

902 KAR 100:137. Therapeutic systems above one (1) MeV.

RELATES TO: KRS 211.842-211.850, 211.990(4)

STATUTORY AUTHORITY: KRS 194.050, 211.090, 211.844

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Human Resources is authorized by KRS 211.844 to provide by regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. The purpose of this administrative regulation is to provide special requirements for the possession, use and operation of therapeutic x-ray and electron systems which operate at energies of one (1) MeV and above.

Section 1. Applicability. This administrative regulation shall apply to therapeutic x-ray and electron systems which operate at energies of one (1) MeV and above and to persons, equipment and materials used in connection with the possession, use or operation of these systems.

Section 2. Leakage Radiation to the Patient Area.

(1) Systems registered after March 2, 1977 shall meet the following requirements:

- (a) For operating conditions producing maximum leakages the absorbed dose in rads due to leakage radiation (including electrons, x-rays and neutrons) at a point in a circular plane of radius two (2) meters centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam shall not exceed one-tenth (0.1) percent of the maximum absorbed dose in rads of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements, excluding those for neutrons, shall be averaged over an area up to but not exceeding 100 square centimeters at the position specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters; and
- (b) The registrant shall determine or obtain from the manufacturer, for each system, the leakage radiation existing at the points specified in paragraph (a) of this subsection for specified operating conditions. Records of radiation leakage shall be maintained at the installation.

(2) Systems registered before March 2, 1977, shall meet the following requirements:

- (a) For operating conditions producing maximum leakage radiation, the absorbed dose rate in rads due to leakage radiation (excluding neutrons) at a point on the area specified in subsection (1)(a) of this section shall not exceed one-tenth (0.1) percent of the maximum absorbed dose in rads of the unattenuated useful beam dose rate at one (1) meter from the source, for its operating conditions. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters; and
- (b) The registrant shall determine or obtain from the manufacturer for each system the leakage radiation existing at the points specified in subsection (1)(a) of this section for the specified operating conditions. Records of radiation leakage shall be maintained at the installation.

(3) If neutron leakage may be a hazard the cabinet may, by specific order, impose upon a user additional requirements, as it deems appropriate or necessary to protect health and minimize danger to life or property. If imposing additional requirements, the cabinet shall give due consideration to accepted standards of safe practice.

Section 3. Leakage Radiation Outside the Patient Area. The leakage radiation outside the patient area shall meet the following requirements:

- (1) The absorbed dose in rads due to leakage radiation, except in the area defined in Section 2(1)(a) of this administrative regulation, measured at one (1) meter from the path

of the charged particle, before the charged particle strikes the target or window, shall not exceed one-tenth (0.1) percent for x-ray leakage, nor .05 percent for neutron leakage of the maximum absorbed dose in rads of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in Section 2(a) of this administrative regulation; and

(2) The registrant shall determine or obtain from the manufacturer the actual leakage radiation existing at the points specified in Section 2(1)(a) of this administrative regulation for specific operating conditions. Measurements, excluding neutrons, shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

Section 4. Beam Limiting Devices. Adjustable or interchangeable beam limiting devices shall be provided so that the following requirements are met:

(1) Adjustable or interchangeable beam limiting devices shall transmit no more than two percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. Neutrons are not included in this requirement;

(2) If the beam limiting device on existing equipment does not meet the requirements of subsection (1) of this section the cabinet may accept auxiliary equipment or methods for accomplishing attenuation; and

(3) Dose equivalent measurements shall be averaged over an area up to but not exceeding 100 square centimeters at a distance of one (1) meter from the target. If overlapping beam limiting devices are present, the leakage through each set shall be measured independently.

Section 5. Filters. Filters shall be provided so that the following requirements are met:

(1) If the absorbed dose rate information provided in Section 17 of this administrative regulation relates exclusively to operation with a field flattening or beam scattering filter in place, then the filter shall be a permanent filter only removable by the use of tools; and

(2) In therapy systems which use a system of wedge filters or interchangeable field flattening filters or beam scattering filters the following requirements shall be met:

(a) Irradiation shall not be possible until a selection of filter has been made at the control panel;

(b) An interlock system shall be provided to prevent irradiation if the filter is not in the correct position; and

(c) A display shall be provided at the control panel showing the filter(s) (or zero filter) in use.

Section 6. Beam Quality. The beam quality for therapy systems shall meet the following requirements:

(1) The absorbed dose, from x-ray stray radiation in the useful electron beam, on the central axis of the beam at a depth ten (10) cm further than the practical range shall not exceed the following limits:

(a) Three (3) percent of the maximum absorbed dose for electron beam energies to fifteen (15) MeV;

(b) Five (5) percent of the maximum absorbed dose for electron beam energies in the range fifteen (15) to thirty-five (35) MeV;

(c) Ten (10) percent of the maximum absorbed dose for electron beam energies in the range thirty-five (35) MeV to fifty (50) MeV;

(d) Twenty (20) percent of the maximum absorbed dose for electron beam energies fifty (50) MeV or greater; and

(e) Linear interpolation shall be used for values not stated.

(2) The measurements required by subsection (1) of this section shall be made at electron beam maximum size not exceeding fifteen (15) by fifteen (15) cm in a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five (5) cm and whose depth is sufficient to perform the required measurement. The incident surface of the phantom shall be at the normal treatment distance and normal to the central axis of the beam.

(3) At the largest field size available, the absorbed dose from electron stray radiation in the useful x-ray beam, at the surface during x-ray irradiation on the central axis of the beam shall not exceed the following limits;

(a) Eighty (80) percent of the maximum absorbed dose for x-ray beam maximum energies in the range of one (1) to two (2) MeV;

(b) Seventy (70) percent of the maximum absorbed dose for x-ray beam maximum energies in the range of two (2) to five (5) MeV;

(c) Sixty (60) percent of the maximum absorbed dose for x-ray beam maximum energies in the range of five (5) to fifteen (15) MeV;

(d) Fifty (50) percent of the maximum absorbed dose for x-ray beam maximum energies in the range of fifteen (15) to thirty-five (35) MeV;

(e) Forty (40) percent of the maximum absorbed dose for x-ray beam maximum energies in the range of thirty-five (35) through fifty (50) MeV; and

(f) Linear interpolation shall be used for values not stated.

(4) The measurements required by subsection (3) of this section shall be made using a phantom of size and placement which meet the requirements of subsection (2) of this section. An instrument which allows extrapolation to the surface absorbed dose shall be used. Beam modifying devices which are removed without the use of tools, except beam scattering or field flattening filters, shall be removed from the useful beam.

(5) The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation for specified operating conditions.

Section 7. Beam Monitors. Systems registered after March 2, 1977 shall be provided with two (2) radiation detectors in the radiation head. The two (2) detectors shall be incorporated into two (2) dose monitoring systems. Systems registered before March 2, 1977 shall be provided with at least one (1) radiation detector in the radiation head. This detector shall be incorporated into a primary dose monitoring system. Beam monitoring systems shall meet the following requirements:

(1) The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

(2) Each detector shall be capable of independently monitoring, interrupting, and terminating the useful beam;

(3) Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated;

(4) For systems registered after March 2, 1977 the design of the dose monitoring systems of subsection (4) of this section shall ensure that the malfunctioning of one (1) system shall not affect the correct functioning of the second system. In addition the failure of an element which may be common to both systems shall terminate the useful beam; and

(5) Each dose monitoring system shall have a legible display at the control panel. Each display shall also meet the following requirements:

(a) Maintain a reading until intentionally reset to zero;

(b) In the event of power failure, have the capability of retrieving the information displayed in at least one (1) system for twenty (20) minute period of time after failure occurs;

- (c) On systems registered after March 2, 1977 the display shall have only one (1) scale and no scale multiplying factors; and
- (d) A design shall be utilized so that increasing dose is displayed by increasing numbers and shall be so designed that in the event of an overdosage of radiation the absorbed dose may be accurately determined.

Section 8. Beam Symmetry. The useful beam shall be symmetrical within the following requirements:

- (1) For systems registered after March 2, 1977 and inherently capable of producing useful beams with a symmetry exceeding five (5) percent. The asymmetry of the radiation beam in two (2) orthogonal directions shall be monitored before the beam passes through the beam limiting device. Means shall be provided so that, if the difference in the dose rate between one (1) region and another region symmetrically displaced from the central axis of the beam exceeds five (5) percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds ten (10) percent, the irradiation is terminated; and
- (2) On systems registered before March 2, 1977 if the cabinet has determined that beam symmetry is inadequate the use of an automatic beam asymmetry warning system shall be required.

Section 9. Selection and Display of Dose Monitor Units. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the control panel. In addition dose monitor units shall also meet the following requirements:

- (1) After the useful beam terminates it shall be necessary to reset the preselected dose monitor units before treatment can be reinitiated;
- (2) The preselected number of dose monitor units shall be displayed at the control panel until manually reset for the next irradiation; and
- (3) For systems registered after March 2, 1977, it shall be necessary to manually reset the preselected dose monitor units before radiation can be initiated.

Section 10. Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy. Each of the required dose monitoring systems shall terminate irradiation when the preselected number of dose monitor units has been detected by the system. Dose monitoring systems shall also meet the following requirements:

- (1) Each primary system shall 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 second dose monitoring system, that system shall be capable of terminating irradiation when not more than fifteen (15) percent of forty (40) dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system; and
- (3) For systems registered after March 2, 1977 the beam shall terminate automatically when the secondary system detects more than ten (10) percent or twenty-five (25) dose monitor units above the preset dose monitor units and indicators on the central panel shall show which system has terminated the beam.

Section 11. Termination Switches. It shall be possible to terminate irradiation and equipment movement or to go from an interruption condition to termination conditions at once from the control panel.

Section 12. Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at once from the control panel. Following an interruption it shall be possible to restart irradiation by operator action without reselection of operating conditions. If a change

is made of a preselected value during interruption the system shall go to termination condition.

Section 13. Timers. A timer shall be provided, have a display at the control panel, a preset time selector and an elapsed time indicator. The timer shall be a cumulative timer which switches on and off with the irradiation and retains its reading after irradiation is interrupted or terminated. If shall be necessary to zero the elapsed time indicator after irradiation is terminated. To guard against failure of the dose monitoring systems, the timer shall terminate irradiation when a preselected time has elapsed.

Section 14. Selection of Radiation Type. In systems capable of both x-ray and electron therapy the following requirements shall be met:

- (1) Irradiation shall not be possible until a selection of radiation type (x-ray or electrons) has been made at the control panel;
- (2) An interlock system shall be provided to ensure that the system can emit only the radiation type which has been selected;
- (3) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the control panel;
- (4) An interlock system shall be provided to prevent irradiation with x-ray except to obtain a port film if electron applicators are fitted and irradiation with electrons if accessories specific for x-ray therapy are fitted; and
- (5) The radiation type shall be displayed at the control panel before and during irradiation.

Section 15. Selection of Energy. In systems capable of generating radiation beams of different energies the following requirements shall be met:

- (1) Irradiation shall not be possible until a selection of energy has been made at the control panel;
- (2) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the control panel;
- (3) The nominal energy value selected shall be displayed at the control panel before and during irradiation; and
- (4) For equipment registered after the effective date of these administrative regulations, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than twenty (20) percent or three (3) MeV, whichever is smaller, from the selected nominal energy.

Section 16. Selection of Stationary Beam Therapy or Moving Beam Therapy. In systems capable of both stationary and moving beam therapy the following requirements shall be met:

- (1) Irradiation shall not be possible until a selection of stationary or moving beam therapy has been made at the control panel;
- (2) An interlock system shall be provided to ensure that the system can operate only in the mode which has been selected;
- (3) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the control panel;
- (4) The mode of operation shall be displayed at the control panel;
- (5) For equipment registered after the effective date of this administrative regulation, an interlock system shall be provided to terminate irradiation if movement of the gantry occurs during stationary beam therapy or movement of the gantry stops during moving beam therapy unless stoppage is a preplanned function.

(6) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement. Additionally for units registered after the effective date of this administrative regulation:

(a) An interlock system, shall be provided to terminate irradiation if the number of dose monitor units delivered in ten (10) degrees of arc differs by more than twenty (20) percent from the selected value; and

(b) Where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five (5) percent from the value calculated from the absorbed dose per unit angle relationship.

(7) Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be required by Section 10 of this administrative regulation.

Section 17. Absorbed Dose Rate. In systems registered after March 2, 1977 a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in Section 7 of this administrative regulation may form part of this system. In addition the following requirements shall be met:

(1) The dose monitor units shall be displayed at the control panel; and

(2) If the system can deliver an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for machine parameters utilized, a device shall be provided which terminates irradiation if the dose rate exceeds a value not more than twice the specified maximum. The value at which the irradiation is terminated shall be a record maintained by the registrant.

Section 18. Location of Virtual Source and Beam Orientation. The registrant shall determine or obtain from the manufacturer the location with reference to an accessible point on the radiation head the following points:

(1) The x-ray target or the virtual source of x-rays; and

(2) The electron window or the virtual source of electrons if the system has electron beams capabilities.

Section 19. System Checking Facilities. Facilities shall be provided so that radiation safety interlocks can be checked. If preselection of operating conditions requires action in the treatment room and at the control panel, selection at one (1) location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

Section 20. Auxiliary Support of Patients. If a patient is required to be held in position for radiation therapy, mechanical supporting or restraining devices shall be used. No person other than the patient shall be in the treatment room during irradiation.

Section 21. Facility and Shielding Requirements. In addition to shielding adequate to meet the requirements of 902 KAR 100:105, the following requirements shall be met:

(1) Except for entrance doors and beam interceptors the required barriers shall be fixed barriers;

(2) The control panel shall be located outside the treatment room;

(3) Windows, mirror systems, closed-circuit television viewing screens or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position. If the viewing system is by electronic means (e.g., television) an alternate viewing system shall be provided for use in the event of failure of the primary system;

- (4) Provision shall be made for two (2) way aural communication with the patient from the control station. However, if excessive noise levels or treatment requirements make aural communication impractical, other methods of communications shall be used;
- (5) The treatment room shall be so constructed that persons may be able to escape from within;
- (6) Treatment room entrances to which access is possible through more than one (1) entrance, shall be provided with warning lights in a readily observable position near the outside of access doors, which indicate if the useful beam is "on." These warning lights shall be accompanied by an appropriate sign as specified in 902 KAR 100:020, Section 12; and
- (7) Interlocks shall be provided so that entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by a door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.

Section 22. Protection Survey. New facilities, and existing facilities not previously surveyed, shall have a radiation protection survey made by, or under the direction of a qualified expert. The survey shall also be conducted after a change in the facility which might produce a radiation hazard.

- (1) The registrant shall obtain a written report of the survey and a copy of the report shall be transmitted by the registrant to the cabinet within thirty (30) days of receipt of the report.
- (2) The survey and report shall indicate instances where the facility in the opinion of the qualified expert is in violation of the applicable therapy radiation administrative regulations and shall cite the sections violated.

Section 23. Calibrations. The output of each therapeutic x-ray system shall be calibrated by a qualified expert, before it is first used for medical purposed. Calibrations shall be repeated at least once every twelve (12) months and after changes which might significantly increase radiation hazards. Calibration of the therapy beam shall be performed with a measurement instrument having a calibration factor for cobalt - sixty (60) gamma rays, and which shall have been calibrated within the preceding two (2) years and after servicing that may have affected its calibration. Records of calibrations shall be maintained by the registrant for five (5) years after completion of the full calibration. The records shall be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five (5) percent. A copy of the latest calibration shall be available in the area of the control panel. The calibration shall include at least the following determinations:

- (1) Verification that the system is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter, if applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specific depths;
- (2) The absorbed dose rate at various depths of water for the range of and field sizes used and for each effective energy that verifies the accuracy of the dosimetry of therapy procedures utilized with that therapy beam;
- (3) In uniformity of the radiation field an its dependence upon the direction of the useful beam;
- (4) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions; and
- (5) Verification of transmission and electron buildup factors for accessories, i.e., wedges, shadow trays and compensators.

Section 24. Spot Checks. A spot check shall be made monthly and shall include carefully selected representative or indicative measurements which demonstrate the consistency of

relevant system operating characteristics, or lack of same. Spot checks shall meet the following requirements:

- (1) The spot check methods shall be in writing, shall have been designed by a qualified expert and a copy of the procedure shall be submitted to the cabinet prior to its implementation;
 - (2) If a qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the qualified experts within fifteen (15) days;
 - (3) The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration;
 - (4) At intervals not to exceed one (1) week, spot checks shall be made of absorbed dose measurements at a minimum of two (2) depths in a phantom;
 - (5) If a spot check indicates a significant change (as specified in the qualified experts spot check design) in the operating characteristics of a system, the system shall be recalibrated as required by Section 23 of this administrative regulation;
 - (6) If a system has a built in device which provides a self-check of parameters during irradiation, the measurement shall not be utilized as a spot check measurement;
 - (7) The course for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation;
 - (8) Records of spot check measurements shall be maintained by the registrant for a period of two (2) years after completion of the spot check measurements and necessary corrective actions; and
 - (9) If a spot check involves a radiation measurement, the measurement shall be obtained using a system meeting the requirements of Section 23 of this administrative regulation or which has been intercompared with a system meeting those requirements within the previous year.
- (3 Ky.R. 573; eff. 3-2-1977; 12 Ky.R. 1406; eff. 3-4-1986; 18 Ky.R. 1563; eff. 1-10-1992; Crt eff. 8-16-2019.)