

902 KAR 100:136. Therapeutic systems below one (1) MeV.

RELATES TO: KRS 211.842-211.852, 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 administrative 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 systems which operate at energies below one (1) MeV.

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

Section 2. Leakage Radiation. If the x-ray system is operated at its leakage technique factors, the leakage radiation shall not exceed the value given below:

(1) For contact therapy systems the leakage radiation shall not exceed 100 milliroentgens per hour measured five (5) cm anywhere from the tube housing;

(2) For systems operating between zero and 150 kVp and which are registered prior to March 2, 1977, the leakage radiation shall not exceed one (1) roentgen in one (1) hour at one (1) meter from the source;

(3) For systems operating between zero and 150 kVp and which are registered after March 2, 1977, the leakage radiation shall not exceed 100 milliroentgens in one (1) hour at one (1) meter from the source;

(4) For systems operating between 151 and 500 kVp the leakage radiation shall not exceed one (1) roentgen in one (1) hour at one (1) meter from the source; or

(5) For systems operating between 501 and 999 kVp the leakage radiation at one (1) meter from the source shall not exceed one-tenth (0.1) percent of the useful beam one (1) meter from the source.

Section 3. Permanent Beam Limiting Devices. Permanent fixed diaphragms or cones used for collimating the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.

Section 4. Removable Beam Limiting Devices. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one (1) percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

Section 5. Adjustable Beam Limiting Devices. Adjustable beam limiting devices shall meet the following requirements:

(1) Devices installed after March 2, 1977 shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one (1) percent of the original beam at the maximum kilovoltage and maximum treatment filter; or

(2) Devices installed before March 2, 1977, shall for the portion of the useful beam to be blocked by these devices, transmit not more than five (5) percent of the original beam at the maximum kilovoltage and maximum treatment filter.

Section 6. Filter System. The filter system shall be designed to meet the following requirements:

- (1) The filters cannot be accidentally displaced at possible tube orientation;
- (2) Each filter shall be marked as to its material of construction and its thickness and, for wedge filters, the wedge angle shall appear on the wedge or wedge tray; and
- (3) The radiation at five (5) centimeters from the filter insertion slot opening does not exceed thirty (30) roentgens per hour under operating conditions.

Section 7. Focal Spot Marking and Assembly Immobilization. The tube housing assembly shall be marked so that it is possible to determine the location of the focal spot to within five (5) millimeters and the marking shall be readily accessible for use during calibration procedures. In addition the assembly shall be capable of being immobilized during stationary treatments.

Section 8. Contact Therapy Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least five-tenths (0.5) mm lead equivalent material at 100 kVp that can be positioned over the entire useful beam port during periods that the beam is not in use.

Section 9. Beam Monitor System. Therapy x-ray systems registered after March 2, 1977 which are capable of operating above 150 kVp shall be provided with a beam monitoring system which meets the following requirements:

- (1) The beam monitoring system shall have a detector interlock to prevent incorrect positioning;
- (2) The beam monitoring system shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;
- (3) The control panel display shall maintain the administered dose reading until intentionally reset to zero;
- (4) If a system malfunctions or electrical power failure occurs the dose administered to a patient prior to the system's malfunction or power failure can be accurately determined;
- (5) The beam monitoring system shall not allow irradiation until a preselected value of exposure has been made at the treatment control panel;
- (6) The beam monitoring system shall be capable of independently terminating irradiation if the preselected exposure has been reached; and
- (7) The control panel display shall not have scale multiplying factors and shall utilize a design that displays increasing dose by increasing numbers.

Section 10. Timers. Therapeutic x-ray systems shall be provided with timers which meet the following requirements:

- (1) The timer shall have a display at the control panel with a preset time selector and an elapsed time indicator;
- (2) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator after irradiation is terminated and before irradiation can be reinstated.
- (3) The timer shall terminate irradiation after a preselected time has elapsed if a 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 (1) second and shall not permit an exposure if set at zero; and
- (5) The timer shall not activate until the shutter is open if the irradiation is controlled by a shutter mechanism.

Section 11. Control Panel. The control panel, in addition to other display requirements of this ad-

ministrative regulation, shall meet the following requirements:

- (1) The control panel shall indicate the presence of electrical power, the possibility of tube activation, the production of x-rays, and the actual kilovoltage and current across the tube;
- (2) A means shall be provided for terminating an exposure at once;
- (3) A locking device shall be provided which prevents unauthorized use of the x-ray system; and
- (4) A display shall be provided on systems registered after March 2, 1977 which indicates specific filter(s) in the useful beam.

Section 12. Control Panels Which Control More Than One (1) Tube. If a control panel may energize more than one (1) x-ray tube then the following requirements shall be met:

- (1) Only one (1) x-ray tube may be activated at one (1) time;
- (2) The control panel shall indicate which x-ray tube is energized; and
- (3) Each x-ray tube shall indicate whether that tube is energized.

Section 13. Source-to-skin Distance. A means shall be provided to determine the source-to-skin distance to within one (1) centimeter.

Section 14. Shutter Control. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing. Systems using shutter control shall meet the following requirements:

- (1) The shutter shall be electrically controlled by the operator from the control panel; and
- (2) An indication of shutter position shall appear at the control panel. The control panel shall indicate whether the shutter is open or closed.

Section 15. Facility Design and Shielding Requirements for X-ray Systems Capable of Operating Above Fifty (50) kVp. In addition to the shielding adequate to meet the requirements of 902 KAR 100:105, the following requirements shall also be met:

(1) Provision shall be made for two (2) way aural communication with the patient from the control room; however, if excessive noise levels make aural communication impractical other methods of communication shall be used;

(2) Windows, mirror systems, or closed-circuit television viewing screens or an equivalent system 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 primary viewing system is by electronic means (e.g., television) an alternate viewing system shall be available as a back-up if electronic failure occurs;

(3) The therapy room shall be so constructed that persons may be able to escape from within; and

(4) Facilities which contain an x-ray system which may be operated above 150 kVp shall meet the following requirements:

(a) Protective barriers shall be fixed barriers, except for entrance doors or beam interceptors.

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

(c) Doors of the treatment room shall be electrically connected to the control panel so that x-ray production cannot occur unless the door is closed;

(d) Doors referred to in paragraphs (a) and (c) of this subsection, shall be interlocked electrically so that they are closed before treatment can be initiated or continued. If the irradiation is interrupted by a door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

(e) If a door referred to in paragraph (d) of this subsection is opened while the x-ray tube is acti-

vated, the exposure at a distance of one (1) meter from the source shall be reduced to less than 100 milliroentgens per hour.

Section 16. Surveys and Calibrations. New facilities and existing facilities not previously surveyed, shall have a radiation protection survey made by or under the direction of a qualified expert. A survey shall also be conducted after changes in the facility which might cause a significant increase in a radiation hazard.

(1) The registrant shall obtain a written report of this survey from the qualified expert and a copy of this report shall be transmitted by the registrant to the cabinet within thirty (30) days of receipt of the report. The survey and report shall indicate instances where the installation, in the opinion of the qualified expert, is in noncompliance of applicable administrative regulations.

(2) The calibration of an x-ray system shall be performed at intervals not to exceed one (1) year and after changes or replacement of components which are likely to change the radiation output. This calibration shall be performed by or under the direction of a qualified expert who is physically present at the facility during the calibration. Calibration of the radiation output shall be performed with a calibrated dosimetry system which is directly traceable to national standards and which shall have been calibrated within the preceding two (2) years. Records of calibrations shall be maintained by the registrant for five (5) years. The calibration shall include at least the following determinations:

(a) Verification that the system is operating in compliance with the design specifications;

(b) The exposure rate as a function of field size, technique factors, filter, and treatment distance used;

(c) The congruence between the radiation field and field indicated by the localizing device if localizing devices are used for radiation therapy; and

(d) The uniformity of the largest radiation field used.

(3) The calibration determinations prescribed in subsection (2) of this section shall be performed in a manner that the dose at a reference point in soft tissue can be calculated within plus or minus five (5) percent of the intended absorbed dose.

(4) A copy of the most recent x-ray system calibration shall be available at or in the area of the control panel.

(5) Therapeutic x-ray systems capable of operation at greater than 150 kVp shall also have spot checks performed which meet the following:

(a) The spot check procedures shall specify the frequency at which tests or measurements are to be performed. The spot check procedures shall specify that the spot check shall be performed during the calibration specified in subsection (2) of this section. The acceptable tolerance for each parameter measured in the spot check compared to the value for that parameter determined in the calibration specified in subsection (2) of this section shall be stated;

(b) The spot check methods shall be in writing and shall have been designed by a qualified expert. A copy of the procedures shall be submitted to the cabinet prior to its implementation;

(c) If a qualified expert does not perform the spot check measurement, the results of the spot check measurements shall be reviewed by a qualified expert within fifteen (15) days;

(d) If a spot check indicates a significant change in the operating characteristics of a machine, the machine shall be recalibrated as required by subsection (2) of this section;

(e) Records of spot check measurements shall be maintained for two (2) years after completion of the spot check measurements and necessary corrective actions;

(f) The spot check procedures shall specify the frequency at which tests of measurements are to be performed the spot check procedures shall specify that the spot check shall be performed during the calibration specified in subsection (2) of this section shall be stated;

(g) The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation; and

(h) If a spot check involves a radiation measurement, the measurement shall be obtained using a system satisfying the requirements of subsection (2) of this section or which has been intercompared with a system meeting those requirements within the previous year.

Section 17. Operating Procedures. Therapeutic x-ray systems shall be operated so the following requirements are met:

(1) The facility shall be operated in compliance with any limitations indicated by the radiation protection survey which have been approved by the cabinet;

(2) The x-ray system shall not be used in the administration of radiation therapy unless the requirement of Section 16 of this administrative regulation has been met;

(3) Therapeutic x-ray systems shall not be left unattended unless the locking device required by Section 10(3) of this administrative regulation is set to prevent activation of the useful beam;

(4) If a patient is required to be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(5) The tube housing assembly shall not be held by hand during operation unless the system is designed to require holding and the potential difference of the system does not exceed fifty (50) kVp. In this instance the holder shall wear protective gloves and apron of not less than five-tenths (0.5) mm lead equivalency at 100 kVp;

(6) No individual other than the patient shall be in the treatment room unless the individual is protected by a barrier sufficient to meet the requirements of 902 KAR 100:020. No individual other than the patient shall be in the treatment room during exposures from x-ray systems operating above 150 kVp; and

(7) The x-ray system shall not be used in the administration of radiation therapy unless the requirements of subsections (2) and (5)(d) of this section have been met. (3 Ky.R. 570; eff. 3-2-77; Am. 12 Ky.R. 1402; eff. 3-4-86; 18 Ky.R. 1559; eff. 1-10-92.)