Ohio Administrative Code

Rule 3701:1-67-06 Standards for therapy equipment operating at or above one megavolt (MV).

Effective: March 1, 2016

As used in this rule, "therapy equipment"means photon therapy systems and electron therapy systems operating at or aboveone megavolt (MV). In addition to the rules in Chapters 3701:1-38 and 3701:1-67of the Administrative Code, handlers of therapy equipment shall comply with thefollowing:

(A) Upon installation of therapy equipment, acceptance testing shall be performed to verify that the equipment complies with all manufacturer specifications. In the event that manufacturer specifications are unavailable for reference, all therapy equipment shall be tested to ensure compliance with the standards of this rule. Any modification of equipment that occurs pursuant to initial acceptance testing shall entail appropriate retesting in order to re-determine compliance with applicable manufacturer standards or standards of this rule.

(B) Leakage radiation outside the maximum useful beam in photon and electron modes shall not exceed the manufacturer specifications, or in the absence of the manufacturer specifications:

(1) The absorbed dose due to leakage radiation, excluding neutrons, at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance, such as patient plane, shall not exceed a maximum of 0.2 per cent and an average of 0.1 per cent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters at a minimum of sixteen points uniformly distributed in the plane;

(2) Except for the area defined in paragraph (B)(1) of this rule, the absorbed dose due to leakage radiation, excluding neutrons, at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 per cent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters;

(3) For equipment manufactured after July 21, 2014, the neutron absorbed dose outside the useful beam shall be in compliance with "International Electrotechnical Commission Document 60601-2-1:2009/AMD1:2014 (IEC 60601-2-1:2009/AMD1:2014)," (IEC) documents which, may be purchased from the "IEC National Committee of United States of America, ANSI, 25 West 43rd Street, 4th Floor, New York, New York, 10036," telephone (212) 642-4900, http://www.iec.ch/. Evidence of a product conformity assessment (CA) showing the parameter referenced in this rule is in compliance with IEC 60601-2-1:2009/AMD1:2014 shall be considered adequate to meet the requirements of this rule; and

(4) For each piece of therapy equipment, the handler shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs (B)(1) and (B)(2) of this rule for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the department.

(C) Leakage radiation through beam limiting devices shall not exceed the manufacturer specifications, or in the absence of the manufacturer specifications, shall meet the following:

(1) Using photon radiation, all adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed two per cent of the maximum absorbed dose on the central axis of the useful beam measured in a one hundred square centimeter radiation field, or maximum available field size if less than one hundred square centimeters;

(2) Using electron radiation, all adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(a) A maximum of two per cent and average of 0.5 per cent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

(b) A maximum of ten per cent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam; and

(3) Measurements of leakage radiation for:

(a) Photon radiation shall have measurements through the beam limiting devices made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters; and

(b) Electron radiation shall have measurements through the electron applicators made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

(D) Filters and wedges shall comply with the following:

(1) Each wedge that is removable from the system shall be clearly marked with an identification number. For removable wedges, the nominal wedge angle shall appear on the wedge or wedge tray, if it is permanently mounted to the tray. If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

(2) If the absorbed dose rate information required by paragraph (I) of this rule relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by authorized service personnel; and

(3) For equipment manufactured after June 01, 2013, which utilizes wedges, interchangeable field flattening filters, or interchangeable beam scattering foils:

(a) Irradiation shall not be possible until a selection of a wedge or a positive selection to use "no wedge" has been made via the treatment control system, either manually or automatically;

(b) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(c) A display shall be provided by the treatment control system showing the wedges, interchangeable field flattening filter(s), or interchangeable beam scattering foil(s) in use; and

(d) An interlock shall be provided to prevent irradiation if any filter or beam scattering foil selection operation carried out in the treatment room does not agree with the filter or beam scattering foil selection operation carried out via the treatment control system.

(E) For equipment manufactured after July 21, 2014, x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam shall be in compliance with "International Electrotechnical Commission (IEC) Document 60601-2-1:2009/AMD1:2014," (IEC) documents which, may be purchased from the "IEC National Committee of United States of America, ANSI, 25 West 43rd Street, 4th Floor, New York, New York, 10036," telephone (212) 642-4900, http://www.iec.ch/. Evidence of a product CA showing the parameters referenced in this rule are in compliance with IEC 60601-2-1:2009/AMD1:2014 shall be considered adequate to meet the requirements of this rule.

(F) All therapy equipment subject to the requirements of this rule shall be provided with redundant beam monitoring systems. The detectors for these systems shall be fixed in the useful beam during treatment to indicate the dose rate.

(1) Each redundant beam monitoring system shall be provided with an independently powered integrating dose meter. Alternatively, dose meters with shared components may be used if the production of radiation is terminated upon failure of any common components.

(2) The detector and the system into which that detector is incorporated shall meet the following requirements:

(a) Each detector shall form part of a beam monitoring system from whose readings the absorbed dose at a reference point can be calculated;

(b) Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation;

(c) For equipment manufactured after June 01, 2013, the design of the beam monitoring systems shall ensure that the:

(i) Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

(ii) Failure of either system shall terminate irradiation or prevent the initiation of radiation; and

(d) Each beam monitoring system shall have a legible treatment control system display. For therapy equipment manufactured after February 15, 2001, each display shall:

(i) Maintain a reading until intentionally reset;

(ii) Have only one scale and no electrical or mechanical scale multiplying factors;

(iii) Utilize a design such that increasing dose is displayed by increasing numbers; and

(iv) In the event of power failure, the beam monitoring information required in paragraph (F)(2)(d)(iii) of this rule, displayed by the control system at the time of failure shall be retrievable in at least one system for a twenty minute period of time.

(G) The following requirements shall be met for beam symmetry:

(1) A bent-beam linear accelerator with beam flattening filter(s) subject to the requirements of this rule shall be provided with auxiliary device(s) to monitor beam symmetry;

(2) The device(s) referenced in paragraph (G)(1) of this rule, shall be able to detect field asymmetry greater than ten per cent; and

(3) The device(s) referenced in paragraph (G)(1) of this rule, shall be configured to terminate irradiation if the specifications in paragraph (G)(2) of this rule, cannot be maintained.

(H) The following requirements shall be met for the selection and display of monitor units:

(1) Irradiation shall not be possible until a new selection of a number of monitor units has been made via the treatment control system;

(2) The pre-selected number of monitor units shall be displayed by the treatment control system until reset manually for the next irradiation;

(3) After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

(4) For therapy equipment manufactured after June 01, 2013, it shall be necessary for the operator to reset the pre-selected monitor units after each termination of an irradiation and before a new irradiation can be initiated.

(I) For therapy equipment manufactured after June 01, 2013, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in paragraph (F) of this rule may form part of this system. In addition:

(1) The monitor unit rate shall be displayed by the treatment control system;

(2) If the therapy equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the handler;

(3) If the therapy equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the

manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four gray (four hundred rad); and

(4) For each piece of therapy equipment, the handler shall determine, or obtain from the manufacturer, the maximum value(s) specified in paragraphs (I)(2) and (I)(3) of this rule, for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the department.

(J) During stationary beam radiation therapy, termination of irradiation by the beam monitoring systems shall meet the following requirements:

(1) The primary system shall terminate irradiation when the pre-selected number of monitor units set via the control system has been detected by the system;

(2) The secondary system shall be capable of terminating irradiation when not more than fifteen per cent or forty monitor units above the pre-selected number of monitor units set via the control system has been detected by the system; and

(3) For equipment manufactured after February 15, 2001, a treatment control system indicator shall show which monitoring system has terminated irradiation.

(K) It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(L) If the therapy equipment has an interrupt mode, 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, irradiation and equipment movements shall be automatically terminated.

(M) A suitable irradiation control system shall be provided to terminate the irradiation after a pre-set time interval and shall meet the following requirements:

(1) A timer shall be provided which has a treatment control system display. The timer shall have a pre-set time selector and an elapsed time indicator;

(2) The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator; and

(3) The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(N) Therapy equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(1) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made via the treatment control system;

(2) The radiation type selected shall be displayed by the treatment control system before and during irradiation;

(3) An interlock system shall be provided to ensure that the therapy equipment can principally emit only the radiation type that has been selected;

(4) An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

(5) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(6) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the operations selected via the treatment control system.

(O) Therapy equipment capable of generating radiation beams of different energies shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of energy has been made via the treatment control system;

(2) The nominal energy value selected shall be displayed by the treatment control system until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

(3) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location.

(4) For therapy equipment manufactured after July 21, 2014, the selection of energy shall be in compliance with "International Electrotechnical Commission (IEC) Document 60601-2-1:2009/AMD1:2014," (IEC) document which, may be purchased from the "IEC National Committee of United States of America, ANSI, 25 West 43rd Street, 4th Floor, New York, New York, 10036," telephone (212) 642-4900, http://www.iec.ch/. Evidence of a product CA showing the parameter referenced in this rule is in compliance with IEC 60601-2-1:2009/AMD1:2014 shall be considered adequate to meet the requirements of this rule.

(P) Therapy equipment capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

(1) Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made via the treatment control system;

(2) The mode of operation shall be displayed by the treatment control system;

(3) An interlock system shall be provided to ensure that the therapy equipment can operate only in the mode that has been selected;

(4) An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the parameter displayed by the treatment control system;

(5) Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental monitor units and incremental movement. For therapy equipment manufactured after June 01, 2013:

(a) An interlock system shall be provided to terminate irradiation if the number of monitor units delivered in any ten degrees of rotation or one centimeter of linear motion differs by more than twenty per cent from the selected value;

(b) Where angle terminates the irradiation in moving beam radiation therapy, the monitor units delivered shall differ by less than five per cent from the monitor unit value selected;

(c) An interlock shall be provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

(d) An interlock shall be provided to require that a selection of direction be made via the treatment control system in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy; and

(e) Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental monitor units and incremental movement;

(6) Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by paragraph (J) of this rule; and

(7) For equipment manufactured after the effective date of this rule, an interlock system shall be provided to terminate irradiation if movement:

(a) Occurs during stationary beam radiation therapy; or

(b) Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

(Q) The control panel shall have a warning label which cautions individuals that radiation is produced when the therapy equipment is energized.