10A NCAC 15 .0801 is amended with changes as published in 38:19 NCR 1219-1229 as follows:

SECTION .0800 - ~~REQUIREMENTS FOR NON-HUMAN USE OF~~ RADIATION GENERATING DEVICES

10A NCAC 15 .0801 PURPOSE AND SCOPE

(a) This Section provides ~~special~~ additional requirements for use of ionizing radiation generating devices (RGDs) operating above five thousand electron volts (5 keV), but below one million electron volts ~~(1 MeV) that are in addition to~~ (1 MeV). The requirements ~~in~~ of this Section are in addition to the provisions in ~~other sections~~ Sections .0100, .0200, .1000, and .1600 of this Chapter.

(b) This Section does not pertain to radiation safety requirements for ~~x-ray equipment that is covered in other sections~~ industrial radiographic machines for non-human use that are covered in Section .0500 of this ~~Chapter~~ Chapter, ~~(e.g.,~~ x-rays in the healing arts in Section .0600 of this Chapter, and particle accelerators in Section .0900 of this ~~Chapter).~~ Chapter.

(c) RGDs used for the purpose of elemental analysis, microstructural analysis, quality assurance, quality control, research and development, gauging and measurement, or other nondestructive testing and evaluation ~~RGDs addressed in this Section include:~~ in this Section includes:

(1) analytical RGDs;

(2) cabinet x-ray systems;

(3) electron beam ~~device~~ devices operating below 1MeV;

(4) electron microscopes;

(5) ion implantation equipment, low energy;

(6) gauging devices;

(7) radiographic and radioscopic non-healing arts x-ray equipment; and

(8) security screening devices and systems for government use only.

History Note: *Authority G.S. 104E-7;*
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Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended Eff. November 1, 2024.

10A NCAC 15 .0802 is amended with changes as published in 38:19 NCR 1219-1229 as follows:

10A NCAC 15 .0802 DEFINITIONS

In addition to terms found in Rule .0104 of this ~~Chapter~~ Chapter, the following definitions shall apply to this Section:

(1) "Accredited bomb squad" means a law enforcement agency utilizing certified bomb technicians.

(2) "Accessible surface" means the external or outside surface of the enclosure or housing provided by the manufacturer or designer of the RGD. This includes the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware, and including the plane across the exterior edge of any opening.

~~(2)~~(3) "Analytical RGD equipment" means equipment that uses electronic means to generate ionizing radiation for the purpose of examining the microstructure of ~~materials,~~ materials ~~i.e.~~ using direct x-ray transmission, x-ray diffraction, x-ray fluorescence, and x-ray spectroscopy.

~~(3)~~(4) "Analytical RGD system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

~~(4) "Bomb detection RGDs" means RGDs used for the sole purpose of remotely detecting explosive devices.~~

(5) "Certified bomb technician" means a member of an accredited bomb squad who has successfully completed the FBI Hazardous Devices School. Information pertaining to this program can be found ~~on the school website~~ at http://www.fbi.gov/about-us/cirg/hazardous-devices.

(6) "Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to meet the certification requirements specified in 21 CFR ~~1020.40~~ 1020.40, as incorporated by reference in Rule .0117 of this Chapter.

(7) "Certified cabinet x-ray system" means an RGD utilized in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed. These systems shall be certified in accordance with 21 CFR ~~1010.2~~ 1010.2, as incorporated by reference in Rule .0117 of this Chapter, as being manufactured and assembled pursuant to the provisions of 21 CFR ~~1020.40~~ 1020.40, as incorporated by reference in Rule .0117 of this Chapter.

(8) "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

(9) "Control panel" means ~~that~~ the part of the x-ray control where the switches, knobs, pushbuttons, and other hardware are, ~~that are necessary~~ located for manually setting the technique factors.

(10) "Electron Beam Device" means any device using electrons below 1MeV to heat, join, or otherwise irradiate materials.

(11) "Enclosed beam RGD" means an RGD with all possible x-ray beam paths contained in a chamber, coupled chambers, or other beam-path-confinement ~~devices~~ devices, to prevent any part of the body from intercepting the beam during normal operations. Normal access to the primary beam path, such as a sample chamber door, shall be interlocked with the high voltage of the x-ray tube or the shutter

for the beam to be considered "enclosed." An open-beam device placed in an interlocked enclosure is considered an "enclosed beam" unless there are provisions for routine bypassing of the interlocks.

(12) "Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected radiation exposure of an individual exceeding administrative or regulatory ~~limits.~~limits found in Rule 10A NCAC 15 .1601(a)(8) and .1601(a)(15). This procedure shall include the names and telephone numbers of individuals to be ~~contacted~~ contacted, as well as directives for processing individual monitoring devices.

~~(12)~~(13) "Fail-safe characteristics" means a design feature that causes the radiation beam to terminate, port shutters to close, or otherwise prevents emergence of the primary ~~beam,~~ beam upon the failure of a safety or warning device. For example, if an "X-ray On" ~~light indicator or~~ light indicator, ~~shutter indicator~~ shutter indicator, or interlock fails, the radiation beam shall terminate.

(14) "Gauging device" means a mechanism containing a source of ionizing radiation that is designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative composition of materials. It may include components such as radiation shields, useful-beam controls, and other safety features in order to meet the requirements or ~~specifications.~~ specifications of the device.

(15) "General-use system" means a security screening system that delivers an effective dose of 25 microrem (0.25 microSv) or less per screening.

~~(13)~~(16) "Hand-held x-ray system" means any device or equipment that is portable and used for similar purposes as analytical RGD equipment.

~~(14) "Hybrid gauge" means an x-ray gauge device utilizing both x-ray and radioactive sources.~~

~~(15) "Industrial radiography" means RGDs used to make radiographic images to examine the structure of materials by nondestructive methods. These RGDs shall not be contained in a cabinet and are not permanent installations.~~

(17) "Individual responsible for radiation protection" means a person who has the knowledge and responsibility to apply appropriate radiation rules, for persons registered with the agency in accordance with Section .0200 of this Chapter, commensurate with the scope of the activities authorized by the registrant.

~~(17)~~(18) "Inspection Zone" means the area established for the purpose of controlling access where screening is performed. Areas controlled due to the presence of radiation shall include areas of ingress, egress, gates, portals, and traffic paths. The area outside of the inspection zone shall not exceed the limits of Rule .1601(a)(13) of this Section.

~~(18)~~(19) "Interlock" means a feature designed to prevent access to an area of radiation hazard by preventing entry or by automatically removing the hazard.

~~(16)~~(20) "Ion implantation equipment, low-energy" means any enclosed device operating below 1MeV used to accelerate elemental ions and implant them in other materials.

~~(17)~~(21) "Leakage radiation" means radiation emanating from the source assembly housing except for:

(A) the primary beam;

(B) scatter radiation emanating from other components ~~(e.g., shutter or collimator)~~; and

(C) radiation produced when the ~~beam on~~ "beam on" switch or timer is not activated.

~~(21)~~(22) "Limited-use system" means a screening system that is capable of delivering an effective dose greater than 25 microrem (0.25 microSv) per ~~screening~~ screening,but shall not exceed an effective dose of 1 mrem (10 microSv) per ~~screening.~~ screening,

~~(18)~~(23) "Local components" means part of an RGD x-ray system and include areas that are struck by ~~x-rays~~ x rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

~~(19)~~(24) "Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

~~(20)~~(25) "Normal operating procedures" means step-by-step instructions necessary to accomplish a task. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures that are related to radiation safety.

~~(21)~~(26) "Open-beam RGD" means a device or system designed in such a way that the primary beam is not completely enclosed during normal ~~operation~~ operation, ~~and~~ when used for analysis, gauging, or ~~imaging~~ imaging, ~~in which~~ an individual could accidentally place some part of their body in the primary beam or stray radiation path during normal operation.

~~(22) "Permanent radiographic installation" means an RGD utilized in an enclosed shielded room, cell, or vault that allows entry when the RGD is not energized.~~

~~(23)~~(27) "Portable RGD" means RGD equipment designed to be ~~carried.~~ carried by hand.

~~(24)~~(28) "Primary beam" means radiation that passes through an aperture of the source assembly housing by a direct path from the radiation source.

~~(25)~~(29) "Radiation generating device (RGD)" means any system, device, subsystem, or machine component that may ~~generate~~ generate, by electronic ~~means~~ means, x-rays or particle radiation above 5 keV, but below 1 MeV, and not used for healing ~~arts~~ parts on humans or animals. ~~Examples of~~ RGDs ~~are the following~~ may be used as a:

(A) ~~analytical RGD equipment~~ mobile RGD;

(B) ~~certified and certifiable cabinet x-ray systems~~ portable RGD; or

(C) ~~gauging devices using x-ray sources;~~ stationary RGD.

~~(D) hybrid gauging devices;~~

~~(E) e-beam welders;~~

~~(F) baggage scanners;~~

~~(G) industrial radiography RGDs; and~~

~~(H) permanent radiographic installations.~~

~~(26)~~(30) "Remote components" means parts of an RGD x-ray system that are not struck by ~~x-rays~~ x-rays, such as power supplies, transformers, amplifiers, readout devices, and control panels.

~~(30)~~(31) "Safety Device" means a device, interlock or system that prevents the entry of any portion of an individual's body into the primary x-ray beam or that will cause the beam to shut off upon entry into its path.

~~(27)~~(32) "Scattered radiation" means radiation, other than leakage radiation, that during passage through matter, has been deviated in direction or has been modified by a decrease in energy.

~~(32)~~(33) "Screening" means the sum of scans necessary for a security screening system to image concealed objects as intended by the system design under normal operating conditions.

~~(33)~~(34) "Security screening device" means a non-human use open-beam device designed for the detection of contraband or weapons concealed in baggage, mail, packages, or other structures. These devices include bomb detection devices used for the sole purpose of detecting explosive devices.

~~(34)~~(35) "Security screening system" means a system specifically designed to detect contraband and weapons concealed on a person and is used for the sole purpose of public safety and security evaluation by law enforcement.

~~(28)~~(36) "Shutter" means an adjustable device, generally made of lead or other high atomic number material, fixed to a source assembly housing to intercept, block, or collimate the primary beam.

~~(29)~~(37) "Source" means the point of origin of the radiation, such as the focal spot of an x-ray tube.

~~(30)~~(38) "Stationary RGD" means RGD equipment that is installed or placed in a fixed location.

~~(31)~~(39) "Stray radiation" means the sum of leakage and scatter radiation emanating from the source assembly or other ~~components~~ components. except for the primary beam, and radiation produced when the beam on switch or timer is not activated.

~~(39)~~(40) "Warning device" means an audible or visible signal that warns individuals of a potential radiation hazard.

~~(32)~~(41) "X-ray generator" means the part of an x-ray system that provides the accelerating (high) voltage and current for the x-ray tube.

~~(33) "X-ray gauge" means an x-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, or interface location of manufactured products.~~

~~(41)~~(42) "X-ray source housing" means the portion of an RGD system which contains the x-ray tube and emitting target. The housing often contains radiation shielding material or inherently provides shielding.

History Note: *Authority G.S. 104E-7;*
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Amended Eff. November 1, 2024.

10A NCAC 15 .0803 is amended with changes as published in 38:19 NCR 1219-1229 as follows:

10A NCAC 15 .0803 ~~EQUIPMENT REQUIREMENTS~~ PERSONNEL 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 µSv) 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/2.5µSv in one hour.~~

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

(a) The ~~registrant~~ registrant, as defined in 10A NCAC 15 .0104(130), shall document the scope of training and instruction required for the RGD in use.

(b) No individual shall be permitted to operate or maintain RGDs unless the individual has received instruction in the basic principles of radiation protection, training specific to the manufacturer's recommendations for safe operation and unique features of the RGD in use, and instruction in the operating and emergency procedures. Instruction and training shall include:

(1) Basic principles of radiation protection:

(A) radiation fundamentals;

(B) source and magnitude of common sources of radiation exposure;

(C) units of radiation dose and measurements;

(D) potential hazards, biological effects of ionizing radiation, and recognition of symptoms of an acute localized exposure;

(E) ALARA (As Low As Reasonably Achievable) principles for radiation protection concepts of time, distance, and shielding to minimize radiation exposure;

(F) declared pregnancy policy;

(G) occupational, embryo/fetus, and public dose limits; and

(H) proper use of individual monitoring devices and survey instruments.

(2) Device specific training for each RGD:

(A) hands-on training for proper use;

(B) radiation hazards associated with use;

(C) precautions to take or measures required to minimize radiation exposure;

(D) procedures to prevent unauthorized use; and

(E) agency rules regarding use.

(3) Operating and emergency procedure requirements of Rule .0804 in this Section.

(c) Records of instruction and training for each individual operating RGDs, documenting that the requirements of this Rule have been met, shall be maintained and available for agency review during inspection.

(d) ~~Individuals~~ Persons who will be operating the RGD shall be able to demonstrate an understanding in safe operating procedures and use of the RGD according to the manufacturer's specifications and to an authorized representative of the Radiation Protection Section.

(e) Each registrant shall provide ring or wrist individual monitoring devices to individuals:

(1) operating open-beam RGDs; and

(2) performing maintenance on an RDG, if the maintenance procedures require the presence of a primary x-ray beam when any local component in the RGD is disassembled or removed.

History Note: *Authority G.S. 104E-7;*
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10A NCAC 15 .0804 is amended with changes as published in 38:19 NCR 1219-1229 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~~ individual responsible for radiation protection as defined in 10A NCAC 15 .0802(17). ~~protection.~~ ~~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 for review 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 ~~radiaton safety officer~~ individual responsible for radiation protection ~~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 review by the individual responsible for radiation protection ~~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~~ individual responsible for radiation protection 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~~ individual responsible for radiation protection.

(B) Testing records shall include the date test was performed, the list of safety devices tested, the 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 a 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 approval from the ~~radiation safety officer~~ individual responsible for radiation protection. Procedures for bypassing a safety device shall be incorporated into the radiation protection program by the ~~radiation safety officer~~ individual responsible for radiation protection, 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 individual responsible for radiation protection, 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~~ An individual shall determine the tube is ~~off~~ off, and will remain off until safe conditions have been ~~restored:~~ restored, prior to an individual modifying the following:

(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;
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10A NCAC 15 .0805 is amended with changes as published in 38:19 NCR 1219-1229 as follows:

10A NCAC 15 .0805 ~~OPERATING REQUIREMENTS~~ AREA REQUIREMENTS

~~(a) RGDs shall be operated by individuals that have completed the training requirements of Rule .0806 of this Section.~~

~~(b) Normal operating procedures shall be written and available to all RGD operators and support staff.~~

~~(c) No individual shall be permitted to operate RGDs in any manner other than that specified in the operating procedures unless the person has obtained written approval of the individual responsible for radiation or the Radiation Safety Officer (RSO) as defined in Rule .0104 of this Chapter.~~

~~(d) No individual shall bypass a safety device unless the person has obtained the approval of the person responsible for radiation safety or the RSO. This process shall be incorporated into the radiation protection program by the RSO, as set forth in Rule .1603(a), and the operating procedures as set forth in Rule .0603(a)(1)(B). The written approval, as granted by the RSO, shall include an expiration date. 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 radiation source housing and the control panel during the bypassing period.~~

~~(e) Prior to an individual modifying the:~~

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

~~(2) shutters;~~

~~(3) collimators; or~~

~~(4) beam stops~~

~~the individual shall determine the tube is off and will remain off until safe conditions have been restored.~~

~~(f) Safety devices including interlocks, shutters, and warning lights shall be tested once annually for proper operation on all RGDs in operation. Records of the testing shall be retained by the registrant for three years.~~

~~(g) No individual shall hold a sample or object while it is being irradiated.~~

(a) Each radiation area, as defined in Rule .1601(a)(3) of this Chapter, containing RGDs shall be:

(1) conspicuously posted with caution signs, in accordance with the requirements of Rule .1601(a)(34) of this Chapter, bearing the words "CAUTION – RADIATION AREA", or words having a similar meaning; and

(2) supervised continuously during operation of the RDG or shall utilize one or more of the following:

(A) door interlocks;

(B) entry monitors; or

(C) engineering controls.

(b) Access to each restricted area where an individual may receive a dose equivalent exceeding 100 mrem in any year, but does not exceed levels of a radiation area, shall be designated as a controlled area. The area shall be controlled by:

(1) visibly separating adjacent uncontrolled areas so doses do not exceed the limits of Rule .1601(a)(15) of this Chapter; and

(2) posting a sign bearing the words “Warning: X-rays in Use”, or words having a similar meaning.

(c) 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 result in a dose to an individual present in excess of the dose limits in Rule .1601(a)(15) of this Chapter.

(d) Surveys shall be performed for each RGD, as set forth in Rule .1601(a)(23) of this Chapter, to show compliance with Paragraph (c) of this Rule.

(1) Radiation survey instruments shall be:

(A) capable of measuring the radiation energies of the RGD surveyed; and

(B) calibrated annually when a frequency is not recommended by the manufacturer.

(2) Equipment surveys shall confirm radiation levels do not exceed the requirements of Rule .0806(c)(7); ~~(d)(3);~~ .0806(d)(3); and ~~(h)(2)~~ .0806(h)(2) of this Section. Surveys shall be performed:

(A) prior to initial use and include testing of warning and safety devices;

(B) prior to use following any change in the initial arrangement, including the number or type of local components in the system or x-ray tube source housing;

(C) prior to use following any maintenance requiring the disassembly or removal of a local component in the system or x-ray tube source housing that could affect the radiation exposure to personnel; and

(D) during the performance of calibration, maintenance, or any alignment procedure if the presence of a primary x-ray beam is required while any local component in the system is disassembled or removed.

(3) A registrant may apply to the agency for approval of procedures differing from those in Subparagraph (d) of this Rule, provided that the registrant demonstrates satisfactory compliance with Paragraph (c) of this Rule.

(4) Records shall be available for agency review during inspection.

(e) RGDs in Rule .0806(i) and .0807(2) of this Section, installed after the effective date of this Rule, shall ensure the following provisions are met:

(1) A floor plan with equipment arrangement shall be submitted to the agency for review and acknowledgement prior to installation of the system. The floor plan shall include:

(A) the proposed location of the system;

(B) direction of the useful beam;

(C) adjacent areas; and

(D) location of the operator.

(2) An area radiation survey shall be performed prior to initial use to show compliance with dose limits of the rules in Section .1600 of this Chapter. The survey shall include:

(A) a drawing of the room indicating the location of the x-ray tube and orientation of the useful beam;

(B) radiation levels at the operator location and adjacent areas;

(C) survey instrument used; and

(D) name of the service provider that is ~~registered~~ registered, in accordance with Rule .0205 of this ~~Chapter~~ Chapter, and date the survey was performed.

(3) Modifications to the room, RGD, or adjacent areas that may increase the radiation dose to any individual shall require a new survey.

(4) Records of the floor plan with equipment arrangement and survey shall be available for review by an authorized representative of the Radiation Protection Section ~~agency review~~ during inspection.

History Note: *Authority G.S. 104E-7; 104E-12;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0805 Eff. February 1, 2015;
Amended Eff. January 1, 2016; October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended Eff. November 1, 2024.

10A NCAC 15 .0806 is amended with changes as published in 38:19 NCR 1219-1229 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:~~ requirements, except certified and certifiable cabinet x-ray systems in paragraph (a) of this Rule:

(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. The following additional requirements shall be provided on the analyzer:

(1) A power switch with the power logo: I/O.

(2) A label with the words "CAUTION: THIS EQUIPMENT PRODUCES X-RAYS WHEN OPERATED", or words with similar meaning.

(3) Indicators visible to operators when x-rays are on. The indicator shall be in the form of a light and a warning symbol or text with the words "X-RAY ON", or words with similar meaning.

(4) Warning labels near each beam port that 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.

(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)~~ assembly 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, for 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;
Transferred and Recodified from 15A NCAC 11 .0806 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. November 1, 2024.

10A NCAC 15 .0807 is amended with changes as published in 38:19 NCR 1219-1229 as follows:

10A NCAC 15 .0807 ~~PERMANENT RADIOGRAPHIC INSTALLATIONS AND INDUSTRIAL RADIOGRAPHY RGDS~~ SECURITY SCREENING EQUIPMENT REQUIREMENTS FOR GOVERNMENT USE ONLY

~~(a) Permanent radiographic installations and industrial radiography RGDs are exempt from the requirements of the rules of this Section except Rule .0802 and Rule .0804(a), (b)(1)(A), (b)(1)(C), (b)(2), and (b)(3).~~

~~(b) Permanent radiographic installations and industrial radiography RGDs shall comply with the following rules of this Chapter:~~

~~(1) .0501;~~

~~(2) .0502;~~

~~(3) .0506;~~

~~(4) .0509 .0520;~~

~~(5) .0522;~~

~~(6) .0523(a)(1);~~

~~(7) .0523(a)(3);~~

~~(8) .0523(a)(6) .0523(a)(15);~~

~~(9) .0523(b)(1) .0523(b)(4);~~

~~(10) .0523(b)(6) .0523(b)(7);~~

~~(11) .0523(b)(9) .0523(b)(12);~~

~~(12) .0523(c); and~~

~~(13) .0525.~~

(a) All security screening devices shall meet the following additional requirements:

(1) Security screening RGDs shall only be utilized by accredited bomb squads, certified bomb technicians, law enforcement agencies, or forensic investigators.

(2) The operator must be present and maintain access control during operation of the RGD. If the RGD is not operated in a restricted area and the RGD is capable of producing a radiation area, the operator shall:

(A) establish a visible barrier;

(B) perform a visual check of the controlled area to ensure all unauthorized individuals are removed prior to activating or initiating the RGD; and

(C) if the operator is unable to maintain visual control of the area during operation of the RGD, ~~an additional means to control the area shall be provided.~~ the operator is required to implement additional means to control the area so no one can access the radiation area.

(3) Utilization logs shall be maintained each time the RGD is used and accurately include the following:

(A) date and time of use;

(B) location of use; and

(C) operator of the RGD.

(4) Records of utilization logs shall be available for agency review during inspection.

(b) All security screening systems shall meet the following additional requirements:

(1) Security screening systems shall only be utilized in a correctional institution, detention center, jail, or prison for public safety and security screening purposes.

(2) No individual shall be exposed to the useful beam unless authorized by a law enforcement agency representative.

(3) No individual shall be exposed to the useful beam for demonstration or training purposes.

(4) Screening of staff for training purposes is prohibited.

(5) Policies and procedures shall be established for screening of minors and pregnant individuals.

(6) An inspection zone shall be:

(A) established around the system where bystanders are prohibited during operation;

(B) visibly marked; and

(C) the ambient dose equivalent outside the inspection zone shall not exceed 2 mrem (20 microSv) in any 1 hour.

(7) The system shall be stationary, and the exposure switch shall be located in a manner requiring the operator to remain behind a protected barrier during the entire exposure while able to view the following:

(A) the individual being scanned;

(B) the inspection zone; and

(C) any access areas.

(8) Equipment surveys shall be conducted to verify compliance with reference effective dose limits, the inspection zone, and manufacturer specified parameters. Surveys shall be performed:

(A) upon installation;

(B) every 12 months; and

(C) after maintenance that may affect the system's shielding or x-ray beam.

(9) Reference effective dose limits shall be met as follows:

(A) General-use systems reference effective dose shall not exceed 25 microrem (.25 microSv) per screening.

(B) Limited-use systems reference effective dose shall not exceed 1 mrem (10 microSv) per screening.

(C) The reference effective dose received by an individual shall not exceed 25 mrem (250 microSv) in a 12-month period for both general use and limited-use systems.

(10) Compliance to reference effective dose limits shall be demonstrated by the registrant maintaining records of each individual screened. Records shall show one of the following:

(A) the number of screenings each individual received, for General-use systems, does not exceed 1,000 in a 12-month period; or

(B) the reference effective dose multiplied by the number of screenings, for both General-use and Limited-use systems, does not exceed 25 mrem (250 microSv) in a 12-month period.

(11) Records of each individual scanned at the same facility shall be ~~maintained for~~ available for review by an authorized representative of the Radiation Protection Section ~~agency review~~ during inspection.

(12) Each individual being screened shall be informed the system emits radiation and be provided with the following prior to scanning:

(A) the estimated effective dose from one (1) screening;

(B) an example to compare the dose to a commonly known source of radiation; and

(C) confirmation the screening complies with the reference effective dose limits in Subparagraph (b)(9) of this Rule.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, ~~2015.~~ 2015;
Amended Eff. November 1, 2024.

10A NCAC 15 .0808 is amended with changes as published in 38:19 NCR 1219-1229 as follows:

10A NCAC 15 .0808 ~~APPLICABLE RULES FOR BOMB DETECTION RGDS~~ OTHER EQUIPMENT REQUIREMENTS

~~Bomb detection RGDs utilized by accredited bomb squads and certified bomb technicians shall comply with the following rules of this Chapter:~~

~~(1) .0501;~~

~~(2) .0502;~~

~~(3) .0509;~~

~~(4) .0511 .0520 except for the requirements for a direct reading pocket dosimeter and operating alarm ratemeter in .0512(a);~~

~~(5) .0522;~~

~~(6) .0523(a)(1);~~

~~(7) .0523(a)(3);~~

~~(8) .0523(a)(6) .0523(a)(15);~~

~~(9) .0523(b)(1) .0523(b)(4);~~

~~(10) .0523(b)(6) .0523(b)(7);~~

~~(11) .0523(b)(9) .0523(b)(12);~~

~~(12) .0523(c); and~~

~~(13) .0525.~~

(a) RGD's not listed in Rule .0801 of this ~~Section~~ Section, or that are not able to meet the equipment requirements of either Rule .0806 or .0807 of this Section, shall not be sold, installed, or used prior ~~to:~~to the agency completing review of information regarding the RGD and determining if use of the RGD is allowed. The user or manufacturer of the RGD shall submit the following information to the agency for review:

(1) equipment form for application;

(2) manufacturer manual;

(3) description of use;

(4) operator training;

(5) a survey in accordance with Rule.0805(d) of this Section;

(6) an area survey in accordance with Rule.0805(e)(2) of this Section;

(7) the hazard level associated with use of the RGD; and

(8) means to achieve radiation protection equivalent to the ~~Rules~~ rules of this Section.

(b) After receiving the information in Paragraph (a) of this Rule, the agency will respond to the applicant in writing within 30 days. Upon review, the agency may require additional information if use of the RGD is allowed.

History Note: *Authority G.S. 104E-7;*
Eff. October 1, ~~2015.~~ 2015;

Amended Eff. November 1, 2024.