10A NCAC 15 .0806 is proposed for amendment as follows:

10A NCAC 15 .0806 ~~PERSONNEL REQUIREMENTS~~ EQUIPMENT REQUIREMENTS

~~(a) Personnel operating or maintaining RGDs shall comply with the following:~~

~~(1) No person shall be permitted to operate or maintain RGDs unless the person has received instruction in the operating and emergency procedures for the RGD and instruction that is in accordance with Rule .1003 of this Chapter.~~

~~(2) Each registrant operating or maintaining RGDs shall maintain, for inspection by the agency, records of training that demonstrate the requirements of this Rule have been satisfied.~~

~~(b) The registrant shall provide ring or wrist personnel monitoring equipment to:~~

~~(1) individuals using open-beam RGDs not equipped with a safety device; and~~

~~(2) individuals maintaining RGDs if the maintenance procedures require the presence of a primary x-ray beam when any local component in the RGD is disassembled or removed.~~

(a) Certified and certifiable cabinet x-ray systems shall comply with the following provisions of 21 CFR 1020.40, which are hereby incorporated by reference including subsequent amendments and editions.

(1) 21 CFR 1020.40(a) Applicability;

(2) 21 CFR 1020.40(b) Definitions;

(3) 21 CFR 1020.40(c) Requirements; and

(4) 21 CFR 1020.40(d) Modifications of a certified system.

(b) The regulations cited in Paragraph (a) of this Rule are available free of charge at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.40.

(c) All RGD's shall meet the following requirements:

(1) Warning devices shall be labeled so the purpose is easily identified.

(2) Warning lights of a fail-safe design labeled with the words "X-RAY ON", or words having a similar meaning, shall be located:

(A) within sight of any switch that energizes an x-ray tube;

(B) in a conspicuous location near the x-ray tube source housing and x-ray beam, and

(C) visible from all instrument access areas.

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

(4) Each shutter shall be equipped with a "shutter open" warning light or device of a fail-safe design.

(5) A readily visible and legible label bearing the radiation symbol and the words "CAUTION – RADIATION: THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar meaning, shall be located near any switch that energizes an x-ray tube.

(6) Systems containing an x-ray tube shall be equipped with a fail-safe interlock that will shut off high voltage to the tube if the x-ray tube source housing is disassembled or if the tube is removed.

(7) High voltage generator enclosures or any accessible area 5 centimeters from the RGD shall not exceed a dose rate of .25 mrem/hr (.0025 mSv/hr).

(d) All open beam RGDs shall meet the following additional requirements:

(1) Each beam port of the x-ray tube source housing shall be equipped with a beam shutter interlocked with the x-ray accessory coupling, or collimator, so that the port will not open unless a collimator or a component coupling is in place.

(2) Shutters at unused ports shall be secured in the closed position to prevent unintended opening.

(3) The x-ray tube source housing shall be constructed so that when all shutters are closed, the leakage radiation measured at a distance of five centimeters from the housing surface does not exceed 2.5 mrem (25 microSv) in one hour.

(4) A safety device or interlock shall prevent the entry of any portion of an individual's body into the primary x-ray beam or which causes the primary beam to shut off upon entry into its path.

(5) A registrant may apply to the agency, as defined in Rule .0106 of this Chapter, for an exemption from the requirement of a safety device in Subparagraph (d)(3) of this Rule. The request shall include:

(A) justification for the use of an open beam system instead of an enclosed beam system;

(B) a description of other safety devices that have been evaluated and reason why a safety devices cannot be used; and

(C) 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.

(e) All enclosed beam RGDs shall meet the following additional requirements:

(1) The radiation source, sample or object, detector, and analyzing crystal (if used) shall be enclosed to prevent entry of any portion of the body during normal operation.

(2) All doors and panels shall be equipped with an interlock. The interlock shall be of a fail-safe design.

(f) Bimodal beam RGDs with the ability to override interlocks between enclosed and open beam shall be designed to be engaged with a device or tool and meet the following requirements:

(1) The tool or key shall only be used by designated individuals as outlined in operating procedures.

(2) When the tool or key is in use, it shall be captive in the equipment and removal of the tool or key returns the RGD to enclosed beam mode.

(3) System use requirements must follow the current use mode.

(g) Portable x-ray fluorescence analyzers manufactured to be used in a hand-held configuration without safety devices are exempt from the requirements of Subparagraph (d)(4) of this Rule and shall meet the following additional requirements:

(1) Warning labels and indicators shall be provided on the analyzer and on the display screen(s).

(2) A label near each beam port shall bear a radiation symbol and the words "WARNING HIGH INTENSITY X-RAYS – DO NOT EXPOSE ANY PART OF BODY TO BEAM" or words having a similar meaning.

(3) The power switch shall have the power logo: I/O.

(h) All gauging devices shall meet the following additional requirements:

(1) The RGD shall be designed to restrict access to the x-ray beam by personnel who are not trained in accordance with Rule .0803 of this Section.

(2) A useful beam control system shall be provided whenever the useful beam is accessible, and the radiation levels exceed one hundred mrem per hour (100 mrem/hr) (1 mSv/hr) at five centimeters from any accessible surface or five mrem per hour (5 mrem/h) (.05 mSv/h) at thirty centimeters (30 cm). The useful beam controls may include a moving shutter, a moving source, or a high voltage power supply.

(3) On-Off indicators shall be marked with symbols or wording clarifying the status of the device.

(4) Each indicating system for automatic beam controls shall consist of at least one "ON" indicating signal, and one "OFF" indicating signal. If lights are used, green indicates the "OFF" and red indicates any other condition of the useful beam control.

(5) Indicators for RGDs high voltage control shall be a yellow or amber warning light with the words "HIGH VOLTAGE ON" and shall be located on the control panel and near the x-ray tube source housing. The warning light shall illuminate only when power is applied to the RGD.

(6) Interlocks shall be used to prevent accidental exposure to high voltage and ionizing radiation.

(7) The RGD shall be conspicuously marked with a label permanently affixed to the device with the following information:

(A) ANSI device classification;

(B) name of manufacturer;

(C) model; and

(D) serial number.

(8) Radiation safety labels shall provide instructions and precautions for safe operation. If space is limited on the RGD, operating or service manuals may be referenced for the information.

(i) Radiographic and radioscopic non-healing arts x-ray equipment operating below energies of 1 MeV designed for non-medical x-ray shall comply with the following additional requirements:

(1) Written instructions shall be supplied by the manufacturer or supplier at the time of sale or transfer to the first user. When the manufacturer or supplier does not provide services to the RGD, installation instructions shall describe:

(A) radiation safety pertaining to each unit or accessory;

(B) instruction for assembly operations when assembly not performed by manufacturer;

(C) interconnections instructions of interlocks, warning lights and audible alarms systems;

(D) test instructions to determine if the RGD and accessory components are properly operating; and

(E) if the x-ray tube assembly is shielded or non-shielded.

(2) Operating instructions shall be supplied by the manufacturer or supplier, at the time of sale or transfer to the first user, in accordance with operating requirements of Rule .0804 of this Section.

(3) The controls shall be:

(A) clearly marked with for the "on-off" position of the component disconnecting the power; and

(B) equipped with a means to prevent production of x-rays when in the "off" position, such as a key or password. When a key is used, the RGD shall be manufactured so it may only be removed when the key is in the "off" position.

(4) The "X-ray On" indicator control shall be:

(A) yellow or amber in color;

(B) be of a fail-safe design; and

(C) have two indicators viewable from the control panel indicating when x-rays are being produced in a period of greater than 0.5 seconds.

(5) The "X-ray Off" indicators shall be:

(A) red in color; and

(B) permanently marked.

(6) Shutters devices that control emission of the primary beam shall activate two visual indicators of contrasting colors from the operator's station. One shall activate when shutters are fully closed and the other shall activate when the shutters are not fully closed.

(7) Selection indicators shall indicate which tube assembly or focal spot has been selected if more than one x-ray tube assembly(s) or focal spot can be operated from the control panel.

(8) Warning Device: A red warning lamp or audible device shall be provided on or near the tube assembly in an open beam, non-permanent installations.

(j) All RGDs shall be secured to prevent access and operation of the device by any individual not meeting the requirements of Rule .0803 of this Section.

History Note: *Authority G.S. 104E-7; 104E-11; 104E-12;*
Eff. February 1, 1980;
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