

1 10A NCAC 15 .0803 is proposed for amendment as follows:

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3 **10A NCAC 15 .0803 EQUIPMENT REQUIREMENTS PERSONNEL REQUIREMENTS**

4 ~~(a) Certified cabinet x ray systems shall meet the requirements of 21 CFR 1020.40 as incorporated by reference in~~
5 ~~Rule .0117(a)(3) of this Chapter.~~

6 ~~(b) All certified and certifiable cabinet x ray systems shall:~~

7 ~~(1) be constructed so that, the radiation emitted from the system shall not exceed an exposure of 0.5~~
8 ~~milliroentgen (mR) in one hour at any point five centimeters outside the external surface; and~~

9 ~~(2) have a fail safe interlock that prevents irradiation when the cabinet, chamber, or coupled chambers~~
10 ~~are open.~~

11 ~~(c) Open beam analytical RGD systems shall be equipped with a safety device that prevents the entry of any portion~~
12 ~~of an individual's body into the primary x ray beam path that causes the beam to be shut off upon entry into its path.~~

13 ~~(d) Open beam analytical RGDs shall be provided with a visible and legible indication of:~~

14 ~~(1) x ray tube status (ON OFF) located near the radiation source housing, if the primary beam is~~
15 ~~controlled in this manner; or~~

16 ~~(2) shutter status (OPEN CLOSED) or beam status (ON OFF) located near each port on the radiation~~
17 ~~source housing, if the primary beam is controlled in this manner.~~

18 ~~(e) Warning devices on open beam analytical RGDs shall be labeled so that their purpose is identified. On open beam~~
19 ~~analytical RGDs installed after February 1, 1980, warning devices and lights shall have fail safe characteristics.~~

20 ~~(f) Unused ports on radiation source housings for open beam RGDs shall be secured in the closed position in a manner~~
21 ~~that will prevent unintended opening.~~

22 ~~(g) Each port on the radiation source housing on open beam analytical RGDs installed after February 1, 1980 and~~
23 ~~designed to accommodate interchangeable components shall be equipped with a shutter that cannot be opened unless~~
24 ~~a collimator or a component coupling is connected to the port.~~

25 ~~(h) Portable open beam analytical RGDs that shall be manufactured to be used hand held without safety devices are~~
26 ~~exempt from the requirements of Paragraph (c) of this Rule and shall be constructed according to International~~
27 ~~Standard IEC 62495 that is incorporated by reference and includes subsequent amendments. This standard can be~~
28 ~~downloaded for one hundred twenty one dollars (\$121.00) at the following website:~~
29 ~~<http://webstore.ansi.org/FindStandards.aspx?SearchString=IEC+62495+Ed.+1.0+en%3a2011&SearchOption=0&PageNum=0&SearchTermsArray=null%7cIEC+62495+Ed.+1.0+en%3a2011%7cnull>.~~

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31 ~~(i) A registrant may apply to the agency, as defined in Rule .0104 of this Chapter, for an exemption from the~~
32 ~~requirement of a safety device. This request shall include:~~

33 ~~(1) a description of the safety devices;~~

34 ~~(2) the reason safety devices cannot be used; and~~

35 ~~(3) a description of the alternative methods that will be employed to minimize the possibility of an~~
36 ~~accidental exposure, including procedures to assure that operators and others in the area will be~~
37 ~~informed of the absence of safety devices.~~

1 ~~(j) Analytical RGDs shall be provided with a visible and legible label(s) bearing the radiation symbol and the words:~~

2 ~~(1) "CAUTION HIGH INTENSITY X RAY BEAM," or words having a similar meaning, near the~~
 3 ~~exit port to identify the location of the beam; and~~

4 ~~(2) "CAUTION RADIATION THIS EQUIPMENT PRODUCES RADIATION WHEN~~
 5 ~~ENERGIZED", or words having a similar meaning, near any switch that energizes an x ray tube, if~~
 6 ~~the radiation source is an x ray tube.~~

7 ~~(k) Warning lights labeled with the words "X RAYS ON," or other words having similar meaning, shall be located:~~

8 ~~(1) near any switch that activates the high voltage to energize an x ray tube; or~~

9 ~~(2) in a conspicuous location near the radiation source housing and radiation beam(s) and visible from~~
 10 ~~all instrument access areas.~~

11 ~~(l) Warning lights shall activate when the x ray tube is energized.~~

12 ~~(m) Each x ray tube housing shall be:~~

13 ~~(1) constructed that when all shutters are closed the leakage radiation measured at a distance of five~~
 14 ~~centimeters from its surface is not capable of producing an exposure in excess of 2.5 millirem~~
 15 ~~(mrem)/ (25 microsieverts μ Sv) in one hour; and~~

16 ~~(2) if the tube housing is the primary shielding for the x ray tube, does not produce x rays when the~~
 17 ~~housing is opened or disassembled.~~

18 ~~(n) Each x ray generator shall be supplied with a protection cabinet which limits leakage radiation measured at a~~
 19 ~~distance of five centimeters from its surface such that it is not capable of producing an exposure in excess of 0.25~~
 20 ~~mrem/2.5 μ Sv in one hour.~~

21 ~~(o) Permanent radiographic installations and industrial radiography RGDs shall comply with the requirements of Rule~~
 22 ~~.0807 of this Section.~~

23 ~~(a) The registrant shall document the scope of training and instruction required for the RGD in use.~~

24 ~~(b) No individual shall be permitted to operate or maintain RGDs unless the individual has received instruction in the~~
 25 ~~basic principles of radiation protection, training provided by the manufacturer for the specific RGD in use, and~~
 26 ~~instruction in the operating and emergency procedures. Instruction and training shall include:~~

27 ~~(1) Basic principles of radiation protection:~~

28 ~~(A) radiation fundamentals;~~

29 ~~(B) source and magnitude of common sources of radiation exposure;~~

30 ~~(C) units of radiation dose and measurements;~~

31 ~~(D) potential hazards, biological effects of ionizing radiation, and recognition of symptoms of~~
 32 ~~an acute localized exposure;~~

33 ~~(E) ALARA (As Low As Reasonably Achievable) principles for radiation protection concepts~~
 34 ~~of time, distance, and shielding to minimize radiation exposure;~~

35 ~~(F) declared pregnancy policy;~~

36 ~~(G) occupational, embryo/fetus, and public dose limits; and~~

37 ~~(H) proper use of individual monitoring devices and survey instruments.~~

1 (2) Device specific training for each RGD:

2 (A) hands-on training for proper use;

3 (B) radiation hazards associated with use;

4 (C) precautions to take or measures required to minimize radiation exposure;

5 (D) procedures to prevent unauthorized use; and

6 (E) agency rules regarding use.

7 (3) Operating and emergency procedure requirements of Rule .0804 in this Section.

8 (c) Records of instruction and training for each individual operating RGDs, documenting that the requirements of this
9 Rule have been met, shall be maintained and available for agency review during inspection.

10 (d) Individuals who will be operating the RGD shall be able to demonstrate an understanding in safe operating
11 procedures and use of the RGD.

12 (e) Each registrant shall provide ring or wrist individual monitoring devices to individuals:

13 (1) operating open-beam RGDs; and

14 (2) performing maintenance on an RDG, if the maintenance procedures require the presence of a
15 primary x-ray beam when any local component in the RGD is disassembled or removed.

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

18 *Eff. February 1, 1980;*

19 *Transferred and Recodified from 15A NCAC 11 .0803 Eff. February 1, 2015;*

20 *Amended Eff. October 1, 2015;*

21 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22,*
22 *~~2019~~ 2019;*

23 *Amended Eff. October 1, 2024.*