REQUEST FOR TECHNICAL CHANGE

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0611

DEADLINE FOR RECEIPT: Friday, September 15, 2017

***PLEASE NOTE:* This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

On the Submission for Permanent Rule form, in box 9B, should there be a complete citation for "21 CFR"? Please clarify if necessary.

Line 21, replace "is not" with "shall not be"

Line 23, add a comma after "control"

Line 24, replace "must" with "shall"

Page 2, line 2, with the citation to "Paragraph (d) of this Rule" is the intent that the training occurs under "this Paragraph of the Rule" meaning Lines 32 thru 36 on page 1? It reads a little clumsy, but just wanted to verify.

Page 2, lines 10 thru 12, has this outside document been incorporated in a prior rule? Otherwise, consider incorporating for this Rule.

Page 2, line 21 does not have an "and" or "or" but line 22 has an "and". Is that accurate? Consider add a conjunction on line 21.

Page 2, line 35, consider replacing "individual(s)" with "individuals"

Page 3, line 14, what is meant by "Agency"? Is that a defined term in a prior rule referring to the Radiation Protection Commission or Department of Health and Human Services? Is the term referring to Rule 10A NCAC 15 .0104(6)*?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Abigail M. Hammond
Commission Counsel
Date submitted to agency: August 31, 2017

10A NCAC 15 .0611 is adopted as published in 31:19 NCR 1862-1864 as follows:

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 an accredited college or university; and

(B) three years work experience in a clinical CT environment. The work experience shall be supervised and documented by a board certified medical physicist; or

(C) certification in the specific subfield(s) of medical physics with its associated medical health physics aspect by an appropriate national certifying body 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 is not required during the activity.

(3) "personal supervision" means overall direction, control and training of an individual by a qualified supervisor who must 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:

(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 Paragraph (d) of this Rule; and

(4) be specifically trained on the operational features of the unit.

(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). These standards and tolerances may be found at no charge on the ACR and AAPM websites.

(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;

(G) a review of the results of the routine QC, as set forth in Paragraph (f) of this Rule; and

(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 individual(s) 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 Part (f)(1) of this Rule, shall be conducted by individuals that meet the requirements of Part (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;*
Eff. October 1, 2017.