10A NCAC 15 .0601 is readopted as published in 40:04 NCR 410-434 as follows:

SECTION .0600 - ~~X-RAYS IN THE HEALING ARTS~~ RADIATION MACHINES

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10A NCAC 15 .0601 PURPOSE AND SCOPE

~~This Section establishes requirements for x-ay equipment by or under the supervision of an individual authorized by and licensed, in accordance with state statutes, to engage in the healing arts or veterinary medicine The provisions of this Section are in addition to, and not in substitution for, the provisions of Sections .0100, .0200, .0900, .1000, and .1600 of this Chapter.~~

(a) Before installing a radiation machine for use, the registration process shall be initiated in accordance with Section .0200 of this Chapter.

(b) This Section applies to all facilities and service providers using radiation machines for the following:

(1) educational facilities that provide clinical training;

(2) human and veterinary use; and

(3) non-human use, used for forensic medicine, or used by service providers for demonstration purposes.

(4) service providers company who provide operators to end users.

(c) This Section provides additional requirements for the use of radiation machines by or under the supervision of a licensed practitioner authorized by and licensed, in accordance with state statutes, to practice medicine and provide professional services in chiropractic, dentistry, podiatry, research, and veterinary medicine.

(d) This Section provides additional operator requirements to use a radiation machine.

(e) The requirements of this Section are in addition to the provisions in Sections .0100, .0200, .1000, .1100, and .1600 of this Chapter.

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10A NCAC 15 .0602 is readopted as published in 40:04 NCR 410-434 as follows:

10A NCAC 15 .0602 DEFINITIONS

~~(a) As used in this Section, the following definitions shall apply:~~

~~(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.~~

~~(2) "Added filter" means the filter added to the inherent filtration.~~

~~(3) "Aluminum equivalent" means the thickness of aluminum, type 1100 alloy, affording the same attenuation, under specified conditions, as the material in question. The nominal composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum and 0.12 percent copper.~~

~~(4) "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.~~

~~(5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation. Phototimer is described separately.~~

~~(6) "Beam axis" means a line from the source of x-rays through the centers of the x-ray fields.~~

~~(7) "Beam limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.~~

~~(8) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.~~

~~(9) "Changeable filters" means any added filter which can be removed from the useful x-ray beam through any electronic, mechanical or physical process.~~

~~(10) "Contact therapy system" means that the x-ray tube target is put within five centimeters of the surface being treated.~~

~~(11) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.~~

~~(12) "Cooling curve" means the graphical relationship between heat units stored and cooling time.~~

~~(13) "Dead man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.~~

~~(14) "Diagnostic source assembly" means the tube housing assembly with a device attached.~~

~~(15) "Diagnostic type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is operated at its leakage technique factors.~~

~~(16) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.~~

~~(17) "Direct scattered radiation" means that radiation which has been deviated in direction by materials irradiated by the useful beam.(See also scattered radiation).~~

~~(18) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.~~

~~(19) "Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons, negatrons and positrons, liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special unit of exposure is the roentgen.~~

~~(20) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.~~

~~(21) "Filter" means material placed in the useful beam to preferentially attenuate selected radiations.~~

~~(22) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot film device, electrical interlocks and structural material providing linkage between the image receptor and the diagnostic source assembly.~~

~~(23) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.~~

~~(24) "Gonad shield" means a protective barrier used to reduce exposure to the testes or ovaries.~~

~~(25) "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.~~

~~(26) "Healing arts mass screening" means the examination of human beings using x-rays for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts who is legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. It does not include the use of x-ray tests as a requirement for hospital admission or as a condition of employment.~~

~~(27) "Image intensifier" means a device, including housing, which converts an x-ray pattern into a corresponding light image of higher energy density.~~

~~(28) "Image receptor" means any device, such as fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.~~

~~(29) "Inherent filtration" means the filtration permanently in the useful beam; it includes the window of the x-ray tube and any permanent tube or source enclosure.~~

~~(30) "Installation" means the act of physical movement of a radiographic system from one location to another in conjunction with a change of ownership.~~

~~(31) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.~~

~~(32) "Leakage radiation" means radiation emanating from a diagnostic or therapeutic source assembly except for:~~

~~(A) the useful beam and~~

~~(B) radiation produced when the exposure switch or timer is not activated.~~

~~(33) "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly (i.e., tube housing and beam limiting device) which are used in measuring leakage radiation. They are defined as follows:~~

~~(A) for diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated peak tube potential and the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mC) or the minimum obtainable from the unit, whichever is larger;~~

~~(B) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated peak tube potential and the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential; and~~

~~(C) for all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.~~

~~(34) "Light field" means that area of the intersection of the light beam from the beam limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one fourth of the maximum in the intersection.~~

~~(35) "Maximum line current" means the rms (root mean square) current in the supply line of an x-ray machine operating at its maximum rating.~~

~~(36) "Mobile equipment" (see x-ray equipment).~~

~~(37) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.~~

~~(38) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see also "Automatic exposure control").~~

~~(39) "Portable equipment" (see x-ray equipment).~~

~~(40) "Position indicating device (PID)" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam limiting device.~~

~~(41) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for radiation protection purposes, to reduce the radiation exposure.~~

(42) "Protective apron" means an apron made of radiation attenuating materials used to reduce radiation exposure.

(43) "Protective barrier" means a barrier of radiation attenuating material(s) used to reduce radiation exposure. Types of protective barriers are defined in other items of this Rule.

(44) "Protective glove" means a glove made of radiation attenuating materials used to reduce radiation exposure.

(45) "Qualified expert" means an individual who is registered pursuant to Rule .0205 of this Chapter.

(46) "Radiograph" means an image receptor on which the image has been created directly or indirectly by an x-ray pattern and results in a permanent record.

(47) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

(48) "Rating" means the operating limits as specified by the component manufacturer.

(49) "Recording" means producing a permanent form of an image resulting from x-ray photons such as film and video tape.

(50) "Registrant", as used in this Section, means any person who owns or possesses and administratively controls an x-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions contained in Sections .0100 and .0200 of this Chapter to register with the agency.

(51) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid-scale reading.

(52) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See also "direct scattered radiation".)

(53) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

(54) "SID" means source-image receptor distance.

(55) "Source" means the focal spot of the x-ray tube.

(56) "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

(57) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(58) "Stationary equipment" (see x-ray equipment).

(59) "Stray radiation" means the sum of leakage and scattered radiation.

(60) "Technique factors" means the conditions of operation. They are specified as follows:

(A) for capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(B) for field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and

(C) for all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(61) "Therapeutic type protective tube housing" means the tube housing with tube installed, and it includes high voltage and filament transformers and other appropriate elements when they are contained within that housing.

(62) "Transportation equipment" means x-ray equipment which is installed in a vehicle or trailer.

(63) "Tube" means an x-ray tube, unless otherwise specified.

(64) "Tube housing assembly" means the tube housing with tube installed. It includes high voltage and filament transformers and other appropriate elements when they are contained within the tube housing.

(65) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(66) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(67) "Variable-aperture beam limiting device" means a beam limiting device which has capacity for stepless adjustment of the x-ray field size at the given SID.

(68) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

(69) "X-ray control" means a device which controls input power to the x-ray high voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices which control the technique factors of an x-ray exposure.

(70) "X-ray equipment" means an x-ray system, subsystem or component thereof.

(A) "Mobile equipment" means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

(B) "Portable equipment" means x-ray equipment designed to be hand-carried.

(C) "Stationary equipment" means x-ray equipment which is installed in a fixed location.

(71) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(72) "X-ray high voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high voltage switches, electrical protective devices and other appropriate elements.

(73) "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube housing assembly, a

~~beam limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.~~

~~(74) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this Section.~~

~~(75) "X-ray tube" means an electron tube which is designed for the conversion of electrical energy into x-ray energy.~~

~~(b) Other definitions applicable to this Section may be found in Sections .0100 and .0200 of this Chapter.~~

In addition to definitions found in Rules .0104, .0607(b)(3), (18), and (19), .1001, and .1601 of this Chapter, the following definitions shall apply to this Section:

(1) "Added filter" means the filter added to the inherent filtration.

(2) “Advanced practitioner” means an individual performing medical acts, tasks, or functions as a licensed nurse practitioner in accordance with G.S. 90-18.2 or a licensed physician assistant in accordance with G.S. 90-18.1.

(3) “Area radiation survey” means the evaluation of radiation levels around a radiation machine installation and adjacent areas to ensure compliance to dose limits in accordance with Section .1601 of this Chapter.

(4) “Cone beam computed tomography” is a volumetric imaging modality. Volumetric data are acquired using two-dimensional digital detector arrays and a cone-shaped x-ray beam (instead of fan-shaped) that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

(5) “Clinical training” means hands-on experience or clinical simulation to gain practical knowledge, experience, and skills.

(6) "CT qualified expert (CT QE)" means an individual who is registered or is providing service for a registered facility where they are employed, as required by Section .0200 of this Chapter. The individual shall have the following education and experience:

(A) a master's or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from a college or university accredited by an agency recognized by the U.S. Department of Education, and three years of work experience in a clinical CT environment. The work experience shall be supervised and documented by a medical physicist certified in the specialty area of diagnostic medical physics by the American Board of Radiology, the Canadian College of Physicists in Medicine, or the American Board of Medical Physics; or

(B) certification in the specialty area of diagnostic medical physics by the American Board of Radiology, the Canadian College of Physicists in Medicine, or the American Board of Medical Physics and shall abide by the certifying body's requirements for continuing education.

(7) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(8) “Dental assistant” means an individual who works for licensed dentists and meets the education, training, and experience defined by the NC Board of Dental Examiners.

(9) “Dental handheld radiation machine” means a radiation machine used to take dental radiographs, is designed to be handheld during operation, is operated by an individual authorized to take dental radiographs and may be used in multiple locations.

(10) “Dental hygienist” means an individual licensed by the NC Board of Dental Examiners to practice dental hygiene.

(11) “Diagnostic imaging” means visualizing the inside of the body using radiation exposures to determine the cause of illness or injury or to confirm a diagnosis.

(12) "Diagnostic-type protective tube housing" means a tube housing so constructed that the leakage radiation measured at a distance of one meter from the source does not exceed 100 mR in one hour when the tube is operated at its leakage technique factors.

(13) “Diagnostic radiation machine” shall have the same meaning as “Diagnostic x-ray system” as defined in Rule .0607(b)(19) of this Section.

(14) "Entrance exposure rate" means the roentgen per unit time at the point where the center of the useful beam enters the patient.

(15) “Exposure control” shall have the same means as “control panel” as defined in Rule .0607(b)(19) of this Section.

(16) “Extra-oral” means outside the mouth. An extraoral image is produced by exposing, to x-rays, an image receptor positioned outside the mouth.

(17) "Filter" means material placed in the primary beam to preferentially attenuate selected radiation energies.

(18) "General supervision" means the activity is performed under the qualified supervisor's overall direction and control, but the qualified supervisor's physical presence shall not be required during the activity.

(19) "Inherent filtration" means the filtration permanently in the useful beam, including the window of the X-ray tube and any permanent tube or source enclosure.

(20) “Intra-oral” means inside the mouth. An intraoral image is produced by exposing a film, plate, or sensor placed within the mouth to X-rays.

(21) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(22) “Licensed dentist” means an individual licensed by the NC Board of Dental Examiners to practice dentistry.

(23) “Letter of Acknowledgement” means the correspondence provided by the agency acknowledging receipt of a shielding design, in accordance with Rule .0204(b) of this Chapter.

(24) “Mobile radiation machine” shall have the same meaning as “Mobile equipment” in Rule .0607(b)(19) of this Section.

(25) “Notice of Registration” means the correspondence provided by the agency, to the person completing the registration process, containing the information submitted on the agency forms in accordance with Rules .0203 and .0205 of this Chapter.

(26) “Optimal” means desirable or satisfactory.

(27) “Panoramic” means an imaging technique for producing a curved image layer radiograph of maxillary and mandibular dental arches and their supporting structures. This is a curvilinear variant of conventional tomography.

(28) "Personal supervision" means overall direction, control, and training of an individual by a qualified supervisor who shall be physically present during the activities performed by the supervised individual.

(29) "Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation that reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated. See also "Automatic exposure control" in Rule .0607(b)(19) of this Section.

(30) “Portable radiation machine” shall have the same meaning as “Portable equipment” in Rule .0607(b)(19) of this Section.

(31) "Position indicating device (PID)" means a device on dental radiation machines used to indicate the beam position and to establish a definite source-skin distance. It may or may not incorporate or serve as a beam-limiting device.

(32) “Primary beam” shall have the same means as “useful beam” as defined in Rule .0607(b)(19) of this Section and is the beam used to make radiographic images.

(33) "Protective apparel" garments made of a radiation attenuating material used to potentially reduce radiation exposure to an individual wearing the item.

(34) "Qualified expert" means an individual registered in accordance with Rule .0205 of this Chapter.

(35) “Radiation machine” as defined in Rule .0103(b)(10) of this Chapter, shall have the same meaning as “x-ray equipment” as defined in Rule .0607(b)(19) of this Section.

(36) “Radiation subsystem” shall have the same meaning as X-ray subsystem in Rule .0607(b)(19) of this Section.

(37) “Radiation system” shall have the same meaning as X-ray system in Rule .0607(b)(19) of this Section.

(38) “Radiograph" means an image receptor on which the image has been created directly or indirectly by an x-ray pattern and results in a permanent record.

(39) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

(40) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.

(41) "Secondary protective barrier" means a barrier sufficient to attenuate stray radiation.

(42) "Secondary radiation" means the sum of leakage and scattered radiation.

(43) “Shielding design” means the floor plan and structural shielding specifications in accordance with current national standards, demonstrating the barriers which will attenuate radiation so that the dose limit requirements of Rules .1601(a)(8) and .1601(a)(15) of this Chapter are not exceeded.

(44) "Stationary radiation machine" means a radiation machine, components, or system installed and used in a fixed location.

(45) “Structural shielding” means materials incorporated into ceilings, floors, walls, or other structures to ensure the dose limit requirements of Rules .1601(a)(8) and .1601(a)(15) of this Chapter are not exceeded.

(46) “Veterinarian” means a veterinarian licensed pursuant to General Statue Chapter 90, Article 11.

(47) “Veterinary technician” means a veterinary technician registered pursuant to General Statue Chapter 90, Article 11.

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10A NCAC 15 .0605 is readopted as published in 40:04 NCR 410-434 as follows:

10A NCAC 15 .0605 ~~FLUOROSCOPIC X-RAY SYSTEMS~~ OPERATING REQUIREMENTS

~~All fluoroscopic X-Ray systems shall meet the following requirements:~~

~~(1) Limitation of primary beam~~

~~(a) The fluoroscopic tube shall not produce X-Rays unless the primary protective barrier is in position to intercept the entire primary beam at all times.~~

~~(b) The entire cross section of the primary beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID.~~

~~(c) Limitation to the Imaging Surface~~

~~(i) The X-Ray field produced by fluoroscopic equipment without image intensification shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot filming procedures.~~

~~(ii) Image intensified fluoroscopy and spot filming shall comply with the following:~~

~~(A) During fluoroscopic or spot filming procedures, neither the length nor the width of the X-Ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.~~

~~(B) Compliance shall be determined with the beam axis perpendicular to the image receptor. For rectangular X-Ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the X-Ray field which pass through the center of the visible area of the image receptor.~~

~~(iii) In addition to other requirements of this Rule, equipment manufactured after the effective date of these Rules shall comply with the following:~~

~~(A) Means shall be provided between the source and the patient for adjustment of the X-Ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. This adjustment shall be automatically accomplished except when the X-Ray field size in the plane of the film is smaller than that of the selected portion of the film.~~

~~(B) It shall be possible to adjust the X-Ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID, shall be equal to or less than five centimeters by five centimeters.~~

(C) The center of the X-Ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID.

(2) X-Ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-Ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) Entrance exposure rates shall be limited as required in the following:

(a) Fluoroscopic equipment shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of ten roentgens per minute at the point where the center of the primary beam enters the patient, except:

(i) during recording of fluoroscopic images; or

(ii) when provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(b) In addition to the other requirements of this Rule equipment manufactured after August, 1974, which does not incorporate an automatic exposure control (e.g., automatic brightness control or ionization chamber control) shall not be operated at any combination of tube potential and current which will result in an exposure rate in excess of five roentgens per minute at the point where the center of the primary beam enters the patient except during the recording of fluoroscopic images or when provided with an optional high level control.

(c) Compliance with the provisions of Item (3) of this Rule shall be determined as follows:

(i) Movable grids and compression devices shall be removed from the primary beam during the measurement.

(ii) If the source is below the table, the exposure rate shall be measured one centimeter above the tabletop or cradle.

(iii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iv) In a C-arm type fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(d) Periodic measurement of entrance exposure rate limits shall comply with the following:

(i) Such measurements shall be made every two years or after any maintenance of the system which might affect the exposure rate.

(ii) Results of these measurements shall be available or posted where any fluoroscopist may have ready access to them and shall be in the record required in Rule .0603(a)(2)(B) of this Section. Results of the measurements shall include the exposure rate, as well as the physical factors used to determine all data; the name of the person approved by the agency performing the measurements and the date the measurements were performed.

(iii) Entrance exposure rate shall be determined with the attenuation block in Rule .0602(a) in the primary beam.

(4) Radiation transmitted through the primary protective barrier of the fluoroscopic imaging assembly shall comply with the following requirements:

(a) The exposure rate resulting from transmission through the primary protective barrier with the attenuation block in the primary beam, combined with radiation from the image intensifier, if provided, shall not exceed two milliroentgens per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) Measurements to determine compliance with Sub-item (4)(a) of this Rule shall be in accordance with the following:

(i) The exposure rate resulting from transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters;

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly, positioned 30 centimeters above the tabletop.

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters;

(iv) Movable grids and compression devices shall be removed from the primary beam during the measurement;

(v) The attenuation block shall be positioned in the primary beam ten centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(5) During fluoroscopy and cinefluorography, X-Ray tube potential and current shall be continuously indicated.

(6) The source-skin distance shall not be less than:

~~(a) 38 centimeters on stationary fluoroscopes,~~

~~(b) 30 centimeters on all mobile fluoroscopes, or~~

~~(c) 20 centimeters for image intensified fluoroscopes during surgical application.~~

~~(7) Fluoroscopic timers shall meet the following requirements:~~

~~(a) Means shall be provided to preset the cumulative on time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.~~

~~(b) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on time. Such signal shall continue to sound while X-Rays are produced until the timing device is reset.~~

~~(8) Mobile fluoroscopes, in addition to the other requirements of this Rule, shall provide image intensification.~~

~~(9) Scattered radiation shall be controlled in accordance with the following requirements:~~

~~(a) A shielding device of at least 0.25 mm lead equivalent for covering the Bucky slot during fluoroscopy shall be provided.~~

~~(b) A shield of at least 0.25 mm lead equivalent, such as overlapping protective drapes or hinged or sliding panels, shall be provided to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine.~~

~~(c) Upon application to the agency with adequate justification, exceptions from Sub-items (9)(a) or (9)(b) of this Rule may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures.~~

(a) Radiation machines shall only be operated by individuals who meet the operator requirements of Rule .0604 of this Section.

(b) Exposures of individuals to the primary beam:

(1) Individuals shall not be exposed to the primary beam except for diagnostic imaging purposes. Such exposures shall have been authorized by a licensed practitioner as defined in Rule .0103(b)(7) of this Chapter.

(2) Students or candidates in training under the personal supervision of an individual that meets the requirements of Rule .0604 of this Chapter shall not be permitted to perform radiographic imaging unless such exposures have been authorized by a licensed practitioner as defined in Rule .0103(b)(7) of this Chapter.

(3) Deliberate exposure of an individual for training, demonstration, or other non-diagnostic imaging purposes is prohibited.

(4) Radiation exposures for non-human use, used for forensic medicine, or by service providers for demonstration purposes are exempt from Subparagraphs (b)(1) and (2) of this Rule.

(c) The radiation exposure to the patient shall be the minimum exposure required to produce images of optimal diagnostic quality.

(d) Individuals who operate radiation machines shall:

(1) be familiar with the radiation protection program procedures established in accordance with Rule .0603(d)(3) of this Section;

(2) use collimation to limit the primary beam to the area of clinical interest or to the image receptor, whichever is smaller;

(3) use technique factors and dose reduction technologies, according to patient sizes and clinical indication, to optimize patient dose while maintaining optimal image quality;

(4) use mechanical holding devices, whenever medical circumstances permit, when a patient or image receptor must be provided with auxiliary support during a radiation exposure; and

(5) control the area during radiation exposures.

(e) Except for dental handheld radiation machines, individuals who operate radiation machines shall not hold either the X-Ray tube housing or the collimating device during radiation exposures.

(f) No occupational worker shall be designated as the individual who always holds patients or image receptors during radiation exposures. Operators of veterinary radiation machines are exempt from this Rule.

(g) If a human holder is required, they shall be provided with instructions:

(1) for supporting the patient during the radiation exposure;

(2) to wear a lead apron equivalent to 0.25 mm or greater for protection from scatter radiation during the exposure; and

(3) to avoid extremity exposure to the primary beam, or to wear protective gloves equivalent to 0.5 mm of lead or more.

(h) Except for Dual Energy X-Ray Absorptiometry (DEXA or DXA) and intraoral dental handheld radiation machine operators, only the professional staff and individuals required for the medical procedure or those in training shall be in the room of the patient being examined during the radiographic and fluoroscopic exposures.

(1) All individuals other than the patient being examined shall be:

(A) positioned such that no part of the body, including the extremities, which are not protected by 0.5 mm lead equivalent or greater material will be exposed to the primary beam; and

(B) protected from scatter radiation by protective apparel or whole-body protective equipment of 0.25 mm lead equivalent or greater material.

(2) When a mobile or portable radiation machine is used during radiographic or fluoroscopy exposures, patients other than the individual examined who cannot be removed from the room shall be protected from the scatter radiation by:

(A) protective apparel or equipment; or

(B) be positioned so that the nearest portion of the body is six feet or greater from both the tube head and the nearest edge of the image receptor.

(i) CT operators shall have the following made readily accessible during the use of the CT radiation machine and while performing routine QC:

(1) instructions on performing routine QC;

(2) a schedule of routine QC;

(3) any allowable variations set by the CT QE for the indicated parameters;

(4) the results of the most recent routine QC completed on the system; and

(5) established scanning protocols.

(j) Intraoral dental radiation machine operators shall use patient and film holding devices when the techniques permit.

(k) Intraoral dental handheld radiation machine operators shall ensure the following additional requirements are met:

(1) When making an exposure, all individuals other than the patient undergoing the procedure remain at a distance greater than six feet from the patient.

(2) Use an individual monitoring device. When protective apparel is required in accordance with Subparagraph (3) of this Rule, the individual monitoring device shall be used in accordance with Paragraph (m) of this Rule.

(3) Wear protective apparel of 0.25 mm or greater lead equivalent material when the backscatter shield is not parallel to the operator while making an exposure.

(l) Veterinary radiation machine operators shall ensure the following additional requirements are met.

(1) A dead-man type of exposure switch shall be provided, tethered with a cord of a length so that the operator can stand out of the primary beam and six feet or greater 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 are not exceeded.

(2) No individual other than the operator shall be in the X-ray room while exposures are being made unless such an individual's assistance is required.

(m) When protective apparel or equipment is used and an individual monitoring device(s) is required, at least one such monitoring device shall be used as follows:

(1) The individual monitoring device shall be worn at the collar, outside the apparel.

(2) If protective equipment is used in place of protective apparel, the individual radiation monitoring device shall be worn on the torso.

(3) A fetal monitoring device shall be worn at the waist. If protective apparel is worn, the individual radiation monitoring device shall be worn under the protective apparel at the waist.

(4) The dose to the whole body shall be recorded in the reports in accordance with Rule .1601(a)(53) of this Chapter. If more than one device is used, each dose shall be identified with the area where the device was worn on the body.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; May 1, 1992; October 1, 1980;

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Readopted Eff. ~~May 1, 2026.~~August 1, 2026.

10A NCAC 15 .0606 is readopted as published in 40:04 NCR 410-434 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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Readopted ~~May 1, 2026.~~August 1, 2026.

10A NCAC 15 .0607 is readopted as published in 40:04 NCR 410-434 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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10A NCAC 15 .0608 is repealed as published in 40:04 NCR 410-434 as follows:

10A NCAC 15 .0608 THERAPEUTIC X-RAY INSTALLATIONS: LESS THAN ONE MEV

History Note: *Authority G.S. 104E-7;104E-12(a);*
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Amended Eff. January 1, 1994; May 1, 1992; November 1, 1989;
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10A NCAC 15 .0610 is repealed through readoption as published in 40:04 NCR 410-434 as follows:

10A NCAC 15 .0610 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

History Note: *Authority G.S. 104E-7;104E-12(a);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992; November 1, 1989;
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10A NCAC 15 .0611 is repealed through readoption as published in 40:04 NCR 410-434 as follows:

10A NCAC 15 .0611 COMPUTED TOMOGRAPHY (CT) X-RAY SYSTEMS

History Note: Authority G.S. 104E-7;104E-11; 104E-12;
Eff. October 1, 2017.