As used in this rule, "therapy equipment" means therapy equipment operating below one megavolt (MV). In addition to the rules in Chapters 3701:1-38 and 3701:1-67 of the Administrative Code, handlers of therapy equipment shall comply with the following:

(A) When the x-ray tube is operated at its maximum rated tube current for the maximum kilovoltage (kV), the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapy equipment.

(1) For five kV to fifty kV systems, the leakage air kerma rate measured at any position five centimeters from the tube housing assembly shall not exceed one milligray (one hundred millirad) in any one hour.

(2) For greater than fifty kV and less than one MV systems, the leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one centigray (one rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed thirty centigrays (thirty rad) per hour.

(3) 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 (A)(1) and (A)(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.

(B) Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(C) Requirements for adjustable or removable beam limiting devices include:

(1) All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five per cent of the useful beam for the most penetrating beam used; and

(2) When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(D) The filter system shall be so designed that:

(1) Filters can not be accidentally displaced at any possible tube orientation;

(2) An interlock system prevents irradiation if the proper filter is not in place;

(3) The air kerma rate escaping from the filter slot shall not exceed one centigray (one rad) per hour at one meter under any operating conditions; and

(4) Each filter shall be marked as to its material of construction and its thickness.

(E) Requirements for tube immobilization include:
The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

The tube housing assembly shall be capable of being immobilized for stationary portal treatments unless the unit is designed to be hand-held and the peak tube potential of the system does not exceed fifty kV.

The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at one hundred kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

A timer with a display shall be provided by the treatment control system. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

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;

The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

The timer shall not permit an exposure if set at zero;

The timer shall not activate until the shutter is opened if irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

The timer shall be accurate to within one per cent of the selected value or one second, whichever is greater.

The control system, in addition to the displays required by other provisions in this rule, shall have:

An indication of whether electrical power is available to the control system and if activation of the x-ray tube is possible;

An indication of whether x-rays are being produced;

A means for indicating x-ray tube potential and current;

The means for terminating an exposure at any time;

A locking device which will prevent unauthorized use of the therapy equipment;
(6) A positive display of specific filter(s) in the beam; and

(7) A warning label which cautions individuals that radiation is produced when the therapy equipment is energized.

(J) When a control system may energize more than one x-ray tube:

(1) It shall be possible to activate only one x-ray tube at any time;

(2) There shall be an indication at the control panel identifying which x-ray tube is selected to enable irradiation; and

(3) There shall be an indication at the tube housing assembly when that tube is selected to enable irradiation.

(K) There shall be a means of determining the central axis target-to-skin distance (TSD) to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(L) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "on" switch is energized, the beam shall be attenuated by a shutter. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(M) Therapy equipment having a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

Effective: 03/01/2016

Five Year Review (FYR) Dates: 11/10/2015 and 11/15/2020

CERTIFIED ELECTRONICALLY

______________________________
1/15/2016

Date
Promulgated Under: 119.03
Statutory Authority: 3748.04
Rule Amplifies: 3748.01, 3748.02, 3748.04, 3748.05, 3748.06,
3748.07, 3748.12, 3748.121, 3748.13, 3748.14,
3748.15, 3748.17, 3748.18, 3748.19, 3748.20,
3748.22, 3748.99
Prior Effective Dates: 2/15/2001, 9/1/05, 1/14/11, 6/1/13