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 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.

[**ARC 0182D**, IAB 4/1/26, effective 7/1/26]