**Section 360.110 Therapy Systems Operating Below 1 MeV**

In addition to the provisions of Sections 360.10 through 360.30 of this Part, the requirements of this Section apply to x-ray therapy systems and associated facilities operating at energies less than 1 MeV.

a) Facility Design

1) A therapeutic radiological physicist shall be consulted in the design of an x-ray therapy installation.

2) Shielding requirements

A) Each x-ray therapy installation shall be provided with such primary and secondary barriers as are necessary to assure compliance with 32 Ill. Adm. Code 340.

B) For all x-ray therapy systems capable of operating above 150 kVp installed after October 15, 1993, facility design information shall be submitted to the Agency for review prior to installation of the x-ray therapy system. Information submitted to the Agency shall include, but need not be limited to, the following:

i) Name and address of the planned installation.

ii) Name, address and telephone number of the therapeutic radiological physicist who was consulted in the design of the installation.

iii) A scale drawing that includes the location of the therapy system, control panel and doors to the room.

iv) The structural composition and thickness of all walls, doors, partitions, floor and ceiling of the installation.

v) The occupancy of areas adjacent to the installation.

vi) Calculations that demonstrate the adequacy of the amount of shielding specified for each primary and secondary protective barrier.

vii) Projected weekly dose rates in areas adjacent to the installation.

3) Interlock. X-ray therapy systems operating at greater than 150 kVp shall have an interlock installed on each door of the therapy room. The interlock shall be wired into the electrical circuit in such a manner that when the door is opened, for any reason, the generation of x-rays will automatically be terminated and irradiation can be resumed only by manually resetting the controls on the control panel after the door is closed.

4) Doors. The doors to the therapy room shall be designed and installed to allow opening from the inside at all times and shall be capable of being opened manually.

5) Warning Lights. X-ray therapy systems operating above 150 kVp, and all therapy rooms to which access is possible through more than one entrance shall be provided with warning lights in a readily observable position near the outside of all access doors. The warning lights shall indicate when the useful beam is on.

6) Operator and control position

A) X-ray Therapy Systems Operating at 150 kVp and Below. The control panel and operator shall be located either outside the therapy room or behind a protective barrier within the room.

B) X-ray Therapy Systems Operating Above 150 kVp. The control panel and operator shall be located outside the therapy room.

7) Viewing System. Windows, mirrors, closed-circuit television or an equivalent system shall be provided to permit continuous visual observation of the patient during irradiation and shall be located so that the operator can observe the patient from the control panel.

AGENCY NOTE: When the primary viewing system is electronic, a back-up system should be available for use in the event of failure of the primary system in order to ensure compliance with the requirements of subsection (e)(5) of this Section.

8) Communication. The facility design shall permit two-way aural communications between the patient and the operator at the control panel.

9) Signs required by 32 Ill. Adm. Code 340.920 shall be posted in the facility.

b) Equipment Requirements

1) Leakage Radiation. When the tube is operated at its maximum rated continuous current for the maximum rated tube potential, the leakage radiation shall not exceed the value specified in the table below at the distance specified in the table for the classification of that x-ray system. Radiation measurements shall be averaged over an area up to, but not exceeding, 100 square centimeters.

|  |  |  |
| --- | --- | --- |
| X-Ray System | Leakage Limit | Measurement Location |
|  |  |  |
| Contact Therapy | 25.8 microC/kg (0.1 R) per hour | 5 centimeters from the tube housing |
|  |  |  |
| 0 - 499 kVp | 258 microC/kg (1 R) per hour | 1 meter from the source |
|  |  |  |
| 500 kVp - 999 kVp | 0.1 percent of useful beam or 258 microC/kg (1 R) per hour, whichever is greater | 1 meter from the source |

2) Beam-Limiting Devices

A) Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

B) Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one 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.

C) Adjustable beam-limiting devices installed after October 15, 1993 shall meet the requirements of subsection (b)(2)(B) of this Section.

D) Adjustable beam-limiting devices installed on or before October 15, 1993 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than five percent of the useful beam at the maximum kilovoltage and maximum treatment filter.

3) Filter System. The filter system shall be designed so that:

A) The filters are securely positioned and will not become dislodged when the machine is positioned at any possible orientation;

B) The radiation dose at one meter from the filter insertion slot opening does not exceed 258 mC/kg (1 R) per hour when the machine is operated at its maximum current and maximum tube potential;

C) Each filter is labeled with its composition and thickness (for wedge filters, the wedge angle and maximum design field size shall appear on the wedge or wedge tray);

D) If the x-ray therapy system uses changeable filters, there is a filter indication system which permits recognition of any added filter in place and indicates from the control panel the presence of a particular filter or absence of any filter; and

E) For x-ray therapy systems installed after October15, 1993, an interlock prevents irradiation if the selected filter is not installed.

4) Tube/Aperture Alignment. The x-ray tube shall be mounted so that it cannot turn or slide with respect to the housing aperture.

5) Tube Housing Stability. The tube housing shall remain stable during treatment unless tube housing movement is a designed function of the system.

6) Source-Skin Distance (SSD) Indication

A) Means shall be provided to indicate the SSD.

B) The SSD shall be indicated in centimeters and/or inches and the measured SSD shall correspond to the indicated value to within 0.5 percent.

7) Timer. A timer, which has a display at the control panel, shall be provided and shall meet the following requirements:

A) The timer shall be activated with the production of radiation;

B) For systems equipped with a shutter mechanism to control irradiation, the timer shall be activated when the shutter is opened;

C) The timer shall terminate irradiation when a preselected time has elapsed;

D) The timer shall permit presetting and determination of exposure times at least as short as 1 second; and

E) The timer shall not permit an exposure if the operator has not selected a time for the exposure.

AGENCY NOTE: The control panel should be equipped with a count-up timer to serve as a back-up to the control timer.

8) Control Panel Functions. The control panel, in addition to the displays required in other provisions of this Section, shall have:

A) An indication of whether x-rays are being produced;

B) A means for indicating x-ray tube potential and current; and

C) A means for terminating an exposure at any time.

9) Shutters. Equipment that is provided with shutters shall meet the following requirements:

A) The shutters shall have a lead equivalency not less than that of the tube housing assembly;

B) The shutter shall be controlled electrically by the operator at the control panel; and

C) An indication of shutter position shall appear at the control panel.

10) Multiple Tubes. Control panels capable of energizing more than one x-ray tube shall meet the following requirements:

A) It shall be possible to energize only one x-ray tube at any time;

B) There shall be an indication at the control panel identifying which x-ray tube is energized; and

C) There shall be an indication at the tube housing assembly when that tube is energized.

11) Low-Filtration X-Ray Tubes. Each x-ray therapy system equipped with a beryllium window shall be clearly labeled as such upon the tube housing assembly and at the control panel.

c) Radiation Protection Survey. A radiation protection survey shall be performed by a therapeutic radiological physicist on each x-ray therapy system. The registrant shall maintain at the facility a copy of the most recent radiation protection survey report for review by the Agency. Radiation protection surveys shall meet the following additional requirements:

1) X-ray therapy systems installed after October 15, 1993 shall have a radiation protection survey performed by a physicist before the therapy system is first used for irradiation of a patient.

2) For all x-ray therapy systems, a radiation protection survey shall be performed by a physicist after any change in the x-ray therapy system or facility that might produce a radiation hazard. The survey shall be performed before the therapy system is used to treat patients.

3) Survey reports shall include, but need not be limited to, the following:

A) A diagram of the facility that details building structures and the position of the control panel, x-ray therapy system and associated equipment;

B) A description of the x-ray therapy system, including the manufacturer, model number and range of kilovolt potential;

C) A description of the instrumentation used to determine radiation measurements, including the date and source of the most recent calibration for each instrument used;

D) Conditions under which radiation measurements were taken; and

E) Survey data including:

i) Projected weekly dose equivalent in areas adjacent to the therapy room; and

ii) A description of workload, use and occupancy factors employed in determining the projected weekly dose equivalent.

4) The registrant shall retain a copy of the radiation protection survey report and a copy of the report shall be provided to the Agency within 30 days after completion of the survey.

5) Any deficiencies detected during the radiation protection survey that would constitute or result in a violation of 32 Ill. Adm. Code 340 shall be corrected prior to using the machine for treatment of patients.

6) The facility shall be operated in compliance with any limitations indicated by the therapeutic radiological physicist as a result of the radiation protection survey required by the Agency.

d) Calibrations and Quality Assurance Checks.

1) Each x-ray therapy system installed after October 15, 1993 shall be calibrated by a therapeutic radiological physicist before the therapy system is first used for irradiation of a patient. The calibration of the x-ray therapy system shall include, but need not be limited to, determination of the following:

A) The radiation output, expressed as exposure rate in air or dose rate in tissue, as a function of distance, field size, x-ray tube potential and current, filters and treatment applicators used;

B) The half-value layer for each kilovoltage setting and filter combination used;

C) The degree of congruence between the radiation field and the field indicated by each beam-limiting device; and

D) An evaluation of the uniformity of the radiation field.

2) Quality assurance checks shall be made by a therapeutic radiological physicist at intervals not to exceed 1 year. Quality assurance checks shall include, but need not be limited to, determination of the following:

A) The radiation output for a set of operating conditions specified by the therapeutic radiological physicist;

B) The coincidence of the radiation field and the field indicated by the beam-limiting device, except for systems equipped with fixed diaphragms or cones; and

C) The therapeutic radiological physicist shall establish criteria for quality assurance check measurements and shall determine corrective actions to be implemented if the criteria are exceeded.

AGENCY NOTE: Quality assurance checks should be performed at a frequency which is appropriate for the particular therapy system, as determined by the therapeutic radiological physicist and based on the history of stability of the radiation output of the machine. A suggested frequency is one that would result in a quality assurance check being performed at least once during a typical patient's course of treatment.

3) Whenever service or maintenance is performed on the therapy system, a therapeutic radiological physicist shall be notified and shall determine whether a calibration or quality assurance check is necessary to verify the characteristics of the beam.

4) Measurements of the radiation output of the x-ray therapy system shall be performed using a dosimetry system that has been calibrated by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). Calibration of the dosimetry system shall have been performed using a radiation beam of comparable half-value layer to the x-ray system to be calibrated. The dosimetry system shall meet one of the two conditions below:

A) The calibration of the dosimetry system shall have been performed within the previous 2 years and after any servicing that may have affected the calibration of the dosimetry system; or

B) The dosimetry system shall have been calibrated within the previous 4 years and shall have been subjected to a protocol which provides for checks of dosimetry constancy and provides for corrective action when results deviate by more than two percent from the expected values.

5) The registrant shall maintain at the facility records of machine calibrations, quality assurance checks and instrument calibrations for inspection by the Agency for a period of 5 years. Records to be maintained by the registrant shall include, but need not be limited to, the following:

A) Records of machine calibrations and quality assurance checks shall include identification of the x-ray therapy system, radiation measurements, the date the measurements were performed and the signature of the therapeutic radiological physicist who performed the measurements.

B) Instrument calibration records shall include the date of the last calibration and identity of the calibration laboratory. If a dosimetry system has been subjected to a protocol as described in subsection (d)(4)(B) of this Section, records shall be maintained that show the date and results of each constancy check performed on the system.

e) Operating Procedures

1) No x-ray therapy system shall be left unattended unless the system is secured against unauthorized use.

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

3) Other than the patient, no individual shall be in the therapy room unless such individual is protected by a barrier sufficient to meet the requirements of 32 Ill. Adm. Code 340.

4) Other than the patient, no individual shall be in the therapy room during exposures from x-ray therapy systems operating above 150 kVp.

5) The x-ray therapy system shall not be used for treatment of patients unless the operator can maintain visual observation of the patient and audible communication with the patient.

6) On contact therapy systems, a shield of at least 0.5 millimeter lead equivalency at 100 kVp shall be positioned over the entire useful beam exit port during periods when the tube is energized and the beam is not being used.

7) The tube housing assembly shall not be held by hand during operating unless the x-ray therapy system is designed to require such holding and the peak tube potential of the system does not exceed 50 kilovolts. In such cases, the person holding the tube shall wear protective gloves and apron of not less than 0.5 millimeter lead equivalency at 100 kVp.

(Source: Amended at 32 Ill. Reg. 3693, effective February 29, 2008)