10A NCAC 15 .0607 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0607 ~~INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS~~ RADIATION MACHINE REQUIREMENTS

~~(a) In addition to the provisions of Rules .0603 and .0605 of this Section, the requirements of this Rule apply to x-ray equipment and associated facilities used for dental radiography. Criteria for extraoral dental radiographic systems are covered in Rule .0606 of this Section.~~

~~(b) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-skin distance to not less than:~~

~~(1) 18 centimeters, if operated above 50 kilovolts peak; or~~

~~(2) ten centimeters, if operated at or below 50 kilovolts peak.~~

~~(c) The size of the direct radiation beam shall be limited in accordance with the following rules:~~

~~(1) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:~~

~~(A) If the source-skin distance (SSD) is 18 centimeters or more, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than seven centimeters; and~~

~~(B) If the SSD is less than 18 centimeters, the x-ray field at the SSD shall be containable in a circle having a diameter of no more than six centimeters.~~

~~(2) Effective February 1, 1981, equipment manufactured prior to August 1974 shall be equipped with a lead line open position indicating device with at least 0.79 mm lead.~~

~~(d) The timing device shall comply with the following requirements:~~

~~(1) Termination of the exposure after a preset interval;~~

~~(2) Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;~~

~~(3) 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; and~~

~~(4) When four timer tests are performed at identical timer settings equal to five 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)~~

~~(5) Effective February 1, 1983, intraoral dental radiographic systems shall be equipped with an electronic timer.~~

~~(6) Timer accuracy~~

~~(A) 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.~~

~~(B) 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.~~

~~(e) The exposure switch shall comply with the following requirements:~~

~~(1) A control shall be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half second or less.~~

~~(2) Each x-ray control shall be located in such a way as to meet the following criteria:~~

~~(A) For stationary x-ray systems installed after the effective date of this Rule, the exposure switch shall be permanently mounted in a protected area (e.g., corridor outside the room) so that the operator is required to remain in that protected area during the entire exposure.~~

~~(B) For stationary x-ray systems without a protected area and installed before the effective date of this Rule, the exposure switch shall be such that the operator shall stand at least six feet away from the tube and out of the direct beam.~~

~~(C) For mobile and portable x-ray systems the switch shall meet the requirements of Part (e)(2)(B) of this Rule.~~

~~(3) For equipment manufactured after August 1, 1974, the x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.~~

~~(f) 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)~~

~~(g) Patient and film holding devices shall be used when the techniques permit.~~

~~(h) Neither the tube housing nor the position indicating device shall be hand-held during an exposure.~~

~~(i) Dental fluoroscopy without image intensification shall not be used.~~

~~(j) Structural shielding~~

~~(1) All wall, floor and ceiling areas shall have protective barriers sufficient to meet the requirements of Rules .1604 and .1611 of this Chapter.~~

~~(2) When intraoral x-ray systems are installed in adjacent rooms or areas, protective barriers as specified in Subparagraph (j)(1) of this Rule shall be provided between the rooms or areas.~~

(a) All radiation machines shall be:

(1) registered with the agency in accordance with Rule .0203(a) of this Chapter; and

(2) installed according to the manufacturer's specifications.

(b) Each diagnostic radiographic and fluoroscopic radiation machine and associated components shall comply with the following provisions of 21 CFR Subchapter J, Diagnostic x-ray systems and their major components, which are hereby incorporated by reference, including subsequent amendments and editions. The following parts of 21 CFR Subchapter J apply:

(1) Part 1000, "General;"

(2) Subpart A 1000.1, "General Provisions - General;"

(3) Subpart A 1000.3(a) through (1), and (n) through (s), "Definitions;"

(4) Subpart A 1000.15, "Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968;"

(5) Part 1002, "Records and Reports;"

(6) Subpart A 1002.1(a) and (c)(4), "Applicability;"

(7) Subpart D 1002.31, "Preservation and inspection of records;"

(8) Part 1003, "Notification of Defects of Failures to Comply;"

(9) Subpart A 1003.1, "Applicability;"

(10) Subpart A 1003.2, "Defect in an electronic product;"

(11) Subpart C 1003.21, "Notification by the manufacturer to affected persons;"

(12) Part 1010, "Performance Standards for Electronic Products - General;"

(13) Subpart A 1010.1, "Scope;"

(14) Subpart A 1010.2 (a),(b), and (d), "Certification;"

(15) Subpart A 1010.3, "Identification;"

(16) Subpart A 1010.4(a) and (d), "Variances;"

(17) Part 1020, "Performance Standards for Ionizing Radiation Emitting Products;"

(18) Section 1020.20, "Cold-cathode gas discharge tubes;"

(19) Section 1020.30, "Diagnostic x-ray systems and their main components;"

(20) Section 1020.31, "Radiographic equipment;"

(21) Section 1020.32, "Fluoroscopic equipment;" and

(22) Section 1020.33, "Computed tomography (CT) equipment."

(c) The regulations incorporated by reference in Paragraph (b) of this Rule are available free of charge at https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J for Subparagraphs (a)(1) through (a)(22) of this Rule.

(d) Diagnostic radiation machines and their associated components used on humans and certified in accordance with Paragraph (b)(17) of this Rule shall be maintained to ensure compliance with standards in accordance with Paragraph (b) of this Rule.

(e) Radiation machines that do not meet the requirements of Paragraph (b)(1) of this Rule shall not be sold, installed, or used in this state prior to the agency completing a review of the radiation machine in accordance with Rule .0212(a) of this Chapter.

(f) All radiation machines shall meet the following additional requirements:

(1) The tube housing shall remain stable during radiation exposures unless tube housing movement is a designed function of the radiation machine.

(2) All position locking, holding, and centering devices on radiation machine components and systems shall function as intended by the manufacturer.

(g) Veterinary. Radiation machines used in veterinary medicine are exempt from paragraph (c) of this Rule. The requirements of this paragraph shall apply only to veterinary medicine radiographic installations. Veterinary radiation machine installations shall meet the following requirements:

(1) The protective tube housing shall be of the diagnostic type.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of the image receptor and shall provide the same degree of protection as is required in the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50-70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

(4) A device shall be provided to terminate the exposure after a preset time or exposure.

(5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures or behind a protective barrier adequate to assure compliance with dose limit requirements of Rules .1601(a)(8) and .1601(a)(15) of this Chapter.

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