

10A NCAC 15 .0803 EQUIPMENT REQUIREMENTS

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

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

- (1) be constructed so that, the radiation emitted from the system shall not exceed an exposure of 0.5 milliroentgen (mR) in one hour at any point five centimeters outside the external surface; and
- (2) have a fail-safe interlock that prevents irradiation when the cabinet, chamber, or coupled chambers are open.

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

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

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

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

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

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

(h) Portable open-beam analytical RGDs that shall be manufactured to be used hand-held without safety devices are exempt from the requirements of Paragraph (c) of this Rule and shall be constructed according to International Standard IEC 62495 that is incorporated by reference and includes subsequent amendments. This standard can be downloaded for one hundred twenty-one dollars (\$121.00) at the following website: <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>.

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

- (1) a description of the safety devices;
- (2) the reason safety devices cannot be used; and
- (3) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

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

- (1) "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar meaning, near the exit port to identify the location of the beam; and
- (2) "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar meaning, near any switch that energizes an x-ray tube, if the radiation source is an x-ray tube.

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

- (1) near any switch that activates the high voltage to energize an x-ray tube; or
- (2) in a conspicuous location near the radiation source housing and radiation beam(s) and visible from all instrument access areas.

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

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

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

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

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

*History Note: Authority G.S. 104E-7;
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0803 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019.*