10A NCAC 15 .0603 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0603 ~~GENERAL REQUIREMENTS~~ FACILITY RESPONSIBILITIES

~~(a) Administrative controls~~

~~(1) The registrant shall be responsible for directing the operation of the X-ray machines which he has registered with the agency. He or his agent shall assure that the following provisions are met in the operation of the X-ray machine(s):~~

~~(A) An X-ray machine which does not meet the provisions of these Rules shall not be operated for diagnostic or therapeutic purposes, if so ordered by the agency in accordance with Rules .0109 and .0110 of this Chapter.~~

~~(B) Individuals who will be operating the X-ray equipment shall be instructed in the safe operating procedures and use of the equipment and demonstrate an understanding thereof to the registrant.~~

~~(C) In the vicinity of each diagnostic X-ray system's control panel, a chart shall be provided, which specifies for all usual examinations and associated projections which are performed by that system, a listing of information including patient's anatomical size versus technique factors to be utilized at a given source-to-image receptor distance. The chart shall also provide:~~

~~(i) type and size of the film or film-screen combination to be used,~~

~~(ii) type and ratio of grid to be used, if any, and focal spot to film distance,~~

~~(iii) type and placement of gonad shielding to be used.~~

~~(D) Radiation protection programand rules shall be established and made available to each individual operating X-ray equipment under his control. The operator shall be familiar with these rules.~~

~~(E) Only the professional staff and ancillary personnel required for the medical procedure or for training shall be in the room during the radiographic exposure. Other than the patient being examined:~~

~~(i) All individuals shall be positioned such that no part of the body including the extremities which is not protected by 0.5 mm lead equivalent will be exposed to the primary beam.~~

~~(ii) Professional staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent.~~

~~(iii) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least six feet from both the tube head and the nearest edge of the image receptor.~~

(iv) When a portion of the body of a non-occupationally exposed professional staff or ancillary personnel is potentially subjected to stray radiation which would result in that individual receiving one-fourth of the maximum permissible dose as defined in Rule .1604 of this Chapter, additional protective measures shall be employed.

(v) Upon written application to the agency, the agency may waive the requirements in Subparts (a)(1)(E)(ii) and (a)(1)(E)(iii) of this Rule if the registrant demonstrates that such waiver is necessary for best management of patients and will not result in violation of the public and occupational dose limits established in the rules in this Chapter.

(F) Gonad shielding of not less than 0.5 mm lead equivalent shall be used for potentially procreative patients during radiographic procedures in which the gonads are in the direct, or primary beam, except for cases in which this would interfere with the diagnostic procedures.

(G) Individuals shall not be exposed to the primary beam except for healing arts purposes. Such exposures shall have been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other nonhealing arts purposes.

(H) When a patient or film must be provided with auxiliary support during a radiographic exposure:

(i) Mechanical holding devices shall be used whenever medical circumstances permit. Written safety procedures, as required in Part (a)(1)(D) of this Rule shall indicate the requirements for selecting a holder;

(ii) If a human holder is required, radiation protection programas required in Part (a)(1)(D) of this Rule, shall indicate the instructions provided to the holder;

(iii) The human holder shall be protected as required in Part (a)(1)(E) of this Rule;

(iv) No individual shall be used routinely to hold patients or film.

(I) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This includes, but is not limited to, the following requirements:

(i) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

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

(iii) Portable or mobile equipment shall be used only for examinations where it is impractical for medical reasons to transfer the patient to a stationary radiographic installation.

~~(J) All persons who are associated with the operation of an X-ray system are subject to the occupational exposure limits as defined in Rules .1604 and .1638 of this Chapter, and personnel monitoring procedures in Rule .1614 of this Chapter. In addition, when protective clothing or equipment is worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:~~

~~(i) When an apron is worn the monitoring device shall be worn at the collar outside the apron.~~

~~(ii) The dose to the whole body shall be recorded in the reports required in Rule .1640 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.~~

~~(2) The registrant shall maintain at least the following information for each X-ray machine:~~

~~(A) current registration information and other correspondence with the agency regarding that machine;~~

~~(B) records of surveys and calibrations;~~

~~(C) records of maintenance or modifications which affect the primary beam after the effective date of these Rules, along with the names of persons who performed the service.~~

~~(b) Plans Review. Prior to construction or structural modification, the floor plans and equipment arrangement of all installations utilizing X-rays for diagnostic or therapeutic purposes shall be reviewed by a qualified expert. The registrant shall submit recommendations of the expert to the agency.~~

~~(c) Radiation Survey~~

~~(1) For installations of X-ray equipment after the effective date of this Rule, an area radiation survey shall be performed within 30 days following initial operation of each radiation machine to show compliance with Rule .0604(b) of this Section. This survey shall include:~~

~~(A) a drawing of the room in which a stationary X-ray system is located and radiation levels in adjacent areas; and~~

~~(B) the name of the person approved by the agency performing the survey and the date the survey was performed.~~

~~(2) Any modification to the X-ray room or adjacent areas which could increase the radiation dosage to any individual shall require a new survey.~~

~~(3) Records of this survey shall be maintained in accordance with Subparagraph (a)(2) of this Rule.~~

(a) The registrant shall not allow the operation of a radiation machine for diagnostic imaging not meeting the requirements of Rule .0607(b) of this Section.

(b) Mobile or portable radiation machines shall only be used for radiation exposures where transferring the patient to a stationary radiation machine is impractical for medical reasons. The use of a mobile or portable radiation machine as the primary method for diagnostic imaging at a permanent location, instead of a stationary radiation machine, is prohibited.

(c) If ordered by the agency, radiation machines are subject to impounding by an authorized representative of the agency in accordance with Rule .0107 of this Chapter.

(d) The registrant or their designee shall:

(1) be responsible for directing the operation of the radiation machine(s) registered with the agency;

(2) ensure the provisions of this Section are met during the operation of the radiation machine(s) under their control;

(3) establish radiation protection procedures and make them readily available to individuals who operate the radiation machine(s);

(4) ensure QC is performed if required by the manufacturer or registered service provider, in accordance with the instructions provided; and

(5) establish procedures or provide equipment to operators to control the radiation area during radiographic exposures.

(e) Extraoral cephalometric, cone beam computed tomography (CBCT), and panoramic radiation machines designed for use in dental radiography or for facial diagnostic imaging and chiropractic or podiatry radiation machines shall meet shielding design requirements in Rule .0204(b) of this Chapter, shielding barrier requirements in Rule .0606(a) of this Section, and radiation machine requirements in Rule .0607 of this Section; and

(f) Dental intraoral handheld radiation machine additional requirements for maintenance and evaluation:

(1) Maintenance shall be performed by a registered service provider following the manufacturer's specifications.

(2) The machine shall be evaluated by a registered service provider, in accordance with Section .0200 of this Chapter, after the unit is dropped, visibly damaged, or as requested by the agency. Machines with signs of visible damage, or as requested by the agency, shall not be used until being evaluated by a registered service provider.

(g) Cone Beam Computed Tomography (CBCT) radiation machine additional requirements for system performance evaluations:

(1) Maintain documentation of the established standards, tolerances, and testing results.

(2) Implement actions when the QC results are outside of the limits specified in the QC recommendations.

(3) The CBCT radiation machine shall be evaluated by a registered service provider, in accordance with Section .0200 of this Chapter, within 30 days of:

(A) initial installation; and

(B) when there is any change or replacement of components which, in the opinion of the registered service provider, could cause a change in the radiation output or image quality.

(4) The following information shall be readily available to CBCT operators:

(A) instructions on performing routine QC, including the use of the CBCT phantom;

(B) schedule of routine QC appropriate for the system and allowable variations set by the registered service provider, if required, for the indicated parameters; and

(C) results of at least the most recent routine QC completed on the system.

(h) Dental Cone Beam Computed Tomography (CBCT) radiation machines shall not be used:

(A) as the primary or initial imaging modality when a lower dose alternative is adequate for clinical purposes;

(B) for the sole purpose of producing simulated bitewing, panoramic, or cephalometric images; or

(C) for routine or serial orthodontic imaging.

(i) The uses of Cone Beam CT, Veterinary CT, CT simulation, and attenuation correction shall be exempt from Paragraphs (j) and (k) of this Rule.

(j) Computed Tomography (CT) radiation machine shall meet the following additional requirements for system performance evaluations.

(1) Performance evaluations of the CT X-ray system shall be performed by, or under the general supervision of, a CT QE who assumes responsibility for the evaluation.

(2) The performance evaluation of a CT X-ray system shall be performed within 30 days of installation and at least every 14 months.

(3) Performance evaluation standards and tolerances shall meet the manufacturer's specifications or standards and tolerances for the CT X-ray system from the American College of Radiology (ACR) incorporated herein by reference, including subsequent amendments and editions. These standards and tolerances may be found at no charge on the ACR website at https://www.acr.org.

(4) The performance evaluation shall include the following, as applicable to the design of the scanner:

(A) geometric factors and alignment, including alignment light accuracy and table increment accuracy;

(B) image localization from a scanned projection radiograph (localization image);

(C) radiation beam width;

(D) image quality, including high-contrast (spatial) resolution, low-contrast resolution, image uniformity, noise, and artifact evaluation;

(E) CT number accuracy;

(F) image quality for acquisition workstation display devices; and

(G) a review of the results of the routine QC, as set forth in Paragraph (j) of this Rule.

(5) The performance evaluation shall also include the evaluation of radiation output and patient dose indices for the following clinical protocols, if performed:

(A) pediatric head;

(B) pediatric abdomen;

(C) adult head; and

(D) adult abdomen.

(6) Evaluation of radiation output shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated within the preceding two years by persons registered, in accordance with Section .0200 of this Chapter, to provide such services.

(7) The performance evaluation shall be documented and maintained for inspection by the Agency. The documentation shall include the name of the CT QE performing or supervising and any other individuals participating in the evaluation under the general supervision of the CT QE. The documentation shall be retained for 14 months.

(k) Computed Tomography (CT) radiation machines shall meet the following additional requirements for routine quality control (QC)

(1) A routine QC program for the CT radiation imaging system shall be developed by or have written approval by a CT QE and include:

(A) instructions for the routine QC;

(B) intervals for QC testing;

(C) acceptable tolerances for the QC tests;

(D) use of a water equivalent phantom to evaluate each day of clinical use: noise, CT number accuracy, and artifacts; and

(E) routine QC tests that may be performed in place of system performance evaluations after equipment repairs or maintenance. This shall include the process for obtaining approval from the CT QE prior to conducting testing.

(2) The duties in the routine QC program, as described in Parts (i)(1)(A) through (E) of this Paragraph, shall be conducted by individuals who meet the requirements of Rule .0604(j) of this Section, or individuals approved by the CT QE.

(3) The routine QC shall be documented and maintained for inspection by the Agency. The records shall be retained for 14 months.

(l) Records shall be maintained by the registrant as follows:

(1) For each radiation machine under the registrant's custody and control:

(A) the state notice of registration and other correspondence with the agency regarding the radiation machine;

(B) the shielding design and the corresponding letter of acknowledgment granted by the agency;

(C) the report of installation, receipt of sale, disposal notification, or transfer of ownership;

(D) an area radiation survey; and

(E) maintenance or modifications that affect the primary beam and documentation of service(s) performed, along with the names of those who performed the service.

(2) For each individual operating a radiation machine, the operator license, certification, or training documentation.

(m) Records shall be available for agency review during inspection.

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