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 this rule 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.

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