Fiscal Impact Analysis for Proposed Rule Change
NC Division of Health Service Regulation
Radiation Protection Section

Agency:	NC Radiation Protection Commission
Agency Contact:	Jon Granger or Christy Britt NC DHHS – Division of Health Service Regulation Radiation Protection Section 1645 Mail Service Center Raleigh, NC 27699-1645 jon.granger@dhhs.nc.gov christy.britt@dhhs.nc.gov 919-814-2250
Nature of Impact:	State Government Impact – YES Local Government Impact – YES Substantial Economic Impact – NO
Authorizing Statute:	G.S. 104E (See Appendix 1)
Rule Titles:	15A NCAC 11.0502 DEFINITIONS 15A NCAC 11.0518 RADIATION MACHINES 15A NCAC 11.0801 PURPOSE AND SCOPE 15A NCAC 11.0802 DEFINITIONS 15A NCAC 11.0803 EQUIPMENT REQUIREMENTS 15A NCAC 11.0804 AREA REQUIREMENTS 15A NCAC 11.0805 OPERATING REQUIREMENTS 15A NCAC 11.0806 PERSONNEL REQUIREMENTS 15A NCAC 11.0807 PERMANENT RADIOGRAPHIC INSTALLATIONS AND INDUSTRIAL RADIOGRAPHY RGDS 15A NCAC 11.0808 BOMB DETECTION RGDS (See proposed rule text in Appendix 2) **NOTE:** The agency has taken steps to recodify the proposed rules under chapter 10A NCAC 15. See Appendix 3 for more details.

Need for Amendments

With these changes, the Section intends to simplify compliance with regulations on the use of electronic analytical and industrial x-ray machines for facilities. This should result in improved safety for radiation workers and the states' citizens. These amendments are necessary to address the growing number of facilities utilizing electronic x-ray machines for non-medical purposes. Many of these machines utilize technology that has been developed since the last revisions of these Rules in 1999 and 1980. These changes address a number of terms and standards that have changed.

Summary of Amendments

The amendments to 15A NCAC 11 .0502, .0518, .0801, .0802, .0803, .0804, .0805, and .0806 clarify and update the Rules for use of electronic analytical and industrial x-ray machines. The Radiation Protection Section based these amendments primarily on the most current draft of the Suggested State Regulations for these machines. The Suggested State Regulations are documents that the Conference of Radiation Control Programs Directors (CRCPD) maintains and that intend to provide the framework for uniformity of radiation control laws and regulations among states. The Section also based the amendments on the suggestions of the X-ray Working Group and the Radiation Protection Staff. The Section is also adding two new rules, 15A NCAC 11 .0807 and .0808, to clarify the requirements for the use of permanent radiographic installations, industrial radiography machines and bomb detection x-ray machines. The X-ray Working Group requested these additions to simplify the requirements for these specialized x-ray uses.
Section *15A NCAC 11 .0500:* The changes to Section .0500 rules are primarily the removal of references to cabinet x-ray machines. Cabinet x-ray machines will now be regulated under Section .0800 Rules. Section .0800 Rules will continue to regulate industrial radiography and fixed room industrial radiography that utilize electronic x-rays.

Section 15A NCAC 11 .0800: Section .0800 rules are being renamed "Requirements for Non-Human Use of Radiation Generating Devices". This replaces the previous title "Requirements for Analytical X-ray Equipment". Radiation Generating Devices (RGDs) are a general category of electronic x-ray machines that includes analytical x-ray machines, x-ray gauging devices, electronic microscopes, e-beam welders, baggage scanners and cabinet x-ray machines. These machines typically operate at lower energies and are less hazardous than the machines that are regulated in Section .0500 rules. The Section removed references to radioactive materials from this Section since these Rules only apply to electronic devices.

Summary of Impacts

Although these changes will impact state government, local government, and private entities, most of the amendments are administrative and will not have a substantial impact on the affected entities. The most significant impacts are from the new requirement for registrants to perform safety checks on most machines on an annual basis. Registrants would also be required to utilize a meter for radiation surveys that is appropriate and calibrated for the survey. These are new requirements but most registrants are already complying with these and they should have little impact. The new rules for portable open-beam analytical and bomb detection x-ray machines address the use of these new technologies primarily by listing the existing rules with which the operators of these machines must comply.

These changes may also result in a cost-savings for some facilities. These changes address some safety issues with the use of x-ray machines that may benefit facilities by reducing radiation exposure to their operators, other employees and members of the public that may be near their machines. A reduction in radiation exposure will reduce the chances for injuries and lower the risks for radiation induced cancers. A radiation exposure reduction will also reduce the number of investigations and reports of incidents to the Section. Facilities may also notice a reduction in time needed to interpret and train for the requirements because of the clarification of these Rules. The costs and savings to the industry from the proposed change are summaries in Table 1 below.

These changes should result in a cost-savings to our Section. The clarification of the Rules should shorten the time needed for inspections and enforcement. The Section inspects most of the facilities

impacted by these Rules on a three-year frequency. The Section expects to inspect 132 of these facilities each year. For example, if the improvements to the Rules could reduce the inspection time plus enforcement time by 30 minutes per inspection, this could save the Section 66 hours of working time per year. This example would also save the registrant on inspection time.

Table 1. Summary of Estimated Impacts by Rule

Rule #	Estimated Annual Cost Per Facility	Estimated Annual Cost-Total				Estimated Annual Benefit
		State Gov't	Local Gov't	Private Sector	**Total**	
.0502	None	None				Small time savings
.0518	None	None				None
.0801	None	None				None
.0802	None	None				Small time savings
.0803	Possible cost	Possible cost				Possible cost savings
.0804	$550	$6,050	$1,650	$70,950	$78,650	Possible cost savings
.0805	$150-$300	$5,250 - $10,500	$1,350 - $2,700	$44,400 - $88,800	$51,000 - $102,000	Small time savings
.0806	None	None				Small time savings
.0807	None	None				Small time savings
.0808	None	None				Small time savings
Annual Total		$11,300 – $16,550	$3,000 – $4,350	$115,350 - $159,750	$129,650 - $180,650	**Unquantified Benefits**

The impacts estimated in this analysis are based on the following numbers of facilities, devices and operators.

Table 2. Number of Affected Registrants, Devices and Operators by Rule

Rule #	# of Registrants				# of X-Ray Tubes				# of Operators[1]			
	State	Local	Private	**Total**	State	Local	Private	**Total**	State	Local	Private	**Total**
.0502, .0518	1	6	8	**15**	1	6	11	**18**	3	18	33	**54**
.0801-.0806	46	12	395	**453**	158	18	918	**1,094**	474	54	2,754	**3,282**
.0807	2	0	14	**16**	2	0	15	**17**	6	0	45	**51**
.0808	2	13	0	**15**	8	20	0	**28**	6	0	45	**51**

[1] Assumes 3 operators per tube based on the experience from inspection of these facilities (the Section does not collect this information formally).

Impact of Proposed Amendments of 15A NCAC 11 .0502 Definitions

Purpose: To remove an unnecessary definition and to correct and clarify existing definitions.

Description: Amendments to 12 definitions and removal of one definition. The definition changes reflect current practice including updated language and references.

Benefit to the public interest: These revisions make it easier for the general public and x-ray stakeholders to understand and use this Rule. This may result in a minor time savings to registrants that must maintain compliance with this Rule.

Impact of Proposed Repeal of 15A NCAC 11 .0518 Radiation Machines

Purpose: This Rule is being repealed since all machines covered by this Rule will now be under new Rules in the .0800 Section.

Description: Repeal of this Rule.

Benefit to the public interest: These revisions make it easier for the general public and x-ray stakeholders to understand and use this Rule. There is no additional benefit or cost due to the repeal.

Impact of Proposed Amendments of 15A NCAC 11 .0801 Purpose and Scope

Purpose: To define the types and categories of x-ray machines regulated by this Section.

Description: Amend Rule to describe the change in the scope of this Section.

Benefit to the public interest: These revisions make it easier for the general public and x-ray stakeholders to understand and use this Rule.

Impact of Proposed Amendments of 15A NCAC 11 .0802 Definitions

Purpose: To remove unnecessary definitions, correct and clarify existing definitions, and add definitions for the expanded scope of this Section.

Description: Addition of 33 definitions and removal of six definitions.

Benefit to the public interest: The definition changes more accurately reflect current practice including updated language and references.

Impact of Proposed Amendments 15A NCAC 11 .0803 Equipment Requirements

Purpose: The amendments to this Rule are to correct technical errors, update terms and units, and align the language with federal and national standards.

Description: Many of the revisions to this Rule are corrections to formatting and grammar and inclusions of current Federal Requirements referenced below. Many of the paragraphs of the current Rule have been reorganized in the suggested paragraphs to improve the structure of the requirements. Noted below are changes requested by the Radiation Protection Commission's X-Ray Advisory Committee, Working Group members and the Radiation Protection Section.

Paragraph (a) and (b): The suggested paragraph (a) directs the registrant to reference 15A NCAC 11 .0117(a)(3) for the requirements for certified x-ray cabinets which are incorporated, with subsequent editions, from the Code of Federal Regulations 21 CFR 1020.40.[1] Paragraph (b) states the requirements for construction of certified x-ray cabinets. The language of this paragraph aligns with the standard of practice according to the requirements found in 21 CFR 1020.40.

Paragraph (c), (d), (e), (f), and (g): The suggested paragraph (c), clarifies the requirement for construction of open-beam analytical RGDs.

The current paragraph (b) is restated in the suggested paragraphs (d) and (e) along with the addition of suggested information added to paragraph (e) that clarifies the "fail-safe" warning device and light requirement for open-beam analytical RGDs.

Suggested paragraph (f) restates the current paragraph (c) and adds that this requirement only applies to open-beam RGDs (Radiation Generating Devices). Also the word "casual" was replaced with "unintended." This change parallels the language found in the 21.CFR 1020.40, as well as the Suggested State Regulations-Part H, from the CRCPD (Conference of Radiation Control Program Directors).[2]

Paragraph (g) clarifies the language of current paragraph (e) and specifies that this Rule only applies to open-beam "analytical" RGDs installed after February 1, 1980.

Paragraph (h): This paragraph addresses the use of "portable" open-beam RGDs manufactured to be used hand-held without safety devices. Most of these machines are commonly known as "XRFs".

Under the proposed changes, these machines would be exempt from the requirements of suggested paragraph (c) of this Rule. While the exemption suggests the change would result in a cost saving, in practice the rule has never been enforced for XFR machines since they were not available when the agency first adopted the rule. Although the Section does not enforce the safety device requirements for "portable" open-beam RGDs manufactured to be used hand-held without safety devices, registrants are required to apply for a one time waiver from this requirement. This application would not be necessary because of the suggested exemption of these machines. The Section will also save the time required to process exemption requests. These savings are expected to be minimal.

Paragraph (h) also requires hand-held open-beam RGDs to be constructed and maintained according to International Standard IEC 62495 and subsequent amendments.[3] The Section has not discovered any hand-held open-beam RGDs that do not meet the IEC standards and all equipment that is available for purchase is manufactured to this standard. Although it may be possible for an individual to manufacture a machine in this category that does not meet the standard, it is unlikely because of the cost and

---

[1] Code of Federal Regulations :(CFR) (21 CFR 1020.40), retrieved from *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.40*

[2] Conference of Radiation Control Program Directors: (CRCPD), retrieved from *http://www.crcpd.org/SSRCRs/*

[3] International Standard IEC, retrieved from *http://webstore.ansi.org/FindStandards.aspx?SearchString=iec+62495&SearchOption=0&PageNum=0&SearchTermsArray=IEC+62495+Ed.+1.0%7ciec+62495%7cnull*

technology required. Since it is so unlikely to occur it is difficult to determine what the cost to upgrade a machine that did not meet the standards would be.

Paragraph (i): Paragraph (i) includes simplified verbiage from the current paragraph (a). This paragraph outlines what is required for the registrant to obtain an exemption from the safety devices when required in this Rule.

Paragraph (j): These changes include verbiage clarification of the current paragraph (d) that aligns this language with the 21 CFR 1020.40 requirements. "X-ray equipment" was deleted and replaced with "RGD". The requirement for labels was changed from "readily discernable" to "visible and legible" for clarification. Radioactive Material requirements were removed from the current paragraph since it was considered unnecessary by the Working Group and it is not expected to have an impact on the regulated community.

Paragraph (k) and (l): Paragraphs (k) and (l) clarify and correct the current paragraph (f) requirements for warning lights for non-human use RGDs, such as analytical and cabinet machines. The requirement for the warning light to be "outside each entrance into the room" was deleted and replaced with "near any switch which activates the high voltage to energize an x-ray tube or in a conspicuous location near the radiation source housing and radiation beam (s) and visible from all instrument access areas." These changes parallel the 21 CFR 1020.40 language, as well as the Suggested State Regulations. Suggested paragraph (k) and (l) clarify the requirements of where the warning lights are required to be located on the machine as well as when the lights shall activate. The deletion of the item in current paragraph (f), for the lights to be fail safe, occurred due to the fact that the 21 CFR 1020.40 federal manufacturing specifications do not mandate such requirement. The Working Group considered the Radioactive Material requirements unnecessary and recommended their removal.

Registrants could realize a cost savings because of removing the requirement for the warning lights. This warning light is unnecessary for use of these types of machines and most registrants apply for an exemption of this requirement. Removal of this requirement will result in a cost savings since registrants will not have to install warning lights or apply for an exemption. Again, the Section expects these savings to be minimal.

Paragraph (m): Paragraph (m) clarifies the requirements of current paragraph (g) "An exposure" was substituted for "a dose" to correct the leakage requirement for the tube housing as well as to parallel suggested state Rule verbiage. The revision in subparagraph (m)(1), of adding (25 microsieverts μSv), was to update the measurement units to current standards.

Suggested subparagraph (m)(2) requires RGD tube housings that are the primary shielding to "not produce x-rays when the housing is opened or disassembled". The addition of this requirement aligns the Rule with the Suggested State Regulations. This new requirement should impact very few registrants since almost all of the x-ray tubes in use are commercially manufactured to meet this standard. It should only impact registrants that choose to manufacture or modify an x-ray tube. This would not be a common occurrence. There should be many low cost methods for meeting this standard, such as locating the power supply where its removal is required prior to disassembling the housing. There is limited information on exact costs to repair tube housings that may not meet this requirement. A member of the Working Group regulated by the Rule reported that somewhat similar repairs have cost less than $100 to $2,300.

Paragraph (n): Paragraph (n) clarifies and corrects the current paragraph (h) "An exposure" replaces "a dose" in suggested paragraph (n) to correct the terminology for leakage requirements for the generator and parallels the language of the Suggested State Regulations. The change from "0.04mrem" to ".25mrem/2.5µSv" reflects a correction to align with the Suggested State Regulations and 21 CFR 1020.40. Although the leakage requirement for the generator was increased, this will have little impact since the existing requirement is incorrect and we do not believe there are generators that do not meet the corrected leakage requirement.

Paragraph (o): Paragraph (o) is an addition that refers registrants to Rule .0807 for the requirements of industrial radiography RGDs and permanent radiographic installations. This should simplify compliance with the requirements for use of these types of RGDs.

Benefit to the public interest: The changes make corrections and clarify the language and should simplify compliance with the Rule. This should save registrants time and reduce the cost of compliance. Simplification of compliance would result in increased safety to machine operators and the public.

Impact of Proposed Amendments of 15A NCAC 11 .0804 Area Requirements

Purpose: To clarify the requirements of this Section.

Description: The proposed changes include corrections and clarifications on requirements for radiation surveys, calibration of survey instruments, and area requirements where RGDs are used. Noted below are changes requested by the Radiation Protection Commission's X-Ray Advisory Committee, Working Group members, and the Radiation Protection Section.

Paragraph (a): The changes clarify the language, remove outdated terms, and delete a reference to exemptions that is not needed in this Rule.

Paragraph (b)(1): Survey requirements are addressed in paragraph (b)(1) as required per rule .1613(a) and (b). This clarification is addressed in the first sentence of (b)(1), as well as the correction in terminology referencing "RGDs." The specific requirements have been updated to parallel Federal requirements in subparagraphs (A), (B), and (C).The additions to (A),(B), and (C) create deadlines to the conditions that require surveys to be performed. The Section deleted Paragraph (b)(1)(D) since monitoring of individuals conducting service is addressed in Rule .0806. The Working Group initially considered including a requirement for annual surveys for all machines, but they decided against it since after discussions they concluded the benefits of the surveys would not justify the cost to registrants.

Paragraph (b)(2): The only change is the removal of licensee to reflect that there is no radioactive material requirements in this rule.

Paragraph (b)(3): This proposed paragraph is added to reflect the Suggested State Regulations, American National Standards Institute (ANSI) standards, and Federal requirements.[4] This paragraph adds general requirements that are to be met for each survey instrument used to complete required radiation surveys. Although these are new specific requirements for calibrations, the current Rule .1613

[4] American National Standards Institute ANSI, retrieved from http://hps.org/hpssc/N13_49_2001.html

requires that surveys evaluate "the magnitude and extent of radiation levels." To meet this standard a properly calibrated survey instrument is required. The Section quantified the impact in this analysis assuming this is an entirely new requirement although this is a common industrial standard and is considered required under the current Rules; therefore, the estimates below are likely overestimating the impact from the proposal.

This proposed requirement impacts those who conduct radiation surveys for facilities. Based on our best professional judgment half of the registered facilities, or 227 (see Table 2 above) will require a survey during any given year. This reduces the impact of this Rule since calibration of a survey instrument is not required during these years. The Section further assumed that of the 227 registrants conducting a survey in a given year, 114 (or half) would use a service provider to conduct their survey. There are an estimated 30 service providers registered to conduct these surveys, and they use mostly a single instrument to conduct surveys at multiple facilities. Service providers must use instruments that meet the requirements for calibration when providing these services. The Section assumed that the average cost per facility for calibration of one radiation survey instrument per year is $550, which the Section based on the Section's costs to have similar equipment calibrated. The total annual cost of the survey requirement of close to $79,000, as shown in Table 1 above, is based on the 11 state registrants, 3 local government registrants, 99 registrants from the private sector, plus 30 service providers (whose cost is included in the private sector impact shown in Table 1). It is possible that some service providers would utilize multiple instruments within a year, in which case the estimate total annual cost may be somewhat higher than shown above; however, the Section does not have enough information to more accurately estimate the impact from the survey requirement.

Paragraph (c): The amendments in paragraph (c) adjust the verbiage to reflect the use of "RGD" and specify that the caution signs shall be "in accordance with the requirements of Rule .1623 of this Chapter." These changes will help maintain consistency with verbiage throughout the Rules.

Benefit to the public interest: The changes clarify the language and should simplify compliance with the Rule. This should save registrants time and costs of compliance and improve safety for workers and the public.

Impact of Proposed Amendments of 15A NCAC 11 .0805 Operating Requirements

Purpose: To remove unnecessary information and clarify the requirements of this Section.

Description: The proposed changes include corrections, additions, and clarifications to requirements for operator training and safety device implementation where RGDs are used. The additions also include references that clarify Radiation Safety Officers (RSO), radiation protection programs, and operating procedures. Noted below are changes requested by the Radiation Protection Commission's X-Ray Advisory Committee, Working Group members, and the Radiation Protection Section.

Paragraph (a): The suggested paragraph refers operators to Rule .0806 for training requirements. This is a new statement for clarification purposes only.

Paragraph (b): The change from "all analytical x-ray equipment workers" to "RGD operators and support staff," clarifies and promotes continuity with the suggested Rule language.

Paragraph (c): This paragraph is a restatement of the current paragraph (a) but incorporates "RGD" into the language and clarifies who may approve changes in operating procedures.

Paragraph (d): Current paragraph (b) is moved to new paragraph (d) and defines "how" to obtain permission to bypass a safety device. Paragraph (d) clarifies that the approval is required to be "written", as well as "incorporated into the radiation protection program, as set forth in Rule .1613(a) and the operating procedures as set forth in Rule .0603(a)(1)(B)." Having the processes explained in the radiation protection program and operating procedures will make it easier for the registrants to maintain compliance.

This paragraph also changes the period of approvals for bypassing a safety device from "for a specified period of time" to requiring an "expiration date."

The final portion of suggested paragraph (d) only clarifies that any signage posted during bypassing of safety devices be "legible" and required to be posted during the "bypassing period."

Paragraph (e): Paragraph (e) is a new requirement to confirm the x-ray tube is off before modifying any components that are required for the safety of the machine. This is a rare occurrence for most facilities. A majority of facilities will not modify their equipment and will never be impacted by this change. The cost of this requirement could be very small for impacted facilities since this can likely be accomplished by disconnecting the power source for the device. Some facilities may choose to utilize a survey meter to determine that a machine is not generating radiation. This would rarely be necessary to meet this requirement.

Paragraph (f): Paragraph (f) implements a new requirement for safety checks on all safety devices to be performed on all RGDs in use at least annually. Many RGDs remain in storage for long periods of time without use. The safety checks may be conducted by operators, in-house safety personnel, or registered service providers. The safety checks may be completed during the radiation survey that is required by Rule .0804. Currently there are 1,094 machines at 453 facilities affected by this Rule, so on average about 2.4 machines per facility. For the purposes of estimating the impact of the requirement, the Section assumed 75% of the 453 facilities would require safety checks per year based on input from stakeholders and inspection experience. (Not all of these machines would require a safety check annually based on this amendment because of non-use.) Therefore base on the number of x-ray machine registered (see Table 2), about 35 state government, 9 local government, and 296 private sector facilities would require a safety check per year.

Checks of safety devices on RGDs take up to 60 minutes to complete and document per machine. The estimated cost per hour for each safety check is between $62.5 and $125; therefore, the cost per facility could range between $150 and $300. As a result, the annual total cost from this requirement would range between $51,000 and $102,000.

Benefit to the public interest: The changes clarify the language and should simplify compliance with the Rule. This should save registrants time and costs of compliance and improve safety to workers and the public.

Impact of Proposed Amendments of 15A NCAC 11 .0806 Personnel Requirements

Purpose: To remove unnecessary information, consolidate, and clarify the requirements of this Section.

Description: The proposed changes include corrections, additions, and clarifications for personnel requirements and the incorporation of the term RGD.

Paragraph (a)(1): The changes in suggested paragraph (a)(1) define the specific individuals to which this rule applies. The addition of "RGD" and deletion of "analytical x-ray equipment," promotes consistency with all other rule language. The specific training requirements of this paragraph were removed and a reference to the existing instruction requirements in Rule .1003 was added. This may be a cost savings to some facilities since the specific training requirements of this Rule are not necessary for all personnel.

Paragraph (a)(2): The changes remove a reference to licensee and clarify the existing language.

Paragraph (b)(1)(2): The changes in this paragraph clarify the specific requirements for personnel monitoring for open-beam RGDs and maintenance of RGDs.

Benefit to the public interest: The changes clarify the language and should simplify compliance with the Rule. This should save registrants time and costs of compliance and improve safety to workers and the public.

Impact of Proposed Amendments of 15A NCAC 11 .0807 Permanent Radiographic Installations and Industrial Radiography RGDs

Purpose: To incorporate the applicable requirements for use of Permanent Radiographic Installations and Industrial Radiography RGDs from the existing Rules of Section .0500.

Description: This new Rule is a list of the Rules in Section .0500 that apply to use of Permanent Radiographic Installations and Industrial Radiography RGDs. New requirements were not created for these machines. This Rule was only created to clearly show which Rules are applicable to these RGDs.

Benefit to the public interest: The changes clarify the language and should simplify compliance with the Rule. This should save registrants time and costs of compliance and improve safety to workers and the public.

Impact of Proposed Amendments of 15A NCAC 11 .0808 Bomb Detection RGDs

Purpose: To incorporate the applicable requirements for use of Bomb Detection RGDs from the existing Rules of Section .0500.

Description: This new Rule is a list of the Rules in Section .0500 that apply to use of Bomb Detection RGDs. New requirements were not created for these machines. This Rule was only created to clearly show which Rules are applicable to these RGDs.

Benefit to the public interest: The changes clarify the language and should simplify compliance with the Rule. This should save registrants time and costs of compliance and improve safety to workers and the public. Currently bomb squads are required to apply for waivers from various requirements of Section .0500. These bomb squads would gain a time savings because this application would not be necessary due to this new Rule. The Section will also save the time required to process exemption requests.

Appendix 1 – Statute Authorizing Rule-Making

The North Carolina Radiation Protection Act (G.S. 104E) established the North Carolina Radiation Protection Commission with the power to "... adopt, promulgate, amend and repeal such Rules, regulations and standards relating to the manufacture, production, transportation, use, handling, servicing, installation, storage, sale, lease, or other disposition of radioactive materials and machines ..." and to "... provide by Rule and regulation for an electronic product safety program to protect the public health and safety, which program may authorize regulation and inspection of sources of non-ionizing radiation throughout the state.

Appendix 2 -Proposed Rule Text

15A NCAC 11 .0502 is proposed for amendment as follows:

15A NCAC 11 .0502 DEFINITIONS

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

(2) "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.~~ [*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.

~~(11)~~ (10) "Field station" means a facility where licensed material or registered equipment may be stored or used and from which licensed material or registered equipment is dispatched.

~~(12)~~ (11) ~~"Guide tube" (Projection sheath)~~ "Guide tube," commonly called a projection sheath, means a flexible or rigid tube ~~(i.e.,~~ (*i.e.*, "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

~~(13)~~ (12) "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process.

~~(14)~~ (13) "Independent certifying organization" means an independent organization that meets all of the requirements of Rule .0525 of this Section.

~~(15)~~ (14) "Industrial radiography" means the examination of the structure of materials by nondestructive methods utilizing ionizing radiation to make radiographic images.

~~(16)~~ (15) "Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

~~(17)~~ (16) "Off-shore platform radiography" means industrial radiography conducted from a platform over a body of water.

~~(18)~~ (17) "Periodic training" means ~~a periodic review conducted or provided~~ instruction provided at least every 12 months by the licensee or registrant for ~~its employees~~ operators and individuals subject to the requirements of Rule .1003 of this Chapter on radiation safety aspects of radiography. The ~~review~~ topics shall include the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.

~~(19)~~ (18) "Permanent radiographic installation" means an enclosed shielded room, cell, or vault not located at a temporary job-site in which radiography is performed.

~~(20)~~ (19) ~~"Projection sheath",~~ "Projection sheath" means a guide tube.

~~(21)~~ (20) "Practical examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including the use of all appropriate equipment and procedures.

~~(22)~~ (21) "Radiation safety officer" means an individual named by the licensee or registrant who has knowledge of and responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of Rule .0510(h) of this Section.

~~(23)~~ (22) "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these Rules and all license or registration conditions.

~~(24)~~ (23) "Radiographer certification" means written approval received from ~~a~~ an independent certifying organization stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

~~(25)~~ (24) "Radiographer's assistant" means any individual who, under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or survey instruments in industrial radiography.

~~(26)~~ (25) ~~"Radiographic exposure device",~~ "Radiographic exposure device," commonly called a camera or projector, means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

~~(27)~~ (26) "Radiographic operations" means all activities associated with the presence of radioactive or x-ray sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), ~~to include~~ including surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

~~(28)~~ (27) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

~~(29)~~ (28) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

~~(30)~~ (29) "Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement. This position incorporates maximum shielding for the sealed source.

~~(31)~~ (30) "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly also includes the stop ball if one is used to secure the sealed source in the shielded position. The connector attaches to the control cable.

~~(32)~~ (31) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

~~(33)~~ (32) "Storage ~~area"~~ area," as defined in 10 CFR 34.3, means any location, facility or vehicle which is used to store or secure a radiographic exposure device, a storage ~~container~~ container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with or unauthorized removal of the device, storage container or sealed source.

~~(34)~~ (33) "Storage container" means a device in which sealed sources are secured and stored.

~~(35)~~ (34) "Temporary jobsite" means a ~~location,~~ location where radiographic operations are conducted and where licensed material may be stored other than those location(s) of use authorized on the license.

~~(36)~~ (35) "Underwater radiography" means industrial radiography performed when the radiographic exposure device or related equipment are beneath the surface of the water.

~~(b) Other definitions applicable to this Section may be found in Rule .0104 of this Chapter.~~

History Note: *Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*

Authority G.S. 104E-7; 10 CFR 34.3;

Eff. February 1, 1980;

Amended Eff. October 1, 2015; April 1, 1999; May 1, 1995; January 1, 1994; June 1, 1989.

15A NCAC 11 .0518 is proposed for repeal as follows:

15A NCAC 11 .0518 RADIATION MACHINES

~~The following are special requirements for radiography employing radiation machines~~

~~(1) Cabinet radiography using radiation machines shall be exempt from requirements of this Section except that no registrant shall permit any individual to operate a cabinet radiography unit until:~~

~~(a) the registrant has provided the individual a copy of, and instruction in, the operating procedures for the unit; and~~

~~(b) the individual has demonstrated, to the registrant, understanding of the operating procedures for the unit and competence in its use.~~

~~(2) Other radiography using radiation machines are exempt from Rules .0503, .0504, .0505, .0507, .0508 and .0521 of this Section.~~

History Note: *Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
Authority G.S. 104E-7; 104E-12(a)(1);
Eff. February 1, 1980;
Amended Eff. May 1, 1995; June 1, ~~1993.~~1993;
Repealed Eff. XX XX, 2014.

15A NCAC 11 .0801 is proposed for amendment as follows:

SECTION .0800 REQUIREMENTS FOR ~~ANALYTICAL X-RAY EQUIPMENT~~ NON-HUMAN USE OF RADIATION GENERATING DEVICES

This Section .0800, Chapter 11 of Title 15A of the North Carolina Administrative Code (T15A.11 .0800); REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT; has been transferred and recodified from Section .2900, Subchapter 3G of Title 10 of the North Carolina Administrative Code (T10.03G .2900), effective January 4, 1990. The recodification was pursuant to G.S. 143B-279.3.

15A NCAC 11 .0801 PURPOSE AND SCOPE

~~This Section provides special requirements for analytical x-ray equipment which are in addition to, and not in substitution for, applicable requirements in the other sections of this Chapter.~~

(a) This Section provides special 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, and not in substitution for, applicable requirements in the other Sections of this Chapter.

(b) This Section does not pertain to radiation safety requirements for x-ray equipment that is covered in other Sections of this Chapter (*e.g.*, x-rays in the healing arts in Section .0600, and particle accelerators in Section .0900.)

History Note: *Authority G.S. 104E-7;*
Eff. February 1, ~~1980.~~ 1980;
Amended Eff. October 1, 2015.

15A NCAC 11 .0802 is proposed for amendment as follows:

15A NCAC 11 .0802 DEFINITIONS

~~(a) "Analytical x-ray equipment" means equipment used for x-ray diffraction or fluorescence analysis.~~

~~(b) "Analytical x-ray system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.~~

~~(c) "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.~~

~~(d) "Normal operating procedures" mean operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.~~

~~(e) "Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.~~

~~(f) "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.~~

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

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

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

(3) "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 solely for the 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 as incorporated by reference in Rule .0117 of this Chapter.

(7) "Certified cabinet x-ray system" means a 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 as incorporated by reference in Rule .0117 of

this Chapter, as being manufactured and assembled pursuant to the provisions of 21 CFR 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 part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary 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 fully contained in a chamber, coupled chambers, or other beam-path-confinement 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) "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, upon the failure of a safety or warning device. For example, if an "X-ray On" light indicator or shutter indicator or interlock fails, the radiation beam shall terminate.

(13) "Hand-held x-ray system" means any device or equipment that is portable and used for similar purposes as analytical x-ray 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 are not contained in a cabinet and are not permanent installations.

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

(17) "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 switch or timer is not activated.

(18) "Local components" means part of an RGD x-ray system and include areas that are struck by 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) "Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for moving while assembled.

(20) "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) "Open-beam RGD" means a device or system designed in such a way that the primary beam is not completely enclosed during normal operation and used for analysis, gauging or 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) "Portable RGD" means RGD equipment designed to be carried.

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

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

(A) analytical x-ray machines;

(B) certified and certifiable cabinet x-ray systems;

(C) gauging devices using x-ray sources;

(D) hybrid gauging devices;

(E) e-beam welders;

(F) baggage scanners;

(G) industrial radiography RGDs; and

(H) permanent radiographic installations.

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

(27) "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.

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

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

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

(32) "X-ray generator" means the part of an x-ray system which 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.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, ~~1980.~~ 1980;
Amended Eff. October 1, 2015.

15A NCAC 11 .0803 is proposed for amendment as follows:

15A NCAC 11 .0803 EQUIPMENT REQUIREMENTS

~~(a) A safety device which prevents the entry of any portion of an individual's body into the primary x-ray beam path of which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant or licensee may apply to the agency for an exemption from the requirement of a safety device. This application shall include:~~

~~(1) a description of the various safety devices that have been evaluated;~~

~~(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.~~

~~(b) Open-beam configurations shall be provided with a readily discernible indication of:~~

~~(1) X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and~~

~~(2) Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.~~

~~Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of this Rule, warning devices shall have fail-safe characteristics.~~

~~(c) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.~~

~~(d) All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:~~

~~(1) "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray source housing; and~~

~~(2) "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube, if the radiation source is an x-ray tube; or~~

~~(3) "CAUTION - RADIOACTIVE MATERIAL", on the source housing, if the radiation source is a radionuclide.~~

~~(e) On open-beam configurations installed after the effective date of this Rule each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.~~

~~(f) An easily visible warning light labeled with the words "X-RAY ON" or words having a similar intent, shall be located outside each entrance into the room containing an analytical x-ray tube and shall be illuminated only when the tube is energized; or in the case of a radioactive source, shall be illuminated only when the shutter is open. On equipment installed after the effective date of this Rule, warning lights shall have fail-safe characteristics.~~

~~(g) Each x-ray tube housing shall be so 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 a dose in excess of 2.5 mrem in one hour.~~

~~(h) 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 a dose in excess of 0.04 mrem in one hour.~~

(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 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.

(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 easily 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 are 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 and 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 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 which 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 if the tube housing is the primary shielding for the x-ray tube

(2) 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) Industrial radiography RGDs and permanent radiographic installations shall comply with the requirements of Rule .0807 of this Section.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, ~~1980.~~ 1980;
Amended Eff. October 1, 2015.

15A NCAC 11 .0804 is proposed for amendment as follows:

15A NCAC 11 .0804 AREA REQUIREMENTS

(a) The local components of ~~an analytical x-ray system~~ RGDs shall be ~~so located~~ located and arranged ~~and shall include~~ to include sufficient shielding or access control ~~that~~ to ensure no radiation levels exist in any area surrounding the local ~~component group which~~ components that could result in a dose to an individual present therein in excess of the dose limits given in Rule ~~.1611~~ .1611(a) of this Chapter. ~~For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating. A registrant or licensee may apply to the agency for an exemption from this requirement pursuant to Rule .0106(a) of this Chapter.~~

(b) ~~Surveys~~ Survey Requirements

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

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

(B) prior to use following any change in the initial ~~arrangement,~~ 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 ~~which~~ that could affect the radiation exposure to ~~personnel;~~ personnel.

~~(D) radiation monitoring shall be performed during maintenance.~~

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

(3) Surveys must 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 ~~analytical x-ray equipment~~ RGDs shall be conspicuously posted with ~~a sign or signs~~ 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",~~ EQUIPMENT," or words having a similar ~~intent.~~ meaning.

History Note: *Authority G.S. ~~104E-7;~~ 104E-7(a)(2);*
Eff. February 1, 1980;
Amended Eff. October 1, 2015; January 1, 1994.

15A NCAC 11 .0805 is proposed for amendment as follows:

15A NCAC 11 .0805 OPERATING REQUIREMENTS

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

~~(a)~~ (b) Normal operating procedures shall be written and available to all ~~analytical x-ray equipment workers.~~ RGD operators and support staff. ~~No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless the person has obtained written approval of the person responsible for radiation safety.~~

(c) No person 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 person responsible for radiation safety, or Radiation Safety Officer (RSO) as defined in Rule .0104 of this Chapter.

~~(b)~~ (d) No person shall bypass a safety device unless the person has obtained the approval of the person responsible for radiation ~~safety.~~ safety or RSO. ~~Such approval shall be for a specified period of time.~~ This process shall be incorporated into the radiation protection program, as set forth in Rule .1613(a), and the operating procedures as set forth in Rule .0603(a)(1)(B). The written approval shall include an expiration date. When a safety device has been bypassed, a ~~readily discernible~~ legible sign bearing the words "SAFETY DEVICE NOT ~~WORKING",~~ WORKING," or words having a similar ~~intent,~~ meaning shall be placed on the radiation source housing and the control panel during the ~~period such bypassing is in effect.~~ 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 for proper operation on all RGDs in operation once annually. Records of the testing shall be retained for three years.

(g) Individuals shall not hold a sample or object being irradiated.

History Note: *Authority G.S. 104E-7; 104E-12;*
Eff. February 1, ~~1980.~~ 1980;
Amended Eff. October 1, 2015.

15A NCAC 11 .0806 is proposed for amendment as follows:

15A NCAC 11 .0806 PERSONNEL REQUIREMENTS

(a) Instructions of personnel operating or maintaining RGDs shall comply with the following:

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

~~(A) identification of possible radiation hazards and biological effects associated with the use of the equipment;~~

~~(B) significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in these cases;~~

~~(C) proper operating procedures for the equipment;~~

~~(D) appropriate use and limitations of dosimetric devices;~~

~~(E) proper procedures for reporting an actual or suspected exposure.~~

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

~~(b) Personnel monitoring or wrist dosimetric devices shall be provided to, and shall be used by:~~

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

(1) ~~analytical x-ray equipment workers using systems having an open-beam configuration and~~ individuals using open-beam RGDs not equipped with a safety device; and

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

History Note: *Authority G.S. 104E-7; 104E-11; 104E-12;*
Eff. February 1, ~~1980.~~ 1980;
Amended Eff. October 1, 2015.

15A NCAC 11 .0807 is proposed for adoption as follows:

15A NCAC 11 .0807 PERMANENT RADIOGRAPHIC INSTALLATIONS AND INDUSTRIAL RADIOGRAPHY RGDS

(a) Permanent radiographic installations and industrial radiography RGDs are exempt from the requirements of the Rules of this Section except Rules .0802 and .0804 Paragraphs (a), (b)(1)(A), and (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.

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

15A NCAC 11 .0808 is proposed for adoption as follows:

15A NCAC 11 .0808 APPLICABLE RULES FOR BOMB DETECTION RGDS

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.

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

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS
Drexdal Pratt
Division Director

MEMORANDUM

DATE: January 26, 2015

TO: Anca Grozav, Economic Analyst
Office of State Budget and Management

FROM: Nadine Pfeiffer, Rule-making Coordinator NP

RE: Recodification of 15A NCAC 11 Radiation Protection Rules

Pursuant to SL2011-145, s. 13.3(e), (House Bill 200), which became effective on June 15, 2011, we have requested to the Codifier of Rules at the Office of Administrative Hearings to recodify the Radiation Protection rules, currently in the Code under Title 15A, Environment and Natural Resources to Title 10A, Health and Human Services. This request has been granted and will become effective on February 1, 2015.

The approved fiscal note for the proposed analytical and industrial x-ray machine rules will have no change in fiscal impact due to this recodification. However, the proposed rules title and chapter in the fiscal note will now be 10A NCAC 15 instead of 15A NCAC 11. Unless changed due to proposed changes with rulemaking, the actual rule names have remained the same. Please see the table below for the list of proposed rules discussed in the fiscal note by the current title, rule number and name as well as the recodified title, rule number and name.

Current Rule Title/Chapter/Rule Number/Name	Recodified Rule Title/Chapter/Rule Number/Name
15A NCAC 11 .0502 Definitions	10A NCAC 15 .0502 Definitions
15A NCAC 11 .0518 Radiation Machines	10A NCAC 15 .0518 Radiation Machines
15A NCAC 11 .0801 Requirements for Analytical X-Ray Equipment	10A NCAC 15 .0801 Requirements for ~~Analytical X-Ray Equipment~~ Non-Human Use of Radiation Generating Devices
15A NCAC 11 .0802 Definitions	10A NCAC 15 .0802 Definitions
15A NCAC 11 .0803 Equipment Requirements	10A NCAC 15 .0803 Equipment Requirements
15A NCAC 11 .0804 Area Requirements	10A NCAC 15 .0804 Area Requirements
15A NCAC 11 .0805 Operating Requirements	10A NCAC 15 .0805 Operating Requirements
15A NCAC 11 .0806 Personnel Requirements	10A NCAC 15 .0806 Personnel Requirements
15A NCAC 11 .0807 Permanent Radiographic Installations and Industrial Radiography RGDS	10A NCAC 15 .0807 Permanent Radiographic Installations and Industrial Radiography RGDS
15A NCAC 11 .0808 Applicable Rules for Bomb Detection RGDs	10A NCAC 15 .0808 Applicable Rules for Bomb Detection RGDs

http://www.ncdhhs.gov/dhsr/
Phone: 919-855-3750 / Fax: 919-733-2757
Location: 809 Ruggles Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
Mailing Address: 2701 Mail Service Center • Raleigh, North Carolina 27699-2701
An Equal Opportunity / Affirmative Action Employer