10A NCAC 15 .0604 is proposed for readoption with substantive changes as follows:

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

~~(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 Minimum HVL~~
~~(millimeters (millimeters~~
~~of Aluminum) of Aluminum)~~

~~Measured Specified Other~~
~~Designed operating Operating Dental X ray~~
~~range Potential Systems 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.~~

(a) A radiation machine shall not be permitted for human, non-human, or veterinary use except when used in accordance with the operating requirements of Rule .0605 of this Section.

(b) Operators shall be trained in the operational features and safe use of the radiation machines used.

(c) Individuals who operate a radiation machine shall meet the requirements for the modality of use in Paragraphs (e),f),(g),(h), (i), or (j) of this Rule no later than 36 months after the effective date of this Rule.

(d) Individuals who operate a radiation machine for research purposes or for end-of-life imaging are exempt from the requirements in Paragraphs (e),(f),(g),(h),(i), or (j) of this Rule.

(e) The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from the requirement in Subparagraph (i) of this Rule.

(f) Chiropractic

(1) other than the chiropractor, individuals who operate a radiation machine for chiropractic patient care shall be certified by the North Carolina State Board of Chiropractic Examiners as a Certified Chiropractic Assistant – Level 2 in accordance with G.S. 90-143.2 and 21 NCAC 10 .0213;

(2) be a Registered Technologist (RT) by the American Registry of Radiologic Technologists (ARRT) with an active registration in Radiography (R); or

(3) be enrolled in a training program for radiography, and under the personal supervision of an individual who meets the requirements of Subparagraphs (1) or (2) of this Paragraph.

(g) Dentistry

(1) other than the dentist, individuals who operate dental radiation machines shall be a licensed dental hygienist;

(2) shall meet radiography requirements for dental assistants as defined by the NC Board of Dental Examiners; or

(3) shall be enrolled in a training program for radiography, and under the personal supervision of an individual who meets the requirements of Subparagraphs (1) or (2) of this Paragraph.

(h) Podiatry

(1) other than the podiatrist, all podiatric radiation machine operators shall complete radiography training and pass an examination provided by the NC Foot and Ankle Society;

(2) shall hold an active registration in Radiography (R) with the American Registry of Radiologic Technologists (ARRT); or

(3) shall be enrolled in a training program for radiography, and under the personal supervision of an individual who meets the requirements of Subparagraphs (1) or (2) of this Paragraph.

(i) Radiography and Fluoroscopy

(1) Radiography

(A) individuals who operate a radiation machine for plain radiography shall be a Registered Technologist (RT) by the American Registry of Radiologic Technologists (ARRT) with an active registration in Radiography (R); or

(B) shall be enrolled in an accredited radiography educational program and under the personal supervision of an individual who meets the requirements of Part (A) of this Paragraph.

(2) Fluoroscopy

(A) individuals who operate fluoroscopy radiation machines shall be a physician as defined in Rule .0103(b)(8) of this Chapter or an advanced practitioner provider (APP) as defined in Rule .0602(2) of this Section under the personal supervision of a physician who has completed training in accordance with Paragraph (l) of this Rule;

(B) shall be an ARRT-registered RT and hold an active registration in Radiography (R); or

(C) shall be enrolled in an accredited educational program for radiography and under the personal supervision of an individual who meets the requirements of Part (B) of this Subparagraph

(3) Angiography

(A) individuals who operate fluoroscopy radiation machines shall be a physician as defined in Rule .0103(b)(8) of this Chapter;

(B) shall be an ARRT-registered RT and hold an active registration in Radiography (R);

(C) shall be a graduate of a post-secondary educational program in interventional cardiac and vascular technology and a Registered Cardiovascular Invasive Specialist (RCIS) by or a Registered Cardiac Electrophysiology Specialist (RCES) by Cardiovascular Credentialing International (CCI); or

(D) shall be enrolled in an accredited educational program and under the personal supervision of an individual who meets the requirements of Part (B) or (C) of this Subparagraph.

(j) Computed Tomography (CT)

(1) individuals who operate a CT radiation machine for diagnostic imaging shall hold an active Computed Tomography (CT) registration with the ARRT; or

(2) shall be enrolled in an accredited educational program and under the personal supervision of an individual who meets the requirements of Subparagraph (1) of this Paragraph.

(k) Dual Energy X-Ray Absorptiometry (DEXA or DXA)

(1) Individuals who operate a DEXA of DXA radiation machine for diagnostic measurement of bone density or body composition as ordered by a physician or APP shall be:

(A) an ARRT-registered technologist with an active registration in Bone Densitometry (DB);

(B) a Certified Bone Densitometry Technologist (CBDT) by the International Society for Clinical Densitometry (ISCD); or

(C) enrolled in an accredited educational program and under the personal supervision of an individual who meets the requirements of Part (A) or (B) of this Subparagraph.

(2) All individuals who operate a DEXA or DXA radiation machine shall receive training specific to the radiation machine used and training in basic principles of radiation protection prior to using the radiation machine.

(l) Veterinary Imaging

(1) other than the veterinarian, all veterinary radiation machine operators shall be:

(A) under the personal supervision of a veterinarian;

(B) be a veterinary technician; or

(C) under the personal supervision of a veterinary technician.

(2) other than a veterinarian, all veterinary radiation machine operators shall be employed or engaged by a veterinarian or the owner of a veterinary facility registered in accordance with Section .0200 of this Chapter.

(m) For individuals other than radiologists, instruction and training to operate fluoroscopic and angiographic radiation machines by physicians and APPs shall include:

(1) radiation quantities and units;

(2) biological effects of ionizing radiation and recognition of symptoms of acute localized exposure;

(3) radiation dose management and optimization of image quality; and

(4) equipment features.

(n) Training records for each operator of a radiation machine shall be maintained and available for agency review during inspection.

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