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

(a) This Rule provides special requirements for human diagnostic use of computed tomography (CT) x-ray equipment. The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from this Rule. The provisions of this Rule are in addition to, and not in substitution for, the Rules in Sections .0100, .0200, .0600, .0900, .1000, and .1600 of this Chapter.

(b) The following definitions shall apply to this Rule:

(1) "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 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.

(2) "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.

(3) "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.

(c) Equipment and Installation Requirements

(1) CT x-ray systems shall meet the requirements of 21 CFR 1020.33 as incorporated by reference in Rule .0117(a)(3) of this Chapter.

(2) The operator of a CT scanner shall be able to maintain aural communication with the patient from a shielded position at the control panel.

(d) Personnel Requirements. Individuals who operate CT x-ray systems shall be specifically trained on the operational features of the unit and:

(1) hold (CT) registration with the American Registry of Radiologic Technologists (ARRT); or

(2) be a Registered Technologist (R.T.) by the ARRT with registration in radiography (R) or a Certified Nuclear Medicine Technologist by the Nuclear Medicine Technology Certification Board; these individuals shall document training and experience that is equivalent to that required to attain (CT) registration with the ARRT; or

(3) be in training under the personal supervision of an individual that meets the requirements of Subparagraph (d)(1) or (d)(2) of this Rule.

(e) 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 the 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 manufacturer's specifications or standards and tolerances for the CT x-ray system from the American College of Radiology (ACR) and the American Association of Physicists in Medicine (AAPM) 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 and the AAPM website at www.aapm.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 (f) 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;
(D) adult abdomen; and
(E) brain perfusion.

(6) Evaluation of radiation output shall be performed with a dosimetry system that is calibrated. The dosimetry system shall have been calibrated within the preceding two years by persons registered to provide such services pursuant to Rule .0205 of this Chapter.

(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 the evaluation, as well as any other individuals participating in the evaluation under the general supervision of the CT QE. The documentation shall be retained for 14 months.

(f) Routine Quality Control (QC)

(1) A routine QC program for the CT 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 Subparagraph (f)(1) of this Rule, shall be conducted by individuals that meet the requirements of Parargraph (d) of this Rule 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.

(g) Operating Requirements. The following information shall be accessible to the CT operator during use of the 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.

History Note: *Authority G.S. 104E-7; 104E-11; 104E-12;*
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