

10A NCAC 15 .0609 X-RAY AND ELECTRON THERAPY INSTALLATIONS ONE MEV AND ABOVE

(a) The requirements in Paragraphs (b) to (e) of this Rule shall apply only to medical facilities using medical x-ray and electron therapy equipment with energies one MeV and above. In addition, such medical facilities shall also comply with the requirements in Section .0900 of this Chapter.

(b) Equipment requirements are as follows:

- (1) For existing equipment and new equipment manufactured or installed after the effective date of these Rules:
 - (A) The leakage radiation, excluding neutrons, at a distance of one meter from the source shall not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.
 - (B) Within one year after the effective date of these Rules the registrant shall determine or obtain from the manufacturer for each machine the leakage radiation specifications for electrons, x-rays and neutrons existing at the points specified in Part (b)(1)(A) of this Rule for specified operating conditions. Records on radiation leakage shall be maintained at the installation.
 - (C) For equipment from which neutron leakage may be a hazard, a qualified expert shall specify such additional requirements as may be necessary to protect health or minimize danger to life or property. The adequacy of these additional requirements shall be confirmed by a survey. Survey records shall be maintained by the registrant.
- (2) Adjustable or interchangeable beam limiting devices shall be provided and shall meet the following requirements:
 - (A) For existing equipment and new equipment manufactured or installed after the effective date of these Rules:
 - (i) Adjustable or interchangeable beam limiting devices shall attenuate the radiation incident on the beam limiting devices such that the dose equivalent in rems at any distance from the source does not exceed two percent of the maximum dose equivalent in the useful beam measured at an equal distance from the radiation source.
 - (ii) If the beam limiting device does not meet the specifications in Subpart (b)(2)(A)(i) of this Rule, the agency may accept auxiliary equipment or methods for accomplishing attenuation.
 - (B) Dose equivalent measurements may be averaged over an area up to but not exceeding 100 square centimeters at a distance of one meter from the target.
- (3) In equipment which uses a system of wedge filters, interchangeable field flattening filters or beam scattering devices:
 - (A) Irradiation shall not be possible until a selection of filter has been made at the treatment control panel;
 - (B) An interlock system shall be provided to prevent irradiation if the filter is not in the correct position;
 - (C) An indication of the orientation of the wedge filter with respect to the treatment field shall be provided when wedge filters are used; and
 - (D) A display shall be provided at the treatment control panel showing the filter(s) in use, including an indication of "no filters".
- (4) Equipment installed after the effective date of these Rules shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system.
 - (A) Each primary system shall have a detector which is a transmission detector and is a full beam detector and is placed on the patient side of any fixed added filters other than a wedge filter;
 - (B) The detector(s) shall be removable only with tools or shall be interlocked to prevent incorrect positioning.
 - (C) Each detector shall be capable of independently monitoring and turning "off" the useful beam.
 - (D) 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.
 - (E) Each dose monitoring system shall have a legible display at the treatment control panel which shall:
 - (i) maintain a reading until intentionally reset;

- (ii) in the event of power failure, have the capability of retrieving the information displayed at the time of failure.
- (5) Selection and display of dose monitor units shall comply with the following requirements:
 - (A) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
 - (B) After useful beam termination, it shall be necessary to reset the preselected dose monitor units before treatment can be reinitiated.
 - (C) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset for the next irradiation.
- (6) Automatic termination of irradiation by the dose monitoring system shall comply with the following requirements:
 - (A) Each of the monitoring systems shall be capable of independently terminating irradiation. Provisions shall be made to test the correct operation of each system.
 - (B) Each primary system shall terminate irradiation when the preselected number of dose monitor units have been reached, and each secondary system shall be used as a backup.
- (7) It shall be possible to terminate irradiation and equipment movements or to go from an interruption condition to termination conditions at any time from the treatment control panel.
- (8) It shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.
- (9) A timer shall be provided and shall meet the following requirements:
 - (A) The timer shall have a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.
 - (B) The timer shall be a cumulative timer which switches "on" and "off" with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator and the preset time selector after irradiation is terminated, before reactivation is possible.
 - (C) To guard against failure of the dose monitoring systems, the timer shall terminate irradiation when a preselected time has elapsed.
- (10) In equipment capable of both x-ray therapy and electron therapy:
 - (A) Irradiation shall not be possible until a selection of radiation type, x-rays or electrons, has been made at the treatment control panel;
 - (B) An interlock system shall 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;
 - (C) An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when x-ray wedge filters are fitted; and
 - (D) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
- (11) In equipment capable of generating radiation beams of different energies:
 - (A) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
 - (B) An interlock system shall be provided to insure that the equipment emits primarily the energy of radiation which has been selected;
 - (C) An interlock system shall 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; and
 - (D) The energy selected shall be displayed at the treatment control panel before and during irradiation.
- (12) In equipment capable of both stationary-beam therapy and moving-beam therapy:
 - (A) Irradiation shall not be possible until a selection of stationary-beam therapy or moving-beam therapy has been made at the treatment control panel;
 - (B) An interlock system shall 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;

- (C) An interlock system shall be provided to terminate irradiation if the movement stops during moving-beam therapy;
 - (D) Moving-beam therapy shall be so controlled that the required dose monitor units per degree of rotation is obtained; and
 - (E) The mode of operation shall be displayed at the treatment control panel.
- (13) The registrant shall determine or obtain from the manufacturer the location with reference to an accessible point on the radiation head of:
- (A) the x-ray target and the virtual source of x-rays;
 - (B) the electron window or the scattering foil; and
 - (C) all possible orientations of the useful beam.
- (14) Means shall be provided so that all radiation safety interlocks can be checked. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel selection at one location shall not give a display at the other location until the requisite selection operations in both locations have been completed.
- (c) Facility shielding shall be adequate to meet the requirements of Section .1600 of this Chapter.
- (d) Facility design shall meet the following requirements:
- (1) Except for entrance doors, all required barriers shall be fixed barriers.
 - (2) The control panel shall be located outside the treatment room. The door must be closed during radiation production.
 - (3) A viewing 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. When the viewing system is by electronic means (e.g., television), an alternate viewing system shall be available.
 - (4) Provision shall be made for two-way aural communication with the patient from the control room, however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.
 - (5) Treatment 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, preferably at eye level, which will indicate when the useful beam is "on".
 - (6) 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.
- (e) The operating procedures which follow are in addition to those in Rule .0908 of this Chapter.
- (1) Radiation protection surveys shall comply with the following requirements:
 - (A) 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 or equipment which might cause a significant increase in radiation hazard.
 - (B) The expert shall report his findings in writing to the person in charge of the facility, and a copy of the report shall be transmitted by the registrant to the agency at the address in Rule .0111 of this Chapter.
 - (2) No person other than the patient shall be in the treatment room during treatment. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
 - (3) The output of each therapeutic x-ray machine shall be calibrated by, or under the direct supervision of a qualified expert, before it is first used for medical purposes. Calibrations shall be repeated at least once every 12 months and after any change which might significantly increase radiation hazards. Calibration of the therapy beam shall be performed with measurement instruments, 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 calibrations shall be provided to and maintained by the registrant. The calibration shall include at least the following determinations:
 - (A) the exposure rate or dose rate as appropriate for the field sizes used and for each effective energy and for each treatment distance used for radiation therapy;
 - (B) the beam quality (e.g., half-value layer when appropriate) for every proposed combination of operating conditions used for radiation therapy;
 - (C) the congruence between the radiation field and the field indicated by the localized device when used;

- (D) verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and backpointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system and beam flatness and symmetry in air or at the specified depths in a water phantom.
- (4) Spot checks shall be performed monthly.
- (A) The spot check methods shall be in writing and shall be designed by a qualified expert.
 - (B) Whenever a spot check indicates a significant change (as specified in the qualified expert's spot check design) in the operating characteristics of a machine, the machine shall be recalibrated as required in Subparagraph (e)(3) of this Rule.
 - (C) A log shall be kept of all spot check measurements.

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