4732.0930 THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 KV.

Subpart 1. **Equipment requirements.**

A. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate must not exceed the value specified at the distance specified for that classification of therapeutic radiation machine.

B. For 150 kV systems, the leakage air kerma rate measured at any position five centimeters from the tube housing assembly must not exceed 100 mrad (one mGy) in any one hour.

C. For systems greater than 150 kVp and less than 500 kV, the leakage air kerma rate measured at a distance of one meter from the target in any direction must not exceed one rad (one cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly must not exceed 30 rad (30 cGy) per hour.

D. For each therapeutic machine, the registrant must determine, or obtain from the manufacturer, the leakage radiation existing for the specified operating conditions.

E. The registrant must maintain the records on leakage radiation measurements at the facility according to part 4732.0330.

F. Permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.

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

H. The filter system must be designed so that:

(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 must not exceed one rad (one cGy) per hour at one meter under any operating conditions; and

(4) each filter is marked as to its material of construction and its thickness.

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

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

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

L. A suitable irradiation control device must be provided to terminate the irradiation after a preset time interval.

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

(2) The timer must 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 must be necessary to reset the elapsed time indicator.

(3) The timer must terminate irradiation when a preselected time has elapsed, if any dose-monitoring system present has not previously terminated irradiation.

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

(5) The timer must not permit an exposure if set at zero.

(6) The timer must not 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) The timer must be accurate to within 1.0 percent of the selected value or one second, whichever is greater.

M. The control panel, in addition to the provisions in subpart 2, must 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) a 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 filters in the beam.

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

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

(2) there must be an indication at the control panel identifying which x-ray tube is activated; and

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

O. There must be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

P. 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 following conditions must be met:

(1) the beam must be attenuated by shutters having a lead equivalency not less than that of the tube housing assembly;

(2) after the unit is at operating parameters, the shutters must be controlled by the operator from the control panel; and

(3) an indication of shutter position must appear at the control panel.

Q. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window must be clearly labeled as such upon the tube housing assembly and must 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.

Subp. 2. **Facility design requirements.** In addition to shielding requirements of this chapter, the treatment room must meet the following design requirements.

A. Provisions must be made for continuous two-way communication between the patient and the operator at the control panel.

B. Provisions must be made to permit continuous observation of the patient during irradiation. The viewing system must be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine must not be used for patient irradiation unless the viewing system is operational.

C. Treatment rooms, which contain a therapeutic radiation machine capable of operating in a range of 150 kV to 500 kV, must meet the following additional requirements:

(1) all protective barriers must be fixed except for entrance doors or beam interceptors;

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

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

(4) when a door is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source must be reduced to less than 100 mrad (one mGy) per hour.

Subp. 3. **Full calibration measurements.**

A. Full calibration must be performed by, or under the direct supervision of, a therapeutic radiological physicist:

(1) before the first medical use following installation or reinstallation of the therapeutic radiation machine;

(2) at intervals not to exceed 12 months;

(3) before medical use under the following conditions:

(a) whenever quality control check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

(b) following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam; and

(4) notwithstanding the requirements of this subpart:

(a) 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

(b) if the repair, replacement, or modification does not affect all energies, full calibration must be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality control check procedures against the criteria in subpart 4.

B. The registrant must maintain a record of each calibration for the duration of the registration. The record must include:

(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 or electronic signature of the individual responsible for performing the calibration.

Subp. 4. **Periodic quality control checks.**

A. Periodic quality control checks must be performed on therapeutic radiation machines, subject to subpart 3, which are capable of operation at greater than or equal to 150 kV.

B. To satisfy the requirements of this part, quality control checks must meet the following requirements:

(1) the registrant must perform quality control checks according to written procedures established by the therapeutic radiological physicist;

(2) the quality control check procedures must specify:

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

(b) the quality control check is performed during the calibration specified in subpart 3; and

(3) the acceptable tolerance for each parameter measured in the quality control check, when compared to the value for that parameter determined in the calibration specified in subpart 3, must be stated.

C. The cause for a parameter exceeding an established tolerance must be investigated and corrected before the system is used for patient or human research subject irradiation.

D. Whenever a quality control check indicates a significant change in the specified operating characteristics of a system, the system must be recalibrated as required in subpart 3.

E. The registrant must use the dosimetry system described in part 4732.0925, subpart 2, to make the quality control checks required in this part.

F. The registrant must have the therapeutic radiological physicist review and sign the results of each radiation output quality control check within one month of test completion.

G. The registrant must ensure that safety quality control checks of therapeutic radiation machines are performed at intervals not to exceed one month.

H. Notwithstanding the requirements of this part, the registrant must ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality control checks required by this part are completed.

I. Periodic quality control checks must have been performed within the 30 days prior to administration.

J. Safety quality control checks must ensure proper operation of:

(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 doors, control console, and in the radiation therapy room;

(4) viewing systems; and

(5) if applicable, electrically operated treatment room doors from inside and outside the treatment room.

K. The registrant must maintain a record of each quality control check for inspection by the commissioner. The record must include:

(1) the date of the quality control 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 instruments used to measure the radiation output of the therapeutic radiation machine; and

(4) the signature or electronic signature of the individual who performed the periodic quality control check.

Subp. 5. **Operating procedures.**

A. Therapeutic radiation machines must not be left unattended unless secured by means identified in subpart 1.

B. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used.

C. The tube housing assembly must not 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 no exceed 150 kV. In these cases, the holder must wear protective apron and gloves of not less that 0.5 millimeters lead equivalency at 100 kV.

D. A copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console.

E. No individual other than the patient must be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV.

Subp. 6. **Records.** All records must be maintained according to part 4732.0330.

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