10A NCAC 15 .0602 is proposed for readoption with substantive changes 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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