

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.*