

1 10A NCAC 15 .0611 is proposed for adoption as follows:

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3 **10A NCAC 15 .0611 COMPUTED TOMOGRAPHY (CT) X-RAY SYSTEMS**

4 (a) This Rule provides special requirements for human diagnostic use of computed tomography (CT) x-ray equipment.  
5 The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from this  
6 Rule. The provisions of this Rule are in addition to, and not in substitution for, the Rules in Sections .0100, .0200,  
7 .0600, .0900, .1000, and .1600 of this Chapter.

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

9 (1) “CT qualified expert (CT QE)” means an individual who is registered or is providing service for a  
10 registered facility where they are employed, as required by Section .0200 of this Chapter. The  
11 individual shall have the following education and experience:

12 (A) a master’s or doctoral degree in physics, medical physics, biophysics, radiological physics,  
13 medical health physics, or equivalent disciplines from an accredited college or university;  
14 and

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

17 (C) certification in the specific subfield(s) of medical physics with its associated medical health  
18 physics aspect by an appropriate national certifying body and shall abide by the certifying  
19 body’s requirements for continuing education.

20 (2) "general supervision" means the activity is performed under the qualified supervisor’s overall  
21 direction and control but the qualified supervisor’s physical presence is not required during the  
22 activity.

23 (3) "personal supervision" means overall direction, control and training of an individual by a qualified  
24 supervisor who must be physically present during the activities performed by the supervised  
25 individual.

26 (c) Equipment and Installation Requirements

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

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

31 (d) Personnel Requirements. Individuals who operate CT x-ray systems shall:

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

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

1           (3) be in training under the personal supervision of an individual that meets the requirements of  
2           Paragraph (d) of this Rule; and

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

4   (e) System Performance Evaluations

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

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

9           (3) Performance evaluation standards and tolerances shall meet manufacturer's specifications or  
10           standards and tolerances for the CT x-ray system from the American College of Radiology (ACR)  
11           and the American Association of Physicists in Medicine (AAPM). These standards and tolerances  
12           may be found at no charge on the ACR and AAPM websites.

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

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

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

17           (C) radiation beam width;

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

20           (E) CT number accuracy;

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

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

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

25           (A) pediatric head;

26           (B) pediatric abdomen;

27           (C) adult head;

28           (D) adult abdomen; and

29           (E) brain perfusion.

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

33           (7) The performance evaluation shall be documented and maintained for inspection by the Agency. The  
34           documentation shall include the name of the CT QE performing or supervising the evaluation, as  
35           well as any other individual(s) participating in the evaluation under the general supervision of the  
36           CT QE. The documentation shall be retained for 14 months.

37   (f) Routine Quality Control (QC)

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

3           (A) instructions for the routine QC;

4           (B) intervals for QC testing;

5           (C) acceptable tolerances for the QC tests;

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

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

11          (2) The duties in the routine QC program, as described in Part (f)(1) of this Rule, shall be conducted by  
12          individuals that meet the requirements of Part (d) of this Rule or individuals approved by the CT  
13          QE.

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

16          (g) Operating Requirements. The following information shall be accessible to the CT operator during use of the  
17          machine and while performing routine QC:

18           (1) instructions on performing routine QC;

19           (2) a schedule of routine QC;

20           (3) any allowable variations set by the CT QE for the indicated parameters;

21           (4) the results of the most recent routine QC completed on the system; and

22           (5) established scanning protocols.

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

25          *Eff. October 1, 2017.*