10A NCAC 15 .0804 is proposed for amendment as follows:

10A NCAC 15 .0804 ~~AREA REQUIREMENTS~~ OPERATING REQUIREMENTS

~~(a) The local components of RGDs shall be located and arranged to include sufficient shielding or access control to ensure no radiation levels exist in any area surrounding the local components that could result in a dose to an individual present in excess of the dose limits given in Rule .1611(a) of this Chapter.~~

~~(b) Survey Requirements~~

~~(1) Radiation surveys, as set forth in Rule .1613(a) and (b) of this Chapter, of all RGDs sufficient to show compliance with Paragraph (a) of this Rule, shall be performed:~~

~~(A) within 30 days after initial operation of the device;~~

~~(B) prior to use following any change in the initial arrangement, including the number or type of local components in the system; and~~

~~(C) prior to use following any maintenance requiring the disassembly or removal of a local component in the system that could affect the radiation exposure to personnel.~~

~~(2) A registrant may apply to the agency for approval of procedures differing from those in Subparagraph (b)(1) of this Rule, provided that the registrant demonstrates satisfactory compliance with Paragraph (a) of this Rule.~~

~~(3) Surveys shall be performed with a radiation survey instrument capable of the following:~~

~~(A) measuring the radiation energies of the system surveyed;~~

~~(B) confirming that the radiation limits of this Section are met; and~~

~~(C) calibrated according to the manufacture's recommended frequency or at least annually when a frequency is not recommended.~~

~~(c) Each area of use or room containing RGDs shall be conspicuously posted with caution signs in accordance with the requirements of Rule .1623 of this Chapter, bearing the radiation caution symbol and the words "CAUTION X-RAY EQUIPMENT," or words having a similar meaning.~~

(a) RGDs shall only be operated by individuals who have completed the requirements in Rule .0803 of this Section.

(b) No individual shall be permitted to operate an RGD in any manner other than that specified in the operating procedures, unless the individual has obtained written approval from the radiation safety officer as defined in Rule .0104 of this Chapter.

(c) Normal operating and emergency procedures from the manufacturer or supplier of the RGD shall be available to all operators and support staff during the use of an RGD.

(d) Normal operating and emergency procedures shall include the following:

(1) safe use of the RGD;

(2) protocols in the event of device malfunction, emergency, or incident involving radiation exposure; and

(3) instructions on reporting to the radiation safety officer and agency of actual or suspected accidental exposure or other radiation safety concerns, such as any unusual occurrence or malfunction that may involve exposure to radiation.

(e) Open beam and portable handheld RGDs

(1) Registrants shall have operating procedures developed to ensure radiation protective measures are:

(A) provided to meet the requirements of Rule .1601(a)(15) of this Chapter;

(B) taken to avoid exposure to any individual from the transmitted primary x-ray beam in cases where the primary x-ray beam is not intercepted by a detector device during operation; and

(C) available to all individuals operating the RGD.

(2) Operators shall not do the following while operating an RGD:

(A) point the primary beam at any individual including him or herself;

(B) allow their hand to approach the primary beam; or

(C) hold a sample. If a sample is small and it is necessary to hold the sample while operating the RGD, the sample shall be placed in a shielded sample enclosure.

(f) Operating and emergency procedures shall be available for agency review during inspection.

(g) Alignment procedures shall be performed as recommended by the RGD manufacturer.

(h) Special alignment procedures shall only be used when approved by the radiation safety officer and manufacturer of the RGD.

(i) Safety Devices

(1) Testing

(A) Safety devices including interlocks, shutters, and warning lights shall be tested once annually for proper operation on all RGDs in use. If any safety device fails, the RGD shall be taken out of service until corrective action is performed or temporary administrative controls are established and approved in writing by the radiation safety officer.

(B) Testing records shall include the date test was performed, the list of safety devices tested, survey instrument used, the calibration date, the results of the test, the name of the individual that performed the test, and any corrective actions for failed test.

(C) Records of the testing shall be retained by the registrant for agency review during inspection.

(2) Bypassing

(A) No individual shall bypass a safety device unless the person has obtained the approval from the radiation safety officer. Procedures for bypassing a safety device shall be incorporated into the radiation protection program by the radiation safety officer, as set forth in Rule .1601 of this Chapter, and the operating procedures as set forth in Paragraph (c) of this Rule.

(B) The written approval, as granted by the radiation safety officer, shall include the start and end date of approval.

(C) When a safety device has been bypassed, a legible sign bearing the words "SAFETY DEVICE NOT WORKING", or words having a similar meaning, shall be placed on the x-ray source housing and the control panel during the bypassing period.

(j) Prior to an individual modifying the following, the individual shall determine the tube is off and will remain off until safe conditions have been restored:

(1) x-ray tube system, resulting in the removal of tube housings, covers, or shielding materials;

(2) shutters;

(3) collimators; or

(4) beam stops.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0804 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.~~ 2019;
Amended Eff. October 1, 2024.