**10A NCAC 15 .0604 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC SYSTEMS**

(a) In addition to other requirements of this Section, all diagnostic x-ray systems shall meet the following requirements:

(1) The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operation instructions are observed."

(2) Equivalent wording may be used on battery-powered generators; visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 millirem in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(4) The radiation emitted by a component other than the diagnostic source assembly shall not exceed two millirem in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) Beam Quality

(A) Half-Value Layer

(i) The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in the following table. "Specified Dental System" is any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980. "Other X-Ray Systems" shall be all other x-ray systems subject to this Section.

| X-Ray Tube Voltage (kilovolt peak) | | Minimum HVL (millimeters of Aluminum) | Minimum HVL (millimeters of Aluminum) |
|---|---|---|---|
| Designed operating range | Measured Operating Potential | Specified Dental Systems | Other X-ray Systems |
| Below 50---------- | 30 | 1.5 | 0.3 |
| | 40 | 1.5 | 0.4 |
| | 49 | 1.5 | 0.5 |
| 50 to 70---------- | 50 | 1.5 | 1.2 |
| | 60 | 1.5 | 1.2 |
| | 70 | 1.5 | 1.5 |
| Above 70---------- | 71 | 2.1 | 2.1 |
| | 80 | 2.3 | 2.3 |
| | 90 | 2.5 | 2.5 |
| | 100 | 2.7 | 2.7 |
| | 110 | 3.0 | 3.0 |
| | 120 | 3.2 | 3.2 |
| | 130 | 3.5 | 3.5 |
| | 140 | 3.8 | 3.8 |
| | 150 | 4.1 | 4.1 |

If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in the table, linear interpolation or extrapolation may be made. Positive means shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

(ii) The requirements of Subpart (a)(5)(A)(i) of this Rule shall be considered to be met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table:

Filtration Required versus Operating Voltage

| Operating Voltage (kVp) | Minimum total filtration (inherent plus added) (millimeters aluminum equivalent) |
|---|---|
| Below 50 | 0.5 millimeters |
| 50 - 70 | 1.5 millimeters |
| Above 70 | 2.5 millimeters |

(iii) Notwithstanding the requirements of Subpart (a)(5)(A)(ii) of this Rule, all intraoral dental systems manufactured after December 1, 1980, shall have a minimum of 1.5 mm aluminum equivalent filtration permanently installed in the useful beam.

(iv) Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

(v) For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

(vi) The required minimum aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the tube and the patient, such as a tabletop when the tube is mounted under the table and inherent filtration of the tube.

(B) For new x-ray systems installed after the effective date of these Rules and which have variable kVp and selectable filtration for the useful beam, a device shall link the kVp selector with the filter(s), so that the minimum filtration is always present for the kVp selected.

(6) Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected and their location shall be clearly indicated on the master control panel prior to initiation of the exposure.

(7) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a design function of the x-ray system.

(8) The location of the focal spot may be indicated on a readily visible area of the x-ray source housing in the plane parallel to the image receptor when the image receptor is perpendicular to the beam axis.

(9) Technique Indicators

(A) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

(B) Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(C) On equipment having fixed technique factors, the recommendation in Part (a)(9)(A) of this Rule may be met by permanent markings.

(b) Structural Shielding

(1) For stationary diagnostic systems, except for intraoral dental systems which shall meet the requirements of Rule .0607(j) of this Section, structural shielding shall be provided to assure compliance with Rules .1604 and .1611 of this Chapter. The following shall be provided:

(A) All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 84 inches above the floor;

(B) Secondary barriers in the wall, floor and ceiling areas not having a primary barrier or where the primary barrier requirements are lower than the secondary barrier requirements; and

(C) A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposures.

(2) When a mobile system is used routinely in one location, the structural shielding in that location shall meet the requirements for stationary diagnostic systems in Subparagraph (b)(1) of this Rule.

*History Note:* *Authority G.S. 104E-7;*
*Eff. February 1, 1980;*
*Amended Eff. January 1, 1994; October 1, 1980;*
*Transferred and Recodified from 15A NCAC 11 .0604 Eff. February 1, 2015.*