WAC 246-225-130 X-ray and electron therapy systems with energies of one MeV and above. Chapter 246-229 WAC except WAC 246-229-100 (3) and (4) shall apply to medical facilities using therapy systems with energies 1 MeV and above.

(1) *Definitions.* In addition to the definitions provided in WAC 246-225-010, the following definitions shall be applicable to this section.

(a) "Applicator" means a structure which indicates the extent of the treatment field at a given distance from the nominal source and which may or may not incorporate an additional beam-limiting device.

(b) "Beam scattering foil" means a device which scatters and flattens a beam of electrons.

(c) "Central axis of the beam" means a line passing through the origin of the source and the center of the plane figure formed by the edge of the secondary collimating jaws when in a symmetric mode.

(d) "Dose monitoring system" means a system of devices for the detection and display of quantities of radiation.

(e) "Dose monitor unit" means a unit from which the absorbed dose can be calculated.

(f) "Existing equipment" means therapy systems subject to this section which were manufactured on or before the effective date of these regulations.

(g) "Field flattening device" means an absorber used to homogenize the dose rate over the area of a useful beam of X-rays.

(h) "Field size" means the dimensions of an area in a plane perpendicular to the specified direction of the beam of incident radiation at a maximum dose depth. Determine dimensions by fifty percent decrement lines.

(i) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

(j) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of the operating conditions at the control panel.

(k) "Isocenter" means a fixed point in space located at the intersection of the rotation axes of the principal movements of the therapy system.

(l) "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation.

(m) "New equipment" means systems subject to this section which were manufactured after effective date of these regulations.

(n) "Nominal source" means a point from which radiation originates.

(o) "Normal treatment distance" means the distance between the virtual source and a reference point on the central axis of the beam. The reference is located at a position on the central axis at a specified distance from the nominal source.

(p) "Patient" means an individual subjected to examination and treatment.

(q) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

(r) "Primary dose monitoring system" means a system which will monitor the quantity of radiation produced during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

(s) "Radiation treatment prescription" means the absorbed dose which is intended to be delivered to the treatment volume.

(t) "Radiation head" means the structure from which the useful beam emerges.

(u) "Redundant dose monitoring combination" means a combination of two dose monitoring systems in which both systems are arranged to terminate irradiation in accordance with a preselected number of dose monitor units.

(v) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

(w) "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.

(x) "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

(y) "Target" means that part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

(z) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(aa) "Treatment field" means the cross-sectional area of the patient's tissue which is to be irradiated.

(bb) "Treatment volume" means that portion of the patient's body which is to be irradiated.

(2) *Requirements for equipment.*

(a) *Leakage radiation to the patient area.*

(i) New equipment shall meet the following requirements:

(A) For all operating conditions, the dose equivalent in rem due to leakage radiation, including X-ray and electrons, but excluding neutrons, at any point in a circular plane of two meters radius centered on and perpendicular to the central axis of the beam at the normal treatment distance and outside the maximum useful beam, shall not exceed 0.1 percent of the maximum dose equivalent in rem of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements shall be averaged over an area up to but not exceeding one hundred square centimeters at the positions specified; and

(B) For each system the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in (a)(i)(A) of this subsection for specified operating conditions. Records for leakage radiation shall be maintained at the installation for inspection by the department.

(ii) Existing equipment (that installed prior to the effective date of the regulations) shall meet the following requirements:

(A) The leakage radiation, excluding neutrons, at any point in the area specified by (a)(i)(A) of this subsection, where such area intercepts the central axis of the beam one meter from the nominal source, shall not exceed 0.1 percent of the maximum dose equivalent in rems of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the reference circular plane. Measurements shall be averaged over an area up to but not exceeding one hundred square centimeters at the positions specified.

(B) For each system, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in (a)(ii)(A) of this subsection for specified operating conditions. Records for radiation leakage shall be maintained at the installation for inspection by the department.

(b) *Leakage radiation outside the patient area.*

(i) The dose equivalent in rem due to leakage radiation, except in the area specified in (a) of this subsection, when measured at any point one meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for X-ray leakage of the maximum dose equivalent in rems of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in (a) of this subsection.

(ii) The registrant shall determine, or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in (a) of this subsection for specified operating conditions. Measurements shall be averaged over an area up to but not exceeding one hundred square centimeters at the positions specified.

(c) *Beam-limiting devices.* Secondary beam-limiting devices shall be provided and such devices shall transmit no more than two percent of the useful beam for the portion of the useful beam attenuated by the beam-limiting device. The neutron component of the useful beam shall not be included in this requirement.

(d) *Beam-modifying devices.*

(i) When the absorbed dose rate information required by subsection (2)(q) of this section is dependent on operation with a beam-flattening or beam-scattering device in place, the device shall be removable from the machine only by the use of tools.

(ii) In systems using interchangable beam-flattening devices or beam-scattering foils:

(A) Irradiation shall not be possible until a selection of beam-modifying device is made and verified at the treatment control panel;

(B) An interlock system shall be provided to prevent irradiation when the beam-modifying device selected is not in the correct position; and

(C) A display at the control panel shall indicate what beam-modifying device is selected.

(e) Wedges.

(i) Presence of wedges in the beam shall be indicated at the control panel, by direct observation or by electronic means.

(ii) Each wedge removable from the system shall be clearly identified as to that wedge's material of construction, thickness, and wedge angle.

(iii) An interlock shall be provided to prevent irradiation when a wedge selection carried out in the treatment room does not agree with the wedge selection indicated at the control panel.

(f) *Beam quality.* The registrant shall obtain from the therapy X-ray system manufacturer, and have available, the following information:

(i) At various beam energies, the X-ray absorbed dose expressed as a fraction of maximum absorbed dose;

(ii) At various beam energies, the absorbed dose at the surface of the skin as a fraction of the maximum absorbed dose; and

(iii) The maximum percentage absorbed dose due to stray neutrons in the useful beam at specified operating conditions.

(g) *Beam monitors.* Therapy systems shall be provided with radiation detectors in the radiation head.

(i) New equipment shall be provided with two or more radiation detectors. The detectors shall be incorporated into two monitoring systems arranged either as a primary/primary combination or as a primary/secondary combination.

(ii) Existing equipment shall be provided with one or more radiation detectors. The detector shall be incorporated into a primary system.

(iii) The detectors and system where the detector is incorporated shall meet the following requirements:

(A) Each primary system shall have a detector which is a transmission full-beam detector placed on the patient side of beam-modifying devices;

(B) The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning;

(C) Each detector shall be capable of independently monitoring and controlling 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) For new equipment, the design of the dose-monitoring systems of subsection (2)(i) of this section shall assure the malfunctioning of one system shall not affect the correct functioning of the second system. In addition, the failure of an element common to both systems shall terminate irradiation.

(F) Each dose monitoring system shall have a legible display at the treatment control panel. Each display shall:

(I) Maintain a reading until intentionally reset to zero;

(II) Have only one scale and no scale multiplying factors in new equipment; and

(III) Utilize a design so increasing dose is displayed by increasing numbers and shall be designed so, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under normal conditions of use or foreseeable failures.

(G) In the event of power failure, the dose-monitoring information required in subsection (2)(i) of this section displayed at the control panel at the time of failure shall be retrievable in one or more systems.

(h) *Beam symmetry.*

(i) A therapy machine installed after the effective date of these regulations shall have the capability of comparing the dose rates in each of the four quadrants of the central eighty percent of the useful beam.

(ii) Beam symmetry information shall be displayed at the treatment control panel making possible the following differential between quadrants:

(A) Five percent for straight-through accelerators; and

(B) Three percent for bending-magnet accelerators.

(iii) Beam asymmetry in excess of a ten percent quadrant differential shall cause treatment to terminate, or shall prevent irradiation.

(i) *Selection and display of dose monitor units.*

(i) Irradiation shall not be possible until a selection of a number of dose monitor units is made at the treatment control panel.

(ii) After useful beam termination, it shall be necessary manually to reset the preselected dose monitor units before treatment is reinitiated.

(iii) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

(j) *Termination of irradiation by the dose monitoring system.*

(i) Each of the required monitoring systems shall be capable of independently terminating an irradiation. Provision shall be made to test the correct operation of each system.

(ii) Each primary system shall terminate irradiation when the preselected number of dose monitor units is detected by the system.

(iii) Each secondary system shall terminate irradiation when a maximum of the preselected number of dose monitor units plus forty is detected by the system.

(iv) For new equipment, indicators on the control panel shall show which monitoring system terminated the beam.

(k) *Interruption switches.* It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following any interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, the equipment shall go to termination condition.

(l) *Termination switches.* It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

(m) *Timer.*

(i) A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and decimals of minutes. The timer shall have a preset time selector and an elapsed time indicator.

(ii) 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 and subsequently reset the elapsed time indicator and the preset time selector after irradiation is terminated before irradiation shall again be possible.

(iii) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to terminate irradiation.

(n) *Selection of radiation type.* Equipment capable of both X-ray therapy and electron therapy shall meet the following requirements:

(i) Irradiation shall not be possible until a selection of radiation type is made at the treatment control panel;

(ii) An interlock system shall be provided to insure that the equipment can emit only the selected radiation type;

(iii) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out in the treatment control panel;

(iv) With the exception of a specified number of dose monitor units for the purpose of portal film exposures, an interlock system shall be provided to prevent irradiation with X-rays when electron applicators are in place and to prevent irradiation with electrons when accessories for X-ray therapy are in place; and

(v) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

(o) *Selection of energy.* Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(i) Irradiation shall not be possible until a selection of energy is made at the treatment control panel;

(ii) An interlock system shall be provided to insure the equipment can emit only the energy of selected radiation;

(iii) An interlock system shall be provided to prevent irradiation if selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel; and

(iv) The energy selected shall be displayed at the treatment control panel before and during irradiation.

(p) *Selection of stationary beam therapy or moving beam therapy.* Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

(i) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy is made at the treatment control panel;

(ii) An interlock system shall be provided to insure the equipment can operate only in the selected mode;

(iii) An interlock system shall be provided to prevent irradiation when any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;

(iv) An interlock system shall be provided to terminate irradiation when the movement stops during moving beam therapy;

(v) Moving beam therapy shall be controlled so the required relationship between the number of dose monitor units and movement is obtained; and

(vi) The mode of operation shall be displayed at the treatment control panel.

(q) *Absorbed dose rate.* For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated.[3] In addition:

(i) The quotient of the number of dose monitor units by time shall be displayed at the treatment control panel; and

(ii) If the equipment can deliver, under any conditions, an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer's anticipated dose rate for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation is terminated shall be in a registrant-maintained record.

(r) *Location of focal spot and beam orientation.* The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

(i) The X-ray target or the virtual source of X-rays;

(ii) The electron window or the scattering foil;

(iii) All possible orientations of the useful beam.

(s) *System interlock checks.* Capabilities shall be provided to check radiation safety interlocks. When preselection of 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 selected operations in both locations are completed.

(t) *Facility and shielding requirements.* In addition to chapter 246-221 WAC, the following design requirements shall apply:

(i) Except for entrance doors or beam interceptors, required barriers shall be fixed barriers;

(ii) The treatment control panel shall be located outside the treatment room;

(iii) Windows, mirrors, closed-circuit television, or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be located so the operator may observe the patient from the treatment control panel. When the viewing system is by electronic means, for example, by television, an alternate viewing system shall be provided for use in the event of the primary system failure, or, alternatively, treatments shall be discontinued until the viewing system is again functional;

(iv) Provision shall be made for two-way aural communication between the patient and the operator at the treatment control panel. However, where excessive noise levels make aural communications impractical, other methods of communication shall be used;

(v) Treatment rooms to which access is possible through two entrances or more shall be provided with warning lights and shall indicate when the useful beam is "on" in a readily observable position near the outside of all access doors; and

(vi) Interlocks shall be provided so entrance doors shall be closed before treatment is initiated or continued. When the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.

(u) *Surveys, calibrations, spot checks and operating procedures.*

(i) Survey.

(A) New facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. Such surveys shall also be done after a change in the facility or equipment causing a significant increase in radiation hazard.

(B) The registrant shall obtain a written report of the survey from the qualified expert and the registrant shall transmit a copy of the report to the department.

(C) The report shall indicate instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations and shall cite the section violated.

(ii) Calibrations.

(A) The calibration of systems subject to this section shall be performed before the system is first used for irradiation of patient and thereafter at time intervals which do not exceed twelve months and after any change which significantly alters the calibration, spatial distribution, or other characteristics of the therapy beam.

(B) The calibration shall be performed by a qualified expert.

(C) Calibration of the dose equivalent of the therapy beam shall be performed with a measurement instrument of which the calibration is traceable to national standards of exposure or absorbed dose and which shall have been calibrated within the preceding two years.

(D) Calibrations made under subsection (2)(u)(ii) of this section shall require the dose at a reference point in soft tissue be calculated within ± 5 percent.

(E) The calibration of the therapy beam shall include, but not be limited to, the following determinations:

(I) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specified depths;

(II) The output factors in terms of dose per monitor unit or dose per minute at a specific depth in a phantom for the range of field sizes used, for each effective energy, and for each treatment distance used for radiation therapy;

(III) The congruence between the radiation field and the field indicated by the localizing device; and

(IV) The uniformity of the radiation field and its dependency upon the direction of the useful beam.

(F) Records of the calibration performed under subsection (2)(u)(ii) of this section shall be maintained by the registrant for two years after completion of the calibration.

(G) A copy of the latest calibration performed under subsection (2)(u)(ii) of this section shall be available for operator use.

(iii) Spot checks. Spot checks shall be performed on the system subject to this section. Such spot checks shall meet the following requirements:

(A) A qualified expert shall develop, in writing, spot check procedures;

(B) The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics affecting the radiation output of the system or the radiation delivered to a patient during a therapy procedure;

(C) The spot check procedures shall specify the frequency of tests or measurements performed;

(D) For systems where beam quality can vary significantly, spot checks shall include quality checks;

(E) Where a system has built-in devices which provide a self-check of any parameter during irradiation, the spot check procedures shall require the parameter be independently verified at specific time intervals;

(F) Erratic spot checks or inconsistent spot checks of calibration data shall be promptly investigated and corrected before the system is used for patient irradiation;

(G) When a spot check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot check procedures, the system shall be recalibrated as required under subsection (2)(u)(ii) of this section;

(H) Records of spot check measurements performed under subsection (2)(u)(iii) of this section shall be maintained by the registrant for a period of one year or for twice as long as the spot check cycle, whichever is greater;

(I) Operating procedures.

(I) No individual other than the patient shall be in the treatment room during treatment of a patient.

(II) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

(III) The system shall not be used in the administration of radiation therapy unless subsection (2)(u)(i), (ii), and (iii) of this section are met.

[3] The radiation detectors specified under subsection (2)(g) of this section may form part of this system.

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-225-130, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-225-130, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-28-101, filed

12/11/86. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-28-101, filed 12/8/80.]