WAC 246-225-120 Therapeutic X-ray installations less than 1 MeV.

(1) *Equipment requirements.*

(a) *Leakage radiation.* When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of that X-ray system:

(i) Contact therapy systems. Leakage radiation shall not exceed 100 milliroentgens per hour at five centimeters from the surface of the tube housing assembly;

(ii) Zero to one hundred fifty kVp systems. Systems shall have a leakage radiation which does not exceed one roentgen in one hour at one meter from the source;

(iii) One hundred fifty-one to nine hundred ninety-nine kVp systems. The leakage radiation shall not exceed one roentgen in one hour at one meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at one meter from the source equivalent to the exposure within one hour of the useful beam at one meter from the source multiplied by a factor of 0.001.

(b) *Permanent beam limiting devices.* Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as that required by the tube housing assembly.

(c) *Removable and adjustable beam limiting devices.*

(i) Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent of the original X-ray beam at the maximum kilovoltage and maximum treatment filter;

(ii) Adjustable beam limiting devices installed after the effective date of this section shall meet the requirements of (c)(i) of this subsection;

(iii) Adjustable beam limiting devices installed before the effective date of this section shall, for the portion of the X-ray beam to be blocked by these devices, transmit not more than five percent of the original X-ray beam at the maximum kilovoltage and maximum treatment filter.

(d) *Filter and wedge systems.* Filter systems shall meet the following requirements:

(i) Filters cannot be accidently displaced from the useful beam at any possible tube orientation;

(ii) Each filter is marked as to its material of construction and its thickness or wedge angle for wedge filters;

(iii) It shall be possible for the operator to determine the presence or absence of each filter in the useful beam when the operator is at the control panel, either by display at the control panel or by direct observation; and

(iv) The filter insertion slot opening shall be covered with an attenuator equivalent to four-pound lead under operating conditions.

(e) *Tube immobilization.* The tube housing assembly shall be capable of being immobilized during stationary treatments.

(f) *Focal spot marking.* 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 for use during calibration procedures.

(g) *Timer.*

(i) A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and frac-

tions of minutes. The timer shall have a preset time selector and a means of determining elapsed time;

(ii) The timer shall be a cumulative timer which activates with radiation and retains its reading after irradiation is interrupted or terminated;

(iii) The timer shall terminate irradiation when a preselected time has elapsed;

(iv) The timer shall permit accurate presetting and determination of exposure times as short as 1 second;

(v) The timer shall terminate irradiation when set to zero;

(vi) The timer shall not activate until the shutter is opened, when patient irradiation is controlled by a shutter mechanism.

(h) *Control panel functions.* The control panel, in addition to the displays required in other provisions of this chapter, shall have:

(i) An indication of whether X-rays are being produced;

(ii) Means for indicating kV and X-ray tube current;

(iii) The means for terminating an exposure at any time;

(iv) A locking device which will prevent unauthorized use of the X-ray system; and

(v) For X-ray equipment manufactured after the effective date of this section, a positive display of specific filter(s) in the beam.

(i) *Source-to-patient distance.* There shall be means of determining the source-to-patient distance to within five millimeters.

(j) *Shutters.* Unless it is possible to bring the X-ray output to the prescribed exposure parameters within five seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition:

(i) After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel;

(ii) An indication of shutter position shall appear at the control panel.

(k) *Low filtration X-ray tubes.* Each X-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel;

(l) *Alignment.* When the therapy X-ray system is equipped with a light field indicating the X-ray field, the misalignment of one field edge to the other shall not exceed one percent of any source-to-treatment distance.

(2) *Facility design requirements for systems capable of operating above 50 kVp.*

In addition to shielding adequate to meet requirements of chapters 246-235 and 246-221 WAC and the shielding plan review provisions of WAC 246-225-030, the treatment room shall meet the following design requirements:

(a) *Warning lights.* 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, which will indicate when the useful beam is "on." Or, as an alternative, entrances other than the main one shall be equipped with interior locks, activated for the period of exposure, and the main entrance shall be under control of the operator.

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

(c) *Viewing systems.* Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means (e.g., television), an alternate viewing system shall be available for use in the event of electronic failure or treatment must be discontinued until repair is made. If treatment is to be discontinued, this policy shall be included in the written safety procedures. A copy of the safety procedures shall be provided to the operator.

(d) *Additional requirements.* Treatment rooms which contain an X-ray system capable of operating above 150 kVp shall meet the following additional requirements:

(i) All necessary shielding, except for any beam interceptor, shall be provided by fixed barriers;

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

(iii) All doors of the treatment room shall be electronically connected to the control panel such that X-ray production cannot occur unless all doors are closed;

(iv) When the doors referred to in (d)(iii) of this subsection are opened while the X-ray tube is activated:

(A) X-ray production shall terminate within one second; or

(B) The radiation at a distance of one meter from the source shall be reduced to less than 100 milliroentgens per hour within one second.

(v) After the radiation output of the X-ray tube has been affected by the opening of any door referred to in (d)(iii) of this subsection, it shall be possible to restore the X-ray system to full operation only upon:

(A) Closing the door; and subsequently

(B) Reinitiating the exposure at the control panel.

(e) *Calibrations.*

(i) The calibration of an X-ray system shall be performed at intervals not to exceed one year and after any change or replacement of components which could cause a change in the radiation output.

(ii) The calibration of the radiation output of the X-ray system shall be performed by a qualified expert who is physically present at the facility during such calibration.

(iii) Calibration of the radiation output of an X-ray system shall be performed with a calibrated instrument. The calibration of such instrument shall be traceable to a national standard. The instrument shall have been calibrated within the preceding two years.

(iv) The calibrations made pursuant to (e)(i) of this subsection shall be such that the dose at a reference point in soft tissue can be calculated to within ± five percent.

(v) The calibration of the X-ray system shall include, but not be limited to, the following determinations:

(A) The exposure rates for each combination of field size, technique factors, filter, and treatment distance used;

(B) The degree of alignment between the radiation field and the field indicated by the localizing device if such device is present; and

(C) An evaluation of the uniformity of the radiation field symmetry for the field sizes used and any dependence upon tube housing assembly orientation.

(vi) Records of calibration performed pursuant to (e) of this subsection shall be maintained by the registrant for two years after completion of the calibration.

(vii) A copy of the most recent X-ray system calibration shall be available for use by the operator at the control panel.

(f) *Operating procedures.*

(i) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(ii) The tube housing assembly shall not be held by an individual during exposures;

(iii) No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of chapter 246-221 WAC. No individual other than the patient shall be in the treatment room during exposures when the kVp exceeds 150;

(iv) The X-ray system shall not be used in the administration of radiation therapy unless the requirements of (e) of this subsection have been met.

[Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-225-120, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-225-120, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 87-01-031 (Order 2450), § 402-28-091, filed 12/11/86; WSR 83-19-050 (Order 2026), § 402-28-091, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-28-091, filed 12/8/80.]