10A NCAC 15 .0605 is proposed for readoption with substantive changes 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.

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