AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0502

DEADLINE FOR RECEIPT: Friday, September 11, 2015

<u>NOTE WELL:</u> This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

For lines 6 thru 11, just to clarify, the text is almost verbatim of 10 CFR 34.3, so there is no incorporation of that language as allowed under G.S. 150B-21.6? If the intent is to incorporate, please update the language to reflect the incorporation, whether it is subject to subsequent rule-making, the location, and the cost of the information incorporated.

Line 13, add a comma after "guides"

Line 15, add a comma after "tube"

Items (3) and (13) seem almost identical. In the proposed Item (23), the term used is "independent certifying organization," which is (13). In 10A NCAC 15 .0525, the term is "independent certifying organization." The only use of "certifying entity" is in 10A NCAC 15 .0510, which still cross-references 10A NCAC 15 .0525. It appears as though Item (3) is unnecessary. Please clarify.

Line 25, delete the comma after "position"

Line 27, add a comma after "sheath"

Page 2, line 7, define or delete "directly"

Page 2, line 25, what is meant by "practical"? Please clarify.

Page 2, line 26, what is meant by "appropriate"? Please clarify.

Page 3, line 11, add a comma after "equipment"

Page 3, lines 25 thru 28, just to clarify, the text is almost verbatim of 10 CFR 34.3, so there is no incorporation of that language as allowed under G.S. 150B-21.6? If the intent

is to incorporate, please update the language to reflect the incorporation, whether it is subject to subsequent rule-making, the location, and the cost of the information incorporated.

Page 3, line 25, add a comma after "facility"

Page 3, lines 25 and 27, replace "which" with "that"

Page 3, line 28, add a comma after "container"

10A NCAC 15 .0502 is amended as published in NCR 29:21, pp. 2437-2445, as follows:

10A NCAC 15.0502 DEFINITIONS

(a) As used in this Section, In addition to terms found in Rule .0104 of this Chapter, the following definitions shall apply: apply to this Section:

- (1) "Annual refresher safety training" training," as defined in 10 CFR 34.3, means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, include the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or accidents or errors that have been observed, observed, and shall The review shall also provide opportunities for employees to ask safety questions.
- "Associated equipment" means equipment used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides or comes in contact with the sealed source or radiation machines [e.g. guide tube, control tube, control (guide) tube, removable source stop, "J" tube and collimator when it is used as an exposure head].
- (3) "Cabinet radiography using radiation machines" means industrial radiography using radiation machines, which is conducted in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed, and which cabinet is so shielded that every location on the exterior meets conditions for an unrestricted area as specified in Rule .1611 of this Chapter.
- (4) (3) "Certifying entity" means an independent certifying organization meeting the requirements in Rule .0525 of this Section.
- (5) (4) "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to limit the size, shape, and direction of the primary radiation when the sealed source is cranked into position, to make a radiographic exposure.
- (6) (5) "Control device", "Control device," commonly called a crank-out, means the control cable, the protective sheath and control drive mechanism used to move the sealed source from the shielded position in the radiographic device or camera to an unshielded position outside the device for the purpose of making a radiographic exposure.
- (7) (6) "Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.
- (8) (7) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control device mechanism to the radiographic exposure device.
- (9) (8) "Exposure head", "Exposure head," commonly called a source stop, means a device that locates the gamma radiography sealed source in the selected working position.
- (10) (9) "Field examination" means a practical examination.

1 (11) (10) "Field station" means a facility where licensed material or registered equipment may be stored or 2 used and from which licensed material or registered equipment is dispatched. 3 (12) (11) "Guide tube" (Projection sheath) "Guide tube," commonly called a projection sheath, means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable 4 5 from the exposure device to the exposure head. The guide tube may also include the connections 6 necessary for attachment to the exposure device and to the exposure head. 7 (13) (12) "Hands-on experience" means experience in all of those areas considered to be directly involved in 8 the radiography process. 9 (14) (13) "Independent certifying organization" means an independent organization that meets all of the 10 requirements of Rule .0525 of this Section. 11 (15) (14) "Industrial radiography" means the examination of the structure of materials by nondestructive methods utilizing ionizing radiation to make radiographic images. 12 13 (16) (15) "Lay-barge radiography" means industrial radiography performed on any water vessel used for 14 laying pipe. 15 (17) (16) "Off-shore platform radiography" means industrial radiography conducted from a platform over a 16 body of water. 17 (18) (17) "Periodic training" means a periodic review conducted or provided instruction provided at least 18 every 12 months by the licensee or registrant for its employees operators and individuals subject to 19 the requirements of Rule .1003 of this Chapter on radiation safety aspects of radiography. The 20 review topics shall include the results of internal inspections, new procedures or equipment, 21 accidents or errors that have been observed, and opportunities for employees to ask safety questions. 22 (19) (18) "Permanent radiographic installation" means an enclosed shielded room, cell, or vault not located 23 at a temporary job-site in which radiography is performed. 24 (20) (19) "Projection sheath", "Projection sheath" means a guide tube. 25 (21) (20) "Practical examination" means a demonstration through practical application of the safety rules and 26 principles in industrial radiography including the use of all appropriate equipment and procedures. 27 (22) (21) "Radiation safety officer" means an individual named by the licensee or registrant who has 28 knowledge of and responsibility for the overall radiation safety program on behalf of the licensee or 29 registrant and who meets the requirements of Rule .0510(h) of this Section. 30 (23) (22) "Radiographer" means any individual who performs or who, in attendance at the site where sources 31 of radiation are being used, personally supervises industrial radiographic operations and who is 32 responsible to the licensee or registrant for assuring compliance with the requirements of these Rules 33 and all license or registration conditions. 34 (24) (23) "Radiographer certification" means written approval received from a an independent certifying 35 organization stating that an individual has satisfactorily met certain established radiation safety, 36 testing, and experience criteria.

1	(25) <u>(2</u> 5	4) "Radiographer's assistant" means any individual who, under the direct supervision of a radiographer,		
2	uses radiographic exposure devices, sources of radiation, related handling tools, or surv			
3	instruments in industrial radiography.			
4	(26) <u>(2</u>	5) "Radiographic exposure device", "Radiographic exposure device," commonly called a camera or		
5		projector, means any instrument containing a sealed source fastened or contained therein, in which		
6		the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to		
7		unshielded position for purposes of making a radiographic exposure.		
8	(27) <u>(2</u>	6) "Radiographic operations" means all activities associated with the presence of radioactive or x-ray		
9		sources in a radiographic exposure device during use of the device or transport (except when being		
10		transported by a common or contract transport), to include including surveys to confirm the		
11		adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.		
12	(28) <u>(2</u>	7) "S-tube" means a tube through which the radioactive source travels when inside a radiographic		
13		exposure device.		
14	(29) <u>(2</u>	8) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent		
15		leakage or escape of the radioactive material.		
16	(30) <u>(2</u>	9) "Shielded position" means the location within the radiographic exposure device or source changer		
17		where the sealed source is secured and restricted from movement. This position incorporates		
18		maximum shielding for the sealed source.		
19	(31) <u>(3</u>	0) "Source assembly" means an assembly that consists of the sealed source and a connector that		
20		attaches the source to the control cable. The source assembly also includes the stop ball if one is		
21		used to secure the sealed source in the shielded position. The connector attaches to the control cable.		
22	(32) <u>(3</u>	31) "Source changer" means a device designed and used for replacement of sealed sources in		
23		radiographic exposure devices, including those also used for transporting and storage of sealed		
24		sources.		
25	(33) <u>(3</u>	2) "Storage area," as defined in 10 CFR 34.3, means any location, facility or vehicle which is		
26		used to store or secure a radiographic exposure device, a storage container container, or a sealed		
27		source when it is not in use and which is locked or has a physical barrier to prevent accidental		
28		exposure, tampering with or unauthorized removal of the device, storage container or sealed source.		
29	(34) <u>(3</u>	3) "Storage container" means a device in which sealed sources are secured and stored.		
30	(35) <u>(3</u>	4) "Temporary jobsite" means a location, location where radiographic operations are conducted and		
31		where licensed material may be stored other than those location(s) of use authorized on the license.		
32	(36) <u>(3</u>	5) "Underwater radiography" means industrial radiography performed when the radiographic exposure		
33		device or related equipment are beneath the surface of the water.		
34	(b) Other defini	itions applicable to this Section may be found in Rule .0104 of this Chapter.		
35				
36	History Note:	Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the		
37		permanent rule becomes effective, whichever is sooner;		

1	Authority G.S. 104E-7; <u>10 CFR 34.3;</u>
2	Eff. February 1, 1980;
3	Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994; June 1, 1989;
4	Transferred and Recodified from 15A NCAC 11 .0502 Eff. February 1, 2015;
5	Amended Eff. October 1, 2015.

1	10A NCAC 15	.0518 is repealed as published in NCR 29:21, pp. 2437-2445, as follows:
2		
3	10A NCAC 15	.0518 RADIATION MACHINES
4		
5	History Note:	Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the
6		permanent rule becomes effective, whichever is sooner;
7		Authority G.S. 104E-7; 104E-12(a)(1);
8		Eff. February 1, 1980;
9		Amended Eff. May 1, 1995; June 1, 1993;
10		Transferred and Recodified from 15A NCAC 11 .0518 Eff. February 1, 2015;
11		Repealed Eff. October 1, 2015.

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0801

DEADLINE FOR RECEIPT: Friday, September 11, 2015

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In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Lines 10 thru 11, delete the comma after "to" and the phrase "and not in substitution for, applicable"

Line 13, do not italicize "e.g."

Line 14, do not use the small variant symbols ({ }), but use brackets ([]) to reflect the language deleted after publication in the Register.

1 10A NCAC 15 .0801 is amended with changes as published in NCR 29:21, pp. 2437-2445, as follows: 2 3 SECTION .0800 REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT NON-HUMAN USE OF 4 **RADIATION GENERATING DEVICES** 5 6 10A NCAC 15.0801 PURPOSE AND SCOPE 7 This Section provides special requirements for analytical x ray equipment which are in addition to, and not in 8 substitution for, applicable requirements in the other sections of this Chapter. 9 (a) This Section provides special requirements for use of ionizing radiation generating devices (RGDs) operating 10 above five thousand electron volts (5 keV), but below one million electron volts (1 MeV) that are in addition to, and 11 not in substitution for, applicable requirements in the other sections of this Chapter. 12 (b) This Section does not pertain to radiation safety requirements for x-ray equipment that is covered in other sections 13 of this Chapter (e.g., x-rays in the healing arts in Section .0600 of this Chapter, and particle accelerators in Section 14 .0900 of this {Chapter.)} Chapter). 15 16 History Note: Authority G.S. 104E-7; 17 Eff. February 1, 1980; 18 Transferred and Recodified from 15A NCAC 11 .0801 Eff. February 1, 2015. 19 Amended Eff. October 1, 2015.

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0802

DEADLINE FOR RECEIPT: Friday, September 11, 2015

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In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 19, delete the "(a)" as there is no Paragraph (b)

Line 26, delete "solely" and add "sole" between "the purpose"

Line 28, define or delete "successfully" This may be accomplished if there is a scoring system for the FBI Hazardous Devices School. In which case, the standard should be incorporated in accordance with G.S. 150B-21.6. Please update the language to reflect the incorporation, whether it is subject to subsequent rule-making, the location, and the cost of the information incorporated.

Page 2, line 6, add a comma after "join"

Page 2, line 8, define or delete "fully"

Page 2, line 20, what is "analytical x-ray equipment"? The term defined in Item (2) of this Rule is "analytical RGD equipment." The term used on line 20 is defined in the current version of this Rule, but the adopted proposed amendment does not define the term as used in Item 13. Please clarify.

Page 2, line 23, replace "are not" between "RGDs...contained" with "shall not be"

Page 3, line 3, delete the comma after "procedures"

Page 3, line 5, add a comma after "gauging"

Page 3, line 11, replace "which" with "that"

Page 3, line 16, what is "analytical x-ray equipment"? The term defined in Item (2) of this Rule is "analytical RGD equipment." The term used on line 16 is defined in the

current version of this Rule, but the adopted proposed amendment does not define the term as used in Item 13. Please clarify.

Page 3, line 29, add a comma after "block"

Page 3, line 35, replace "which" with "that"

1	10A NCAC 15 .0	0802 is amended as published in NCR 29:21, pp. 2437-2445, as follows:		
2				
3	10A NCAC 15.	0802 DEFINITIONS		
4	(a) "Analytical	x ray equipment" means equipment used for x ray diffraction or fluorescence analysis.		
5	(b) "Analytical	x ray system" means a group of local and remote components utilizing x rays to determine the		
6	elemental compo	osition or to examine the microstructure of materials. Local components include those that are struck		
7	by x rays such	as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras,		
8	goniometers, det	ectors and shielding. Remote components include power supplies, transformers, amplifiers, readout		
9	devices, and con	t rol panels.		
0	(c) "Fail safe ch	aracteristics" means a design feature which causes beam port shutters to close, or otherwise prevents		
1	emergence of the	e primary beam, upon the failure of a safety or warning device.		
12	(d) "Normal op	erating procedures" mean operating procedures for conditions suitable for analytical purposes with		
13	shielding and ba	arriers in place. These do not include maintenance but do include routine alignment procedures.		
14	Routine and emo	ergency radiation safety considerations are part of these procedures.		
15	(e) "Open beam	n configuration" means an analytical x ray system in which an individual could accidentally place		
16	some part of his body in the primary beam path during normal operation.			
17	(f) "Primary bea	m" means ionizing radiation which passes through an aperture of the source housing by a direct path		
18	from the x-ray tu	tbe or a radioactive source located in the radiation source housing.		
9	(a) In addition to	o terms found in Rule .0104 of this Chapter the following definitions shall apply to this Section:		
20	(1)	"Accredited bomb squad" means a law enforcement agency utilizing certified bomb technicians.		
21	(2)	"Analytical RGD equipment" means equipment that uses electronic means to generate ionizing		
22		radiation for the purpose of examining the microstructure of materials, i.e. x-ray diffraction and x-		
23		ray spectroscopy.		
24	(3)	"Analytical RGD system" means a group of local and remote components utilizing x-rays to		
25		determine the elemental composition or to examine the microstructure of materials.		
26	(4)	"Bomb detection RGDs" means RGDs used solely for the purpose of remotely detecting explosive		
27		devices.		
28	<u>(5)</u>	"Certified bomb technician" means a member of an accredited bomb squad who has successfully		
29		completed the FBI Hazardous Devices School. Information pertaining to this program can be found		
30		on the school website at http://www.fbi.gov/about-us/cirg/hazardous-devices.		
31	<u>(6)</u>	"Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to		
32		meet the certification requirements specified in 21 CFR 1020.40 as incorporated by reference in		
33		Rule .0117 of this Chapter.		
34	(7)	"Certified cabinet x-ray system" means an RGD utilized in an enclosed, interlocked cabinet, such		
35		that the radiation machine will not operate unless all openings are securely closed. These systems		
36		shall be certified in accordance with 21 CFR 1010.2 as incorporated by reference in Rule .0117 of		

1		this Chapter, as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40
2		as incorporated by reference in Rule .0117 of this Chapter.
3	(8)	"Collimator" means a device or mechanism by which the x-ray beam is restricted in size.
4	(9)	"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs,
5		pushbuttons, and other hardware necessary for manually setting the technique factors.
6	<u>(10)</u>	"Electron Beam Device" means any device using electrons below 1MeV to heat, join or otherwise
7		irradiate materials.
8	<u>(11)</u>	"Enclosed beam RGD" means an RGD with all possible x-ray beam paths fully contained in a
9		chamber, coupled chambers, or other beam-path-confinement devices to prevent any part of the
10		body from intercepting the beam during normal operations. Normal access to the primary beam path,
1		such as a sample chamber door, shall be interlocked with the high voltage of the x-ray tube or the
12		shutter for the beam to be considered "enclosed." An open-beam device placed in an interlocked
13		enclosure is considered an "enclosed beam" unless there are provisions for routine bypassing of the
14		interlocks.
15	(12)	"Fail-safe characteristics" means a design feature that causes the radiation beam to terminate, port
16		shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety
17		or warning device. For example, if an "X-ray On" light indicator or shutter indicator or interlock
18		fails, the radiation beam shall terminate.
19	(13)	"Hand-held x-ray system" means any device or equipment that is portable and used for similar
20		purposes as analytical x-ray equipment.
21	(14)	"Hybrid gauge" means an x-ray gauge device utilizing both x-ray and radioactive sources.
22	(15)	"Industrial radiography" means RGDs used to make radiographic images to examine the structure
23		of materials by nondestructive methods. These RGDs are not contained in a cabinet and are not
24		permanent installations.
25	<u>(16)</u>	"Ion implantation equipment, low-energy" means any closed device operating below 1MeV used to
26		accelerate elemental ions and implant them in other materials.
27	<u>(17)</u>	"Leakage radiation" means radiation emanating from the source assembly housing except for:
28		(A) the primary beam;
29		(B) scatter radiation emanating from other components (e.g., shutter or collimator); and
30		(C) radiation produced when the beam on switch or timer is not activated.
31	<u>(18)</u>	"Local components" means part of an RGD x-ray system and include areas that are struck by x-rays
32		such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras,
33		goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers,
34		readout devices, and control panels.
35	(19)	"Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for
36		moving while assembled.

1	(20)	"Normal operating procedures" means step-by-step instructions necessary to accomplish a task.
2		These procedures shall include sample insertion and manipulation, equipment alignment, routine
3		maintenance by the registrant, and data recording procedures, that are related to radiation safety.
4	(21)	"Open-beam RGD" means a device or system designed in such a way that the primary beam is not
5		completely enclosed during normal operation and used for analysis, gauging or imaging in which
6		an individual could accidentally place some part of their body in the primary beam or stray radiation
7		path during normal operation.
8	(22)	"Permanent radiographic installation" means an RGD utilized in an enclosed shielded room, cell, or
9		vault that allows entry when the RGD is not energized.
10	(23)	"Portable RGD" means RGD equipment designed to be carried.
11	(24)	"Primary beam" means radiation which passes through an aperture of the source assembly housing
12		by a direct path from the radiation source.
13	(25)	"Radiation generating device (RGD)" means any system, device, subsystem, or machine component
14		that may generate by electronic means x-rays or particle radiation above 5 keV, but below 1 MeV,
15		and not used for healing arts on humans or animals. Examples of RGDs are the following:
16		(A) analytical x-ray machines;
17		(B) certified and certifiable cabinet x-ray systems;
18		(C) gauging devices using x-ray sources;
19		(D) hybrid gauging devices;
20		(E) e-beam welders;
21		(F) baggage scanners;
22		(G) industrial radiography RGDs; and
23		(H) permanent radiographic installations.
24	(26)	"Remote components" means parts of an RGD x-ray system that are not struck by x-rays such as
25		power supplies, transformers, amplifiers, readout devices, and control panels.
26	(27)	"Scattered radiation" means radiation, other than leakage radiation, that during passage through
27		matter, has been deviated in direction or has been modified by a decrease in energy.
28	(28)	"Shutter" means an adjustable device, generally made of lead or other high atomic number material,
29		fixed to a source assembly housing to intercept, block or collimate the primary beam.
30	(29)	"Source" means the point of origin of the radiation, such as the focal spot of an x-ray tube.
31	(30)	"Stationary RGD" means RGD equipment that is installed or placed in a fixed location.
32	(31)	"Stray radiation" means the sum of leakage and scatter radiation emanating from the source
33		assembly or other components except for the primary beam, and radiation produced when the beam
34		on switch or timer is not activated.
35	(32)	"X-ray generator" means the part of an x-ray system which provides the accelerating (high) voltage
36		and current for the x-ray tube.

1	(33)	"X-ray gauge" means an x-ray producing device designed and manufactured for the purpose of
2		detecting, measuring, gauging, or controlling thickness, density, level, or interface location of
3		manufactured products.
4		
5	History Note:	Authority G.S. 104E-7;
6		Eff. February 1, 1980;
7		Transferred and Recodified from 15A NCAC 11 .0802 Eff. February 1, 2015:
8		Amended Eff. October 1, 2015.

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0803

DEADLINE FOR RECEIPT: Friday, September 11, 2015

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In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Page 2, line 11, add a comma after "chamber"

Page 2, line 13, replace "which" with "that"

Page 2, line 20, define or delete "easily"

Page 2, line 25, what is the purpose of the comma after "RGDs"? It seems unnecessary. Consider deleting.

Page 2, line 26, what is the purpose of the comma after "components"? It seems unnecessary. Consider deleting.

Page 2, line 28, replace "are" with "shall be"

Page 2, line 30, please clarify that this standard is being incorporated pursuant to G.S. 150B-21.6. Consider the following rewrite:

"62495 that is incorporated by reference and includes subsequent..."

Page 2, line 34, specify who is meant by "agency" Is there a specific contact person that could be specified by position title or division? Is the information to contact said person or division available?

Page 2, line 37, is this an accurate statement? Is it the reason why the safety device would exist and could not be used or is it the reason why there needs to be a deviation from the standard? As written, it sounds like the device has safety devices and the request is to opt out of use. Please clarify.

Page 3, line 11, replace "which" with "that"

Page 3, lines 16 thru 20, is this text an accurate statement? Should the text beginning after "and" on line 18 be moved to Subparagraph (m)(2)? Please clarify.

Page 3, line 24, please flip the terms to match the title of the cross-referenced rule.

1	10A NCAC 15 .0803 is amended as published in NCR 29:21, pp. 2437-2445, as follows:
2	
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 ar
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 preven
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. Or
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
- 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
- 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
- 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 <u>a collimator or a component coupling is connected to the port.</u>
- 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 <u>dollars</u> (\$121.00) at the following website:
- 32 <u>http://webstore.ansi.org/FindStandards.aspx?SearchString=IEC+62495+Ed.+1.0+en%3a2011&SearchOption=0&Pa</u>
- 33 geNum=0&SearchTermsArray=null%7cIEC+62495+Ed.+1.0+en%3a2011%7cnull.
- 34 (i) A registrant may apply to the agency for an exemption from the requirement of a safety device. This request shall
- 35 <u>include:</u>
- 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 R	(j) Analytical RGDs shall be provided with a visible and legible label(s) bearing the radiation symbol and the words:				
5	<u>(1)</u>	"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	<u>(2)</u>	"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 lig	hts labeled with the words "X-RAYS ON," or other words having similar meaning, shall be located:				
11	<u>(1)</u>	near any switch which activates the high voltage to energize an x-ray tube; or				
12	<u>(2)</u>	in a conspicuous location near the radiation source housing and radiation beam(s) and visible from				
13		all instrument access areas.				
14	(1) 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		$\underline{\text{(mrem)}}$ / (25 microsieverts μSv) in one hour; and if the tube housing is the primary shielding for the				
19		<u>x-ray tube</u>				
20	<u>(2)</u>	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/2.5µSv in	one hour.				
24	(o) Industrial ra	diography RGDs and permanent radiographic installations shall comply with the requirements of Rule				
25	.0807 of this Sec	ction.				
26						
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:				
30		Amended Eff. October 1, 2015.				

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0804

DEADLINE FOR RECEIPT: Friday, September 11, 2015

<u>NOTE WELL:</u> This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 6, delete "therein"

Line 15, add a comma after "arrangement"

Line 24, replace "must" with "shall be"

1	10A NCAC 15.	0804 is a	mended as published in NCR 29:21, pp. 2437-2445, as follows:
2			
3	10A NCAC 15.	0804	AREA REQUIREMENTS
4	(a) The local co	omponen	ts of an analytical x ray system RGDs shall be so located <u>located</u> and arranged and shall
5	include to includ	<u>e</u> sufficie	ent shielding or access control that to ensure no radiation levels exist in any area surrounding
6	the local compos	nent grou	p which components that could result in a dose to an individual present therein in excess of
7	the dose limits g	given in I	Rule .1611 .1611(a) of this Chapter. For systems utilizing x ray tubes, these levels shall be
8	met at any spec	ified tub	e rating. A registrant or licensee may apply to the agency for an exemption from this
9	requirement purs	suant to I	Rule .0106(a) of this Chapter.
10	(b) Surveys Sur	vey Requ	<u>uirements</u>
11	(1)	Radiati	on surveys, as required by Rule .1613 as set forth in Rule .1613(a) and (b) of this Chapter,
12		of all a	nalytical x-ray systems RGDs sufficient to show compliance with Paragraph (a) of this Rule,
13		shall be	e performed:
14		(A)	upon installation of the equipment; within 30 days after initial operation of the device;
15		(B)	prior to use following any change in the initial arrangement, arrangement including the
16			number or type of local components in the system; and
17		(C)	prior to use following any maintenance requiring the disassembly or removal of a local
18			component in the system which that could affect the radiation exposure to personnel;
19			personnel.
20		(D)	radiation monitoring shall be performed during maintenance.
21	(2)	A licen	see or \underline{A} registrant may apply to the agency for approval of procedures differing from those
22		in Subp	paragraph (b)(1) of this Rule, provided that the $\frac{1}{1}$ registrant demonstrates satisfactory
23		compli	ance with Paragraph (a) of this Rule.
24	(3)	Survey	s must be performed with a radiation survey instrument capable of the following:
25		(A)	measuring the radiation energies of the system surveyed;
26		<u>(B)</u>	confirming that the radiation limits of this Section are met; and
27		<u>(C)</u>	calibrated according to the manufacture's recommended frequency or at least annually
28			when a frequency is not recommended.
29	(c) Each area of	use or re	oom containing analytical x-ray equipment <u>RGDs</u> shall be conspicuously posted with a sign
30	or signs caution	signs in a	accordance with the requirements of Rule .1623 of this Chapter, bearing the radiation caution
31	symbol and the	words "	CAUTION - X-RAY EQUIPMENT", EQUIPMENT," or words having a similar intent.
32	meaning.		
33			
34	History Note:	Author	ity G.S. 104E-7; <u>104E-7(a)(2);</u>
35		Eff. Fel	bruary 1, 1980;
36		Amend	ed Eff. January 1, 1994;
37		Transfe	erred and Recodified from 15A NCAC 11 .0804 Eff. February 1, 2015. <u>2015;</u>

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0805

DEADLINE FOR RECEIPT: Friday, September 11, 2015

<u>NOTE WELL:</u> This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Lines 4, 9, 10, 12, 19, 24, and 27 use different terms: "individual" and "person." Please choose a consistent term.

Line 10, and lines 12 thru 13, is there both a "person responsible for radiation safety" and a "Radiation Safety Officer"? The terms seem redundant. Please clarify.

Line 14, who is responsible for incorporating this process into the program? Please clarify.

Line 15, who is providing the "approval"? Please clarify.

Line 26, who is keeping the records? Please clarify.

1 10A NCAC 15 .0805 is amended as published in NCR 29:21, pp. 2437-2445, as follows: 2 3 10A NCAC 15.0805 **OPERATING REQUIREMENTS** 4 (a) RGDs shall be operated by individuals that have completed the training requirements of Rule .0806 of this Section. 5 (a) (b) Normal operating procedures shall be written and available to all analytical x-ray equipment workers. RGD 6 operators and support staff. No person shall be permitted to operate analytical x ray equipment in any manner other 7 than that specified in the procedures unless the person has obtained written approval of the person responsible for 8 radiation safety. 9 (c) No person shall be permitted to operate RGDs in any manner other than that specified in the operating procedures 10 unless the person has obtained written approval of the person responsible for radiation safety, or Radiation Safety Officer (RSO) as defined in Rule .0104 of this Chapter. 11 12 (b) (d) No person shall bypass a safety device unless the person has obtained the approval of the person responsible 13 for radiation safety, safety or RSO. Such approval shall be for a specified period of time. This process shall be 14 incorporated into the radiation protection program, as set forth in Rule .1613(a), and the operating procedures as set 15 forth in Rule .0603(a)(1)(B). The written approval shall include an expiration date. When a safety device has been 16 bypassed, a readily discernible legible sign bearing the words "SAFETY DEVICE NOT WORKING," 17 or words having a similar intent, meaning shall be placed on the radiation source housing and the control panel during 18 the period such bypassing is in effect. bypassing period. 19 (e) Prior to an individual modifying the: 20 (1) x-ray tube system, resulting in the removal of tube housings, covers, or shielding materials; 21 (2) shutters; 22 (3) collimators; or 23 (4) beam stops; 24 the individual shall determine the tube is off and will remain off until safe conditions have been restored. 25 (f) Safety devices including interlocks, shutters, and warning lights shall be tested for proper operation on all RGDs 26 in operation once annually. Records of the testing shall be retained for three years. 27 (g) Individuals shall not hold a sample or object being irradiated. 28 29 Authority G.S. 104E-7; 104E-12; History Note: 30 Eff. February 1, 1980; 31 Transferred and Recodified from 15A NCAC 11 .0805 Eff. February 1, 2015; 32 Amended Eff. October 1, 2015.

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15.0806

DEADLINE FOR RECEIPT: Friday, September 11, 2015

<u>NOTE WELL:</u> This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

Line 4, is the term "Instructions of" necessary"? Please consider deleting.

Line 16, who is the "agency" inspecting? Please clarify.

Line 19, is the concept of a "ring or wrist personnel monitoring equipment" a commonly known term? Please clarify.

1	10A NCAC 15 .0	806 is amended as published in NCR 29:21, pp. 2437-2445, as follows:
2		
3	10A NCAC 15.0	9806 PERSONNEL REQUIREMENTS
4	(a) Instructions of	of personnel operating or maintaining RGDs shall comply with the following:
5	(1)	No person shall be permitted to operate or maintain analytical x ray equipment RGDs unless the
6		person has received instruction in : instruction in the operating and emergency procedures for the
7		RGD and instruction that is in accordance with Rule .1003 of this Chapter.
8		(A) identification of possible radiation hazards and biological effects associated with the use
9		of the equipment;
10		(B) significance of the various radiation warning and safety devices incorporated into the
11		equipment, or the reasons they have not been installed on certain pieces of equipment and
12		the extra precautions required in these cases;
13		(C) proper operating procedures for the equipment;
14		(D) appropriate use and limitations of dosimetric devices;
15		(E) proper procedures for reporting an actual or suspected exposure.
16	(2)	Each licensee or registrant shall maintain, for inspection by the agency, records of training which
17		demonstrate that demonstrate the requirements of this Rule have been met. satisfied.
18	(b) Personnel mo	onitoring or wrist dosimetric devices shall be provided to, and shall be used by:
19	(b) The registran	t shall provide ring or wrist personnel monitoring equipment to:
20	(1)	analytical x ray equipment workers using systems having an open beam configuration and
21		individuals using open-beam RGDs not equipped with a safety device; and
22	(2)	$\underline{\text{personnel_maintaining analytical x ray equipment}} \ \underline{\text{individuals maintaining RGDs}} \ \text{if the maintenance}$
23		procedures require the presence of a primary x-ray beam when any local component in the analytical
24		x-ray system RGD is disassembled or removed.
25		
26	History Note:	Authority G.S. 104E-7; 104E-11; 104E-12;
27		Eff. February 1, 1980;
28		Transferred and Recodified from 15A NCAC 11 .0806 Eff. February 1, 2015;
29		Amended Eff. October 1, 2015.

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0807

DEADLINE FOR RECEIPT: Friday, September 11, 2015

<u>NOTE WELL:</u> This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

For this Rule, is the intent that only the identified rules in Sections .0500 and .0800 apply? Do other rules set forth in this Chapter apply to permanent radiographic installations and industrial radiography RDG? Please clarify.

Line 6, please note that the text of this Rule differs from what was published on page 2445 in the 29 NCR 21. The published language is the following:

(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).

Please track the highlighted language.

1 10A NCAC 15 .0807 is adopted as published in NCR 29:21, pp. 2437-2445, as follows: 2 3 10A NCAC 15 .0807 PERMANENT RADIOGRAPHIC INSTALLATIONS AND INDUSTRIAL 4 **RADIOGRAPHY RGDS** 5 (a) Permanent radiographic installations and industrial radiography RGDs are exempt from the requirements of the 6 Rules of this Section except Rules .0802 and .0804 Paragraphs (a), (b)(1)(A), and (C), (b)(2), and (b)(3). 7 (b) Permanent radiographic installations and industrial radiography RGDs shall comply with the following Rules of 8 this Chapter: 9 .0501; (1) 10 (2) .0502; 11 .0506; (3) 12 (4) .0509-.0520; .0522; 13 (5) 14 (6) .0523(a)(1); 15 (7) .0523(a)(3); 16 (8) .0523(a)(6) -.0523(a)(15); 17 (9) .0523(b)(1) -.0523(b)(4); <u>(10)</u> 18 .0523(b)(6) -.0523(b)(7); 19 <u>(11)</u> .0523(b)(9) -.0523(b)(12); 20 (12) .0523(c); and 21 (13).0525. 22 23 History Note: *Authority G.S. 104E-7;* 24 Eff. October 1, 2015.

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0808

DEADLINE FOR RECEIPT: Friday, September 11, 2015

<u>NOTE WELL:</u> This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this rule prior to the Commission's next meeting. The Commission has not yet reviewed this rule and therefore there has not been a determination as to whether the rule will be approved. You may call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made. Approval of any rule is contingent upon making technical changes as set forth in G.S. 150B-21.10.

For this Rule, is the intent that only the identified rules in Sections .0500 apply? Do other rules set forth in this Chapter apply to bomb detection RDG? Please clarify.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 15 .0808 is adopted as published in NCR 29:21, pp. 2437-2445, as follows: 2 3 10A NCAC 15.0808 APPLICABLE RULES FOR BOMB DETECTION RGDS 4 Bomb detection RGDs utilized by accredited bomb squads and certified bomb technicians shall comply with the 5 following Rules of this Chapter: 6 (1) .0501; 7 .0502; (2) 8 .0509; (3) 9 (4) .0511-.0520 except for the requirements for a direct reading pocket dosimeter and operating alarm 10 ratemeter in .0512(a); .0522; 11 (5) 12 .0523(a)(1); (6) 13 (7) .0523(a)(3);14 (8) .0523(a)(6) -.0523(a)(15); 15 (9) .0523(b)(1) - .0523(b)(4);(10) 16 .0523(b)(6) -.0523(b)(7); 17 **(11)** .0523(b)(9) -.0523(b)(12); 18 (12) .0523(c); and 19 .0525. (13) 20 21 History Note: Authority G.S. 104E-7; 22 Eff. October 1, 2015.