10A NCAC 15 .0606 is proposed for readoption with substantive changes as follows:

**10A NCAC 15 .0606 ~~SYSTEMS OTHER THAN FLUOROSCOPIC AND DENTAL INTRAORAL~~ AREA REQUIREMENTS**

~~(a) Unless specifically provided otherwise by the rules in this Chapter, the requirements in this Rule shall apply to all x-ray systems, except for fluoroscopic and dental intraoral x-ray systems. The useful beam of x-ray systems subject to provisions of this Rule shall be limited to the area of clinical interest or the image receptor, whichever is smaller.~~

~~(1) General purpose stationary and mobile x-ray systems shall meet the following special requirements:~~

~~(A) There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.~~

~~(B) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.~~

~~(C) Notwithstanding Parts (a)(1)(A) and (B) of this Rule, equipment manufactured before August 1, 1974 may employ fixed cones and diaphragms or variable collimators without beam defining lights.~~

~~(2) In addition to the requirements of Subparagraph (a)(1) of this Rule, all stationary x-ray systems, except equipment originally manufactured before the effective date of this Rule, shall meet the following requirements:~~

~~(A) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;~~

~~(B) The beam limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;~~

~~(C) Indication of field size dimensions and SID's shall be specified in inches or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent of the SID when the beam axis is perpendicular to the plane of the image receptor.~~

~~(3) Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.~~

~~(4) Special purpose x-ray systems shall meet the following requirements:~~

(A) These systems shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

(B) Such systems shall also be provided with means to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.

(C) The requirements in Parts (a)(4)(A) and (B) of this Rule may be met with a system that meets the requirements for a general purpose x-ray system as specified in Subparagraph (a)(1) of this Rule or, when alignment means are also provided, as follows:

(i) an assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where each device has clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(ii) a beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which the unit is designed, where the device has permanent, clearly legible, markings indicating image receptor size and SID for which each aperture is designated and indicating which aperture is in position for use.

(b) Radiation exposure control devices shall meet the following requirements:

(1) Means shall be provided to terminate the exposure after a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition:

(A) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero except during serial radiography, and

(B) It shall not be possible to make an exposure when the timer is set to a zero or "off" position if either position is provided.

(2) Control over x-ray exposures shall be in accordance with the following requirements:

(A) A control shall be incorporated into each x-ray system such that the operator can terminate an exposure at any time except for serial radiography where means may be provided to permit completion of any single exposure of the series in process.

(B) Each x-ray control shall be located in such a way as to meet the following criteria.

(i) For stationary x-ray systems, the control shall be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(ii) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, except for equipment originally manufactured before the effective date of this Rule, a signal audible to the operator shall indicate that the exposure has terminated.

(3) When an automatic exposure control (e.g., phototimer) is provided the following requirements shall be met, except equipment originally manufactured before the effective date of this Rule:

(A) Indication shall be made on the control panel when this mode of operation is selected;

(B) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

(C) The minimum exposure time for all equipment other than that specified in Part (b)(3)(B) of this Rule shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;

(D) Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(E) A visible signal shall indicate when an exposure has been terminated at the limits described in Part (b)(3)(D) of this Rule and manual resetting shall be required before further automatically timed exposures can be made.

(4) When four timer tests are performed at identical timer setting equal to 5.0 seconds or less, the average time period (T) shall be greater than five times the difference between the maximum period (Tmax) and the minimum period (Tmin) in accordance with the formula:

$T > 5(Tmax - Tmin)$

(c) Source-skin or source-image receptor distance shall meet the following requirement:
All radiographic systems shall be provided with a durable, securely fastened means to limit the source-skin distance to at least 30 centimeters. This is considered to be met when the collimator or cone provides the required limits.
(d) The exposure produced shall be reproducible to within the following criteria:
When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to be met if, when four exposures at identical technique factors are made, the value of the average exposure (E)is greater than five times the difference between the maximum exposure (Emax) and the minimum exposure (Emin) in accordance with the formula:

$E > 5(Emax - Emin)$

~~(e) Standby radiation from capacitor energy storage equipment, when the exposure switch or timer is not activated, shall not exceed a rate of two milliroentgens per hour at five centimeters from any accessible surface of the diagnostic source assembly with the beam-limiting device fully open.~~

~~(f) Linearity~~

~~(1) When the equipment allows a choice of x-ray tube current settings, the average ratios of exposure to the indicated milliampere-seconds product, i.e., mR/mAs, obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, i.e., /mean of x1 - x2/ < minus 0.10 mean of (x1+ x2), where the mean of x1 and x2 are the average mR/mAs values obtained at each of two consecutive tube current settings.~~

~~(2) Compliance shall be determined at the most commonly used mA stations by measuring mR/mAs at those stations and at one adjacent station to each.~~

~~(g) Timer accuracy~~

~~(1) For indicated values of 0.10 seconds and above, the measured value shall be within plus or minus 15 percent of the indicated values for equipment manufactured before August 1, 1974.~~

~~(2) For equipment manufactured after August 1, 1974, the deviation of measured values from indicated values shall not exceed the limits specified for that system by its manufacturer.~~

(a) Structural barriers shall be installed so that the dose limits of Rules .1601(a)(8) and .1601(a)(15) of this Chapter are not exceeded.

(1) Stationary radiation machine systems shall be installed in areas with the following:

(A) primary protective barriers for all walls, floor, ceiling, or other structures that will intercept the primary beam;

(B) secondary protective barriers in the walls, doors, floor, and ceiling areas or other structures that will intercept and attenuate leakage and scatter radiation; and

(C) a window, to include a frame and lead-equivalent glass, meeting the same structural barriers as required by the adjacent barrier, or a mirror system shall be provided so the operator can see the patient from behind the protective barrier during radiation exposures.

(2) Intraoral dental handheld radiation machines shall be used in a controlled area, as defined in Rule .1601(a)(3) of this Chapter and controlled by separating adjacent uncontrolled areas six feet or greater from the patient.

(b) The exposure switch for radiation machines shall be installed meeting the following requirements:

(1) Stationary radiation machine systems shall have the exposure switch permanently mounted:

(A) behind a protected barrier 40 inches (1 meter) from the edge of the control booth; or

(B) so that the operator is required to remain behind the protective barrier area during the entire radiation exposure.

(2) Dental intraoral radiation machines shall have the exposure switch permanently installed so that the operator is required to be:

(A) behind a protective barrier height of 7 feet (2.3 meters) or greater; or

(B) located 6 feet (1.8 meters) or greater from the tube housing assembly.

(3) Mobile, portable, and veterinary radiation machines shall have an exposure switch that allows the operator to stand six feet or greater from the tube during radiation exposures.

(c) Stationary CT radiation machine operators shall maintain aural communication with the patient while the operator is required to remain behind a protective barrier at the control panel.

(d) Use of video monitors that do not have a direct power source is prohibited.

(e) Any mobile or portable radiation machine used in one location or used as a primary imaging system shall have structural shielding in that location that meets the requirements for stationary diagnostic radiation machines for stationary diagnostic imaging systems in Subparagraph (a)(1) of this Rule.

(f) An area radiation survey shall be performed for installations of radiation machines within 30 days following the initial use to show compliance with Paragraph (a) of this Rule.

(1) This survey shall include:

(A) a scaled drawing of the room in which the stationary radiation machine system is located;

(B) radiation levels in adjacent areas; and

(C) the name of the person, approved by the agency performing the survey, and the date the survey was performed.

(2) Any modification that could increase the radiation dosage for any individual to the following shall require a new survey:

(A) radiation machine configuration;

(B) radiation output; or

(C) occupancy factors if the x-ray room or adjacent areas are changed.

(3) Area radiation survey records shall document compliance with dose limits in accordance with Rules .1601(a)(8) and (15) of this Chapter.

(4) Records of the area radiation survey shall be maintained in accordance with Rule .0603(m) of this Section.

(g) Technique Charts or imaging protocols for each radiation machine not equipped with an operational anatomic programming or phototimer option shall be readily available to the operator of the radiation machine(s). If pediatric and adult patients are imaged, a chart is required for both and shall include the following information:

(1) patient's anatomical size;

(2) technique factors to be used;

(3) source to image receptor distance used; and

(4) type of image receptor.

(h) Each area, as defined in Rule .1601(a)(3) of this Chapter, where a radiation machine is used shall be conspicuously posted with a sign, in accordance with the requirements of Rule .1601(a)(34) of this Chapter, bearing the words "CAUTION – RADIATION AREA", or words having a similar meaning.

(i) Exemptions apply to the following:

(1) intraoral dental radiation machines from Parts (a)(1)(A) and (C) of this Rule.

(2) Dual Energy X-Ray Absorptiometry (DEXA or DXA) and veterinary radiation machines from Subparagraph (b)(1) of this Rule.

(3) dental handheld radiation machines from Subparagraph (b)(2) of this Rule; and

(4) dental radiation machines from Subparagraph (g)(3) of this Rule.

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