

1 10A NCAC 15 .0805 is proposed for amendment as follows:

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3 **10A NCAC 15 .0805 OPERATING REQUIREMENTS AREA REQUIREMENTS**

4 ~~(a) RGDs shall be operated by individuals that have completed the training requirements of Rule .0806 of this Section.~~

5 ~~(b) Normal operating procedures shall be written and available to all RGD operators and support staff.~~

6 ~~(c) No individual shall be permitted to operate RGDs in any manner other than that specified in the operating~~
7 ~~procedures unless the person has obtained written approval of the individual responsible for radiation or the Radiation~~
8 ~~Safety Officer (RSO) as defined in Rule .0104 of this Chapter.~~

9 ~~(d) No individual shall bypass a safety device unless the person has obtained the approval of the person responsible~~
10 ~~for radiation safety or the RSO. This process shall be incorporated into the radiation protection program by the RSO,~~
11 ~~as set forth in Rule .1603(a), and the operating procedures as set forth in Rule .0603(a)(1)(B). The written approval,~~
12 ~~as granted by the RSO, shall include an expiration date. When a safety device has been bypassed, a legible sign bearing~~
13 ~~the words "SAFETY DEVICE NOT WORKING" or words having a similar meaning shall be placed on the radiation~~
14 ~~source housing and the control panel during the bypassing period.~~

15 ~~(e) Prior to an individual modifying the:~~

16 ~~(1) x ray tube system, resulting in the removal of tube housings, covers, or shielding materials;~~

17 ~~(2) shutters;~~

18 ~~(3) collimators; or~~

19 ~~(4) beam stops~~

20 ~~the individual shall determine the tube is off and will remain off until safe conditions have been restored.~~

21 ~~(f) Safety devices including interlocks, shutters, and warning lights shall be tested once annually for proper operation~~
22 ~~on all RGDs in operation. Records of the testing shall be retained by the registrant for three years.~~

23 ~~(g) No individual shall hold a sample or object while it is being irradiated.~~

24 (a) Each radiation area, as defined in Rule .1601(a)(3) of this Chapter, containing RGDs shall be:

25 (1) conspicuously posted with caution signs, in accordance with the requirements of Rule .1601(a)(34)
26 of this Chapter, bearing the words "CAUTION – RADIATION AREA", or words having a similar
27 meaning; and

28 (2) supervised continuously during operation or shall utilize one or more of the following:

29 (A) door interlocks;

30 (B) entry monitors; or

31 (C) engineering controls.

32 (b) Access to each restricted area where an individual may receive a dose equivalent exceeding 100 mrem in any year,
33 but does not exceed levels of a radiation area, shall be designated as a controlled area. The area shall be controlled by:

34 (1) visibly separating adjacent uncontrolled areas so doses do not exceed the limits of Rule .1601(a)(15)
35 of this Chapter; and

36 (2) posting a sign bearing the words "Warning: X-rays in Use", or words having a similar meaning.

1 (c) The local components of RGDs shall be located and arranged to include sufficient shielding or access control to
2 ensure no radiation levels exist in any area surrounding the local components that result in a dose to an individual
3 present in excess of the dose limits in Rule .1601(a)(15) of this Chapter.

4 (d) Surveys shall be performed for each RGD, as set forth in Rule .1601(a)(50) of this Chapter, to show compliance
5 with Paragraph (c) of this Rule.

6 (1) Radiation survey instruments shall be:

7 (A) capable of measuring the radiation energies of the RGD surveyed; and

8 (B) calibrated annually when a frequency is not recommended by the manufacturer.

9 (2) Equipment surveys shall confirm radiation levels do not exceed the requirements of Rule
10 .0806(c)(7); (d)(3); and (h)(2) of this Section. Surveys shall be performed:

11 (A) prior to initial use and include testing of warning and safety devices;

12 (B) prior to use following any change in the initial arrangement, including the number or type
13 of local components in the system or x-ray tube source housing;

14 (C) prior to use following any maintenance requiring the disassembly or removal of a local
15 component in the system or x-ray tube source housing that could affect the radiation
16 exposure to personnel; and

17 (D) during the performance of calibration, maintenance, or any alignment procedure if the
18 presence of a primary x-ray beam is required while any local component in the system is
19 disassembled or removed.

20 (3) A registrant may apply to the agency for approval of procedures differing from those in
21 Subparagraph (d) of this Rule, provided that the registrant demonstrates satisfactory compliance
22 with Paragraph (c) of this Rule.

23 (e) RGDs in Rule .0806(i) and .0807(2) of this Section, installed after the effective date of this Rule, shall ensure the
24 following provisions are met:

25 (1) A floor plan with equipment arrangement shall be submitted to the agency for review and
26 acknowledgement prior to installation of the system. The floor plan shall include:

27 (A) the proposed location of the system;

28 (B) direction of the useful beam;

29 (C) adjacent areas; and

30 (D) location of the operator.

31 (2) An area radiation survey shall be performed prior to initial use to show compliance with dose limits
32 of the rules in Section .1600 of this Chapter. The survey shall include:

33 (A) a drawing of the room indicating the location of the x-ray tube and orientation of the useful
34 beam;

35 (B) radiation levels at the operator location and adjacent areas;

36 (C) survey instrument used; and

1 (D) name of the service provider that is registered in accordance with Rule .0205 of this Chapter
2 and date the survey was performed.

3 (3) Modifications to the room, RGD, or adjacent areas that may increase the radiation dose to any
4 individual shall require a new survey.

5 (4) Records of the floor plan with equipment arrangement and survey shall be available for agency
6 review during inspection.

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8 *History Note:* *Authority G.S. 104E-7; 104E-12;*
9 *Eff. February 1, 1980;*
10 *Transferred and Recodified from 15A NCAC 11 .0805 Eff. February 1, 2015;*
11 *Amended Eff. January 1, 2016; October 1, 2015;*
12 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*
13 *~~2019.~~ 2019;*
14 *Amended Eff. October 1, 2024.*