
	Treatment couch position indicators	2mm/1deg
	Latching of wedges, blocking tray	functional
	Jaw symmetry[e]	2mm
	Field Light intensity	functional
Annual	Dosimetry	
	X-ray/electron output calibration constancy	2%
	Field size dependence of X-ray output constancy	2%
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X-ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%

Frequency	Procedure	Tolerance[a]
	Off-axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturer's test procedures	functional
	Mechanical	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values $\pm$ the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

[b] All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.

[c] A constancy check with a field instrument using temperature pressure corrections.

[d] Whichever is greater. Should also be checked after change of light field source.

[e] Jaw symmetry is defined as the difference in distance of each jaw from the isocenter.

[f] Most wedges' transmission factors are field size and depth dependent.

CHAPTER 42—APPENDIX B

INFORMATION ON RADIATION REQUIRED FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and department registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—subrule 37.11(3).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerator" (1984).

D. NCRP Report 144, "Radiation Protection for Particle Accelerator Facilities" (2003).