Ohio Administrative Code

Rule 3701:1-67-08 Shielding design and survey requirements.

Effective: March 1, 2016

(A) Therapy equipment subject to the rules in Chapter 3701:1-67 of the Administrative Code shall be provided with such primary and secondary barriers as are necessary to ensure compliance with rules 3701:1-38-12 and 3701:1-38-13 of the Administrative Code which prescribe occupational and public dose limits respectively. Specifically:

(1) All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers; and

(2) Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

(B) Treatment room design shall provide for:

(1) Continuous two-way aural communication between the patient and the operator at the control panel; and

(2) Continuous observation of the patient during irradiation. This viewing system shall be so located that the operator can observe the patient from the control panel. Therapy equipment shall not be used for patient irradiation unless at least one viewing system is operational.

(C) For therapy equipment operating above 150kV, treatment rooms shall meet the following:

(1) All protective barriers shall be fixed, except for entrance access doors to the treatment room or movable beam interceptors;

(2) The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room; and

(3) Interlocks shall be provided such that all entrance doors, including doors to any interior booths if

applicable, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any 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.

(D) For therapy equipment operating at or above one MV, treatment rooms shall meet the following:

(1) In addition to other requirements specified in Chapter 3701:1-67 of the Administrative Code, the control panel shall:

(a) Be located outside the treatment room;

(b) Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(c) Provide an indication of whether radiation is being produced; and

(d) Include an access control or locking device that will prevent unauthorized use of the therapy equipment;

(2) Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will state in words when the useful beam is on;

(3) Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the therapy equipment to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

(4) If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with paragraph (A) and paragraph (B) of rule 3701:1-38-13 of the Administrative Code, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

(5) At least one emergency power cutoff switch shall be located in the radiation therapy room and

shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required on the treatment control panel. All emergency power cutoff switches shall include a manual reset so that the therapy equipment cannot be restarted from the unit's control console without resetting the emergency cutoff switch; and

(6) All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapy equipment.

(E) A qualified medical physicist shall design shielding, verify shielding design or verify that the existing shielding is adequate for installation of therapy equipment.

(F) The facility design information for all new installations of therapy equipment or installations of equipment of higher energy or capable of producing a larger maximum useful beam into a room not previously designed for that energy or beam size shall be submitted to the department prior to installation of the therapy equipment. The minimum facility design information that shall be submitted is listed in the appendix to this rule.

(G) The handler shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated in accordance with rule 3701:1-67-07 of the Administrative Code.

(H) The radiation protection survey shall be performed by, or under the direct supervision of a qualified medical physicist.

(I) With the largest clinically available treatment field and with a scattering phantom in the useful beam when evaluating secondary protective barriers and no phantom in the useful beam when evaluating primary protective barriers, and with the therapy equipment in a "beam-on" condition, the qualified medical physicist shall verify that:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in rule 3701:1-38-12 of the Administrative Code; and

(2) Radiation levels in unrestricted areas do not exceed the limits specified in rule 3701:1-38-13 of

the Administrative Code.

(J) In addition to the requirements of paragraphs (G) to (I) of this rule, a radiation protection survey shall also be performed prior to any subsequent medical use and:

(1) After making any change in the treatment room shielding;

(2) After making any change in the location of the therapy equipment within the treatment room except for portable contact therapy equipment, electronic brachytherapy equipment or portable external beam radiation therapy equipment capable of electron production only;

(3) After relocating the therapy equipment except for portable contact therapy equipment, electronic brachytherapy equipment or portable external beam radiation therapy equipment capable of electron production only;

(4) Before using the therapy equipment in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room; or

(5) After changes are made to the therapy equipment, the therapy equipment shielding, or the treatment room shielding following a survey that failed to ensure compliance with the requirements of this rule.

(6) Determination of residual activity for all therapy equipment capable of generating photon and electron energies above ten MV shall be performed to determine compliance with occupational dose limits prior to machining, removing, or working on therapy equipment components which may have become activated due to photo- neutron production.

(K) If the results of the surveys required by paragraphs (G) to (J) of this rule indicate any radiation levels in excess of the respective limits, the handler shall lock the control in the "off" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the therapy equipment, the therapy equipment shielding, or the treatment room shielding;

(2) Until either the equipment is provided with appropriate beam directional interlocks or additional radiation shielding is added to ensure compliance with rules 3701:1-38-12 and 3701:1-38-13 of the Administrative Code;

(3) Until implementation of administrative controls to reduce radiation levels below the respective limits; or

(4) Until the handler has requested and received a variance from the department that authorizes radiation levels in unrestricted areas greater than those permitted by rules 3701:1-38-12 and 3701:1-38-13 of the Administrative Code.

(L) The survey record shall indicate:

(1) All instances where the facility, in the opinion of the qualified medical physicist, is in violation of applicable regulations;

(2) The date of the measurements;

(3) The reason the survey is required;

(4) The manufacturer's name, model number and serial number of the therapy equipment;

(5) The manufacturers' names, model numbers, serial numbers, and dates of calibration of the instruments used to measure radiation levels;

(6) A plan of the areas surrounding the treatment room that were surveyed;

(7) The measured dose rate at a representative number of points in each area expressed in microsieverts (millirem) per hour;

(8) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and

(9) The name and signature of the individual responsible for conducting the survey.

(M) The handler shall maintain a record of each shielding design and survey for the duration of the registration and make the records and measurements available upon request during an inspection.