4732.0940 THERAPEUTIC RADIATION MACHINES - PHOTON THERAPY SYSTEMS (500 KV AND ABOVE) AND ELECTRON THERAPY SYSTEMS (500 KEV AND ABOVE).

Subpart 1. **Equipment requirements.**

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

(1) The absorbed dose due to leakage radiation, excluding neutrons, at any point outside the maximum-sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance, such as patient plane, must not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

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

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

(4) Records of leakage radiation measurements must be maintained according to part 4732.0330.

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

(1) All adjustable or interchangeable beam-limiting devices must attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam-limiting devices must not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a ten centimeter by ten centimeter radiation field.

(2) All adjustable or interchangeable electron applicators must attenuate the radiation 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 must not exceed:

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

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

C. Measurement of leakage radiation must meet the following:

(1) Measurements of leakage radiation through the beam-limiting devices must be made with the beam-limiting devices closed and any residual aperture blocked by at least two-tenths value layers of suitable absorbing material. In the case of overlapping beam-limiting devices, the leakage radiation through each set must be measured independently at the depth of maximum dose. Measurements must be made using a radiation detector with an area not exceeding ten square centimeters.

(2) Measurements of leakage radiation through the electron applicators must be made with the electron beam directed into the air and using a radiation detector with an area up to, but not exceeding, one square centimeter suitably protected against radiation that has been scattered from material beyond the radiation detector. Measurements must be made using one centimeter of water equivalent buildup material.

D. Filters and wedges must meet the following:

(1) Each wedge filter that is removable from the system must be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle must appear on the wedge or wedge tray if permanently mounted to the tray. If the wedge or wedge tray is significantly damaged, the wedge transmission factor must be redetermined.

(2) If the absorbed dose rate information required by this subpart relates exclusively to operation with a field-flattening or beam-scattering filter in place, the filter must be removable only by the use of tools.

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

(a) irradiation must not 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;

(b) an interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;

(c) a display must be provided at the treatment control panel showing the wedge filters; and

(d) an interlock must 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.

E. For equipment manufactured after July 9, 1997, the registrant must 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.

F. All therapeutic radiation machines must be provided with redundant beam monitoring systems. The sensors for these systems must be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(1) Equipment manufactured after July 9, 1997, must 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, must be provided with at least one radiation detector. This detector must be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated must meet the following requirements:

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

(b) each detector must 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 must be capable of independently monitoring, interrupting, and terminating irradiation.

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

(a) malfunctioning of one system must not affect the correct functioning of the other systems; and

(b) failure of any element common to both systems that could affect the correct function of both systems must terminate irradiation or prevent the initiation of radiation.

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

(a) maintain a reading until intentionally reset;

(b) have only one scale and no electrical or mechanical scale multiplying factors;

(c) utilize a design such that increasing dose is displayed by increasing numbers; and

(d) in the event of a power failure, the beam-monitoring information required in this subpart displayed at the control panel at the time of failure must be retrievable in at least one system for a 20-minute period of time.

(6) Bent-beam linear accelerators must be provided with auxiliary devices to monitor beam symmetry.

(7) The devices referenced in this subpart must be able to detect field asymmetry greater than ten percent, and must be configured to terminate irradiation if field asymmetry cannot be maintained at ten percent or less.

G. Selection and display of dose monitor units.

(1) The preselected number of dose monitor units must be displayed at the treatment control panel until reset manually.

(2) After termination of irradiation, it must be necessary to reset the dosimeter display before subsequent treatment can be initiated.

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

H. For equipment manufactured after July 9, 1997, a system must 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 this subpart may form part of this system. In addition:

(1) the dose monitor unit rate must 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 must 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 must be a record maintained by the registrant;

(3) if the equipment can deliver under any fault conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device must 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);

(4) for each therapeutic radiation machine, the registrant must determine, or obtain from the manufacturer, the maximum values in this subpart for the specified operating conditions; and

(5) records of these maximum values must be maintained at the facility for inspection by the commissioner.

I. Termination of irradiation by the beam-monitoring system or systems during stationary beam radiation therapy.

(1) Each primary system must terminate irradiation when the preselected number of dose monitor units has been detected by the system.

(2) If the original design of the equipment included a secondary dose-monitoring system, that system must 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 has been detected by the secondary dose-monitoring system.

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

J. It must 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. If a therapeutic radiation machine has an interrupt mode, it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it must be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements must be automatically terminated.

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

(1) A timer must be provided that has a display at the treatment control panel. The timer must have a preset time selector and an elapsed time 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 the dose-monitoring systems have not previously terminated irradiation.

M. Equipment capable of both x-ray therapy and electron therapy must meet the following additional requirements:

(1) irradiation must not 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 must be displayed at the treatment control panel before and during irradiation;

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

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

(5) an interlock system must be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(6) an interlock system must 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. Equipment capable of generating radiation beams of different energies must meet the following requirements:

(1) irradiation must not be possible until a selection of energy has been made at the treatment control panel;

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

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

O. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy must meet the following requirements:

(1) irradiation must not be possible until a selection of stationary beam radiation therapy or rotational arc radiation therapy has been made at the treatment control panel;

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

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

(4) an interlock system must 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 must be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

(a) an interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation differs by more than 20 percent from the selected value;

(b) where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered must differ by less than five percent from the dose monitor unit value selected;

(c) an interlock must be provided to prevent motion of more than five degrees beyond the selected limits during moving beam radiation therapy;

(d) an interlock must 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; and

(e) moving beam radiation therapy must be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;

(6) where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation must be as required by part 4732.0930, subpart 1; and

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

(a) occurs during stationary beam radiation therapy; or

(b) does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

Subp. 2. **Facility design requirements for therapeutic radiation machines operating above 500 kV.** In addition to shielding adequate to meet requirements of part 4732.0380, the following design requirements are made.

A. Protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors.

B. In addition to other requirements in this subpart, the control panel must also:

(1) be located outside the treatment room;

(2) provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(3) provide an indication of whether radiation is being produced; and

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

C. Provisions must be made for continuous two-way audio communication between the patient and the operator at the control panel. The therapeutic radiation machine must not be used for irradiation of patients unless continuous two-way audio communication is possible.

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

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

F. Interlocks must 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 must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

G. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with part 4732.0380, interlocks must be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers.

H. At least one emergency power cutoff switch must be located in the radiation therapy room on either side of the primary beam and must terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subpart 1. All emergency power cutoff switches must 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.

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

J. Surveys for residual activity must 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.

K. A facility location authorized to use a therapeutic radiation machine according to this part must have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, the equipment must 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. The survey instruments must be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

Subp. 3. **Therapeutic radiological physicist support.**

A. The registrant must obtain the support of a therapeutic radiological physicist. The therapeutic radiological physicist must be responsible for:

(1) full calibrations required by subpart 5 and protection radiation surveys required by part 4732.0925, subpart 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 control check review required by subpart 6;

(5) consultation with the registrant in treatment planning, as needed; and

(6) performing calculations and assessments regarding medical events.

B. If the therapeutic radiological physicist is not a full-time employee of the registrant, the operating procedures required by subpart 4 must also specifically address how the therapeutic radiological physicist is to be contacted for problems or emergencies,

as well as the specific actions, if any, to be taken until the therapeutic radiological physicist can be contacted.

Subp. 4. **Operating procedures.**

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

B. Therapeutic radiation machines must not be made available for medical use unless the requirements of part 4732.0925 and this part have been met.

C. Therapeutic radiation machines, when not in operation, must be secured to prevent unauthorized use.

D. When adjustable beam-limiting devices are used, the position and shape of the radiation field must be indicated by a light field.

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

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

Subp. 5. **Full calibration measurements.**

A. Full calibration of a therapeutic radiation machine 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) full calibration must include measurement of all parameters in this chapter. Although it must not be necessary to complete all elements of a full calibration at the same time, all parameters, for all energies, must be completed at intervals not to exceed 12 months, unless the commissioner requires a more frequent interval;

(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. Therapeutic radiation machines with multienergy or multimode capabilities, or both, must only require measurements for those modes or energies that are not within their acceptable range; and

(b) 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, full calibration must be performed on the effected mode/energy that is in most frequent clinical use at

the facility. The remaining energies/modes may be validated with quality control check procedures against the criteria in this subpart.

B. The registrant must use the dosimetry system described in part 4732.0925, subpart 2, to measure the radiation output for one set of exposure conditions.

C. 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 the therapeutic radiation machine;

(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. 6. **Periodic quality control checks.**

A. Periodic quality control checks must be performed at intervals as specified in this chapter.

B. To satisfy the requirement of this subpart, quality control checks must include determination of central axis radiation output and a representative sampling of periodic quality control checks contained in this chapter. Representative sampling must include all referenced periodic quality control checks at intervals not to exceed 12 months.

C. The registrant must use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in part 4732.0925, subpart 2, to make the periodic quality control checks required in this subpart.

D. The registrant must perform periodic quality control checks required by this subpart according to procedures established by the therapeutic radiological physicist.

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

(1) the registrant and therapeutic radiological physicist must be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine must not be made available for subsequent medical use until the therapeutic radiological physicist has determined that all parameters are within their acceptable tolerances;

(2) if all quality control check parameters appear to be within their acceptable range, the quality control check must be reviewed and signed by either the registrant or therapeutic radiological physicist within seven working days; and

(3) the therapeutic radiological physicist must review and sign the results of each radiation output quality control check within 20 working days of completion.

F. Therapeutic radiation machines subject to this part must have safety quality control checks of each external beam radiation therapy machine performed at intervals not to exceed one week.

G. To satisfy the requirement of this subpart, safety quality control checks must ensure proper operation of:

(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) audio systems; and

(6) electrically operated treatment room doors from inside and outside the treatment room.

H. Emergency power cutoff switches must be checked for proper operation at intervals not to exceed three months. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch must be tested on a rotating basis. Safety quality control 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.

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

Subp. 7. **Records.** The registrant must maintain records according to part 4732.0330. The record must include:

A. the date of the quality control check;

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

C. the manufacturer's name, model number, and serial number of the instruments used to measure the radiation output of the therapeutic radiation machine; and

D. the signature or electronic signature of the individual who performed the periodic quality control check.

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