

**10A NCAC 15 .0608 THERAPEUTIC X-RAY INSTALLATIONS: LESS THAN ONE MEV**

(a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply only to therapeutic x-ray installations which are not capable of operating at or above one MeV. Therapeutic x-ray equipment subject to the provisions of this Rule shall comply with the following requirements:

- (1) When the tube is operated at its leakage technique factors, the leakage radiation in any direction shall not exceed the value specified at the distance specified for the classification of that x-ray system.
  - (A) For contact therapy systems, the leakage radiation shall not exceed 100 mR/hr at five centimeters from the tube housing.
  - (B) Systems operating from zero to 150 kVp which are manufactured or installed prior to the effective date of this Rule shall have a leakage radiation which does not exceed one R in one hour at one meter from the source.
  - (C) Systems operating from zero to 150 kVp which are manufactured on or after the effective date of this Rule shall have a leakage radiation which does not exceed 100 mR in one hour at one meter from the source.
  - (D) Systems operating from 151 to 999 kVp shall have leakage radiation which does not exceed one R in one hour at one meter from the source, except systems which operate in excess of 500 kVp may have a leakage radiation in one hour at one meter from the source equivalent to 0.1 percent of the exposure in the useful beam in one hour at a distance of one meter from the source.
- (2) Permanent beam limiting devices used for collimating the useful beam shall provide the same or higher degree of protection as that required by the tube housing assembly.
- (3) Adjustable or removable beam limiting devices shall transmit not more than five percent of the useful beam as determined at the maximum tube potential and maximum treatment filter.
- (4) The filter system shall be so designed that:
  - (A) Filters cannot be accidentally displaced from the useful beam at any tube orientation;
  - (B) Each filter is marked as to its material of construction and its thickness or wedge angle for wedges;
  - (C) It shall be possible for the operator to determine the presence of and identify each filter and the orientation of each wedge filter in the useful beam when the operator is positioned at the control panel either by display at the control panel or by direct observation;
  - (D) The filters and filter insertion slot opening shall be so designed that the radiation at five centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under all operating conditions; and
  - (E) Each machine equipped with a beryllium or other low filtration window shall be clearly labeled as such upon the tube head housing and upon the control panel.
- (5) The tube housing assembly shall be immobilized during stationary treatments.
- (6) The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five millimeters and such marking shall be readily accessible.
- (7) Equipment of greater than 150 kVp installed after the effective date of this Rule shall be provided with a beam monitor system.
- (8) The exposure timer shall meet the following requirements:
  - (A) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and shall terminate irradiation when a preselected time has elapsed.
  - (B) The timer shall switch on and off with the radiation and retain its reading after irradiation is interrupted or terminated.
- (9) The control panel shall have:
  - (A) an indication of whether electrical power is present and activation of the x-ray tube is possible;
  - (B) an indication of whether x-rays are being produced;
  - (C) the means for indicating kVp and x-ray tube current;
  - (D) the means for terminating an exposure at any time;
  - (E) a locking device which will prevent unauthorized use of the x-ray system and, for systems not having a lock at the control panel, an alternate method of preventing unauthorized use, shall be provided;

- (F) for equipment manufactured after the effective date of this Rule, a positive display of specific filter(s) in the beam.
  - (10) When a control panel may energize more than one x-ray tube:
    - (A) It shall be possible to activate only one x-ray tube during any one time interval;
    - (B) There shall be an indication at the control panel identifying which x-ray tube can be energized; and
    - (C) There shall be an indication at the x-ray tube if that tubehead can be energized.
  - (11) There shall be means of determining the target to patient distance to within one centimeter.
  - (12) If exposures are controlled by a timer, that timer:
    - (A) shall permit the setting of exposure times at least as short as one second, and
    - (B) shall not permit an exposure if set at zero or "off".
  - (13) Unless it is possible to bring the x-ray exposure rate to its prescribed value within five seconds of actuating the x-ray "on" control, the tube housing shall be fitted with a shutter operable only from the control panel, and of lead equivalent not less than that of the tube housing. In addition:
    - (A) The status of the shutter "Beam On", "Beam Off" or "Shutter Open", "Shutter Closed" or equivalent description, shall be indicated at the control panel.
    - (B) It shall not be possible to initiate an exposure sequence unless the shutter has first been placed in the "Beam Off" or "Shutter Closed" position.
    - (C) The shutter shall automatically go to the "Beam Off" or "Shutter Closed" position if the exposure is terminated by:
      - (i) the operation of the timer,
      - (ii) the dose monitoring system, if provided,
      - (iii) the operation of a safety interlock, or
      - (iv) a power failure.
- (b) In addition to shielding adequate to meet requirements of Section .1600 of this Chapter, the following treatment room design requirements shall be met:
- (1) Treatment room entrances shall be provided with warning lights in a readily observable position, which will indicate when the useful beam is "on".
  - (2) Provision shall be made for two-way communication with the patient from the control room.
  - (3) A 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.
  - (4) Facilities which contain an x-ray system which may be operated above 150 kVp shall:
    - (A) have all necessary shielding, except for any beam interceptor, provided by fixed barriers;
    - (B) have the control panel in a protected area which is outside the treatment room;
    - (C) have all entrance doors to the treatment room electrically connected such that the x-ray production cannot be initiated unless all doors are closed and shall cease if any door is opened during x-ray production;
    - (D) if the radiation output of the x-ray tube is affected by any door opening, be so designed that it is possible to initiate x-ray production only by:
      - (i) closing all doors and, subsequently,
      - (ii) reinitiating the exposure by manual action at the control panel.
- (c) Operating procedures, surveys, and calibration shall comply with the following requirements:
- (1) All new facilities and existing facilities not previously surveyed shall have a radiation protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the facility which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the facility, and a copy of this report shall be transmitted by the registrant to the agency at the address in Rule .0111 of this Chapter.
  - (2) The radiation output of each therapeutic x-ray machine shall be calibrated by, or under the direction of a qualified expert who is physically present at the facility during the calibration procedure. The calibration shall be repeated after any change, in or replacement of, components of the x-ray generating equipment which could cause a change in x-ray output. Calibration of the therapy beam shall be performed with a measurement instrument, the calibration of which is traceable to national standards for exposure or absorbed dose, and which shall have been calibrated within the preceding 12 months. Records of radiation outputs shall be provided to and maintained by the registrant.

- (3) Each therapeutic x-ray machine shall be calibrated as described in Subparagraph (c)(2) of this Rule at time intervals not exceeding one year. The calibration shall include at least the following determinations:
  - (A) the accurate determination of the air exposure rate or the dose rate at a reference point within a suitable phantom, as appropriate;
  - (B) the congruence between the radiation field and light localizer, when such is used;
  - (C) the half-value layer for every combination of kVp and filter used for radiation therapy.
- (4) Therapeutic x-ray systems capable of operation at greater than 150 kVp, in addition to the annual calibration required in Subparagraphs (c)(2) and (3) of this Rule, shall have spot checks performed.
  - (A) The spot check methods and frequency shall be designed and in writing by a qualified expert. Spot checks shall include verification of continued congruency between the radiation field and the localizing device where an optical field illuminator is used.
  - (B) Whenever a spot check indicates a significant change in the operating characteristics of a machine, as specified in the qualified expert's spot check design, the machine shall be recalibrated as required.
  - (C) A log shall be kept of all spot check measurements.
- (5) Therapeutic x-ray machines shall not be left unattended unless the locking device required by Part (a)(10)(E) of this Rule is set to prevent activation of the useful beam.
- (6) Except as provided in Rule .0603(a)(1)(H) of this Section, no individual other than the patient shall be in the treatment room during exposures unless he is protected by a barrier sufficient to meet the requirements of Rule .1604 of this Chapter, and no individual other than the patient shall be in the treatment room when the kVp exceeds 150 during exposures.
- (7) The tube housing assembly shall not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.

*History Note: Authority G.S. 104E-7; 104E-12(a);  
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