

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

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

4 ~~(a) A safety device which prevents the entry of any portion of an individual's body into the primary x-ray beam path~~
5 ~~of which causes the beam to be shut off upon entry into its path shall be provided on all open beam configurations. A~~
6 ~~registrant or licensee may apply to the agency for an exemption from the requirement of a safety device. This~~
7 ~~application shall include:~~

8 ~~(1) a description of the various safety devices that have been evaluated;~~

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

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

13 ~~(b) Open beam configurations shall be provided with a readily discernible 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; and~~

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

18 ~~Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective~~
19 ~~date of this Rule, warning devices shall have fail safe characteristics.~~

20 ~~(c) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent~~
21 ~~casual opening.~~

22 ~~(d) All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol~~
23 ~~and the words:~~

24 ~~(1) "CAUTION HIGH INTENSITY X RAY BEAM," or words having a similar intent, on the x-ray~~
25 ~~source housing; and~~

26 ~~(2) "CAUTION RADIATION THIS EQUIPMENT PRODUCES RADIATION WHEN~~
27 ~~ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube, if the~~
28 ~~radiation source is an x-ray tube; or~~

29 ~~(3) "CAUTION RADIOACTIVE MATERIAL", on the source housing, if the radiation source is a~~
30 ~~radionuclide.~~

31 ~~(e) On open beam configurations installed after the effective date of this Rule each port on the radiation source~~
32 ~~housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected~~
33 ~~to the port.~~

34 ~~(f) An easily visible warning light labeled with the words "X RAY ON" or words having a similar intent, shall be~~
35 ~~located outside each entrance into the room containing an analytical x-ray tube and shall be illuminated only when the~~
36 ~~tube is energized; or in the case of a radioactive source, shall be illuminated only when the shutter is open. On~~
37 ~~equipment installed after the effective date of this Rule, warning lights shall have fail safe characteristics.~~

1 ~~(g) Each x-ray tube housing shall be so constructed that when all shutters are closed the leakage radiation measured~~
2 ~~at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 mrem in one hour.~~

3 ~~(h) Each x-ray generator shall be supplied with a protection cabinet which limits leakage radiation measured at a~~
4 ~~distance of five centimeters from its surface such that it is not capable of producing a dose in excess of 0.04 mrem in~~
5 ~~one hour.~~

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

8 (b) All certified and certifiable cabinet x-ray systems shall:

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

11 (2) have a fail-safe interlock that prevents irradiation when the cabinet, chamber or coupled chambers
12 are open.

13 (c) Open-beam analytical RGD systems shall be equipped with a safety device which prevents the entry of any portion
14 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.

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

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

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

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

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

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

28 (h) Portable open-beam analytical RGDs that are manufactured to be used hand-held without safety devices are
29 exempt from the requirements of Paragraph (c) of this Rule and shall be constructed according to International
30 Standard IEC 62495 and subsequent amendments. This standard can be downloaded for one hundred twenty-one
31 dollars (\$121.00) at the following website:
32 <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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34 (i) A registrant may apply to the agency for an exemption from the requirement of a safety device. This request shall
35 include:

36 (1) a description of the safety devices;

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

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

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

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

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

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

11 (1) near any switch which activates the high voltage to energize an x-ray tube; or

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

14 (l) Warning lights shall activate when the x-ray tube is energized.

15 (m) Each x-ray tube housing shall be:

16 (1) constructed that when all shutters are closed the leakage radiation measured at a distance of five
17 centimeters from its surface is not capable of producing an exposure in excess of 2.5 millirem
18 (mrem)/ (25 microsieverts μ Sv) in one hour; and if the tube housing is the primary shielding for the
19 x-ray tube

20 (2) does not produce x-rays when the housing is opened or disassembled.

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

24 (o) Industrial radiography RGDs and permanent radiographic installations shall comply with the requirements of Rule
25 .0807 of this Section.

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

28 *Eff. February 1, 1980;*

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

30 *Amended Eff. October 1, 2015.*