Fiscal Impact Analysis of
Permanent Rule Amendment

Agency: Department of Health and Human Services
Division of Health Service Regulation
Radiation Protection Section

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Impact Summary

Federal Government:	No Impact
State Government:	Yes
Local Government:	Yes
Regulated Community:	Yes
Substantial Impact:	No

Rule Citation(s)

Rule Amendment:	10A NCAC 15 .0801	PURPOSE AND SCOPE
	10A NCAC 15 .0802	DEFINITIONS
	10A NCAC 15 .0803	PERSONNEL REQUIREMENTS
	10A NCAC 15 .0804	OPERATING REQUIREMENTS
	10A NCAC 15 .0805	AREA REQUIREMENTS
	10A NCAC 15 .0806	EQUIPMENT REQUIREMENTS
	10A NCAC 15 .0807	SECURITY SCREENING REQUIREMENTS FOR GOVERNMENT USE ONLY
	10A NCAC 15 .0808	OTHER EQUIPMENT REQUIREMENTS

*See text in Appendix

Rulemaking Authority G.S. 104E-7; 104E-7(a)(2); 104E-10(b); 104E-11
21 CFR 1010; 21 CFR 1020

Purpose

The rules in 10A NCAC 15 regulate the use of radioactive materials and radiation machines in the State of North Carolina pursuant to G.S. 104E. Rules in Section .0800 of Chapter 15 regulate all registrants who use radiation generating devices (RGDs) in the state.

Pursuant to G.S. 150B-21.3A, Periodic Review and Expiration of Existing Rules, all rules are reviewed at least every 10 years, or they shall expire. As a result of the periodic review of the rules in Chapter 10A NCAC 15, Radiation Protection, 10A NCAC 15 Section .0800 had eight rules, .0801 - .0808, that were determined to be "Necessary Without Substantive Public Interest" and will be amended with this rulemaking action.

As mandated by G.S. 150B-19 (4) the agency may not adopt a rule that repeats the content of a law, a rule, or a federal regulation. To comply with this mandate, the federal regulations in 21 CFR 1010.2 and 21 CFR 1020.40 are proposed for incorporation by reference, including subsequent amendments and editions. The federal regulations are being incorporated by reference into Rules 10A NCAC 15 .0802(6), .0802(7), and .0806(a).

Introduction

The North Carolina Department of Health and Human Services (DHHS), Division of Health Service Regulation (DHSR), Radiation Protection Section (RPS) regulates the use of Radiation Generating Devices (RGD's) by any Individual or entity in possession of RGD in North Carolina (NC). As part of the readoption process, these proposed amendments clarify existing rule requirements, reflect current practice, and updates terminology. The Radiation Protection Section intends the proposed amendments to simplify compliance and reduce the amount of time stakeholders, registrants, and agency staff spend interpreting rules, while maintaining current safety requirements for radiation workers and NC citizens.

A Radiation-Generating Device (RGD) is a piece of equipment designed to produce radiation for various purposes, including but not limited to:

1. Analyzing Elements and Microstructures: RGDs are often used in scientific and industrial settings to analyze the composition of materials at the atomic and molecular levels. Techniques such as X-ray diffraction (XRD) and X-ray fluorescence (XRF) fall under this category.
2. Quality Assurance and Quality Control: RGDs are employed in industries to ensure the quality of materials and products through nondestructive testing and evaluation.
3. Research and Development: RGDs play a crucial role in scientific research and development activities, aiding in the study of materials, compounds, and structures.
4. Gauging and Measurement: RGDs are utilized for precise measurements, especially in industries where accuracy in gauging is critical.
5. Nondestructive Testing and Evaluation: RGDs inspect and evaluate materials without causing damage.

Examples of RGDs include X-ray diffraction machines, X-ray fluorescence analyzers, enclosed cabinet scanners, open beam devices, hand-held devices, security screening devices, and security screening systems (for government use only). The three main types of registrants who commonly use RGDs are state government agencies, local government entities, and private sector industries involved in various manufacturing and testing processes.

Historically, rules for RGDs were based primarily on the most current draft of the Suggested State Regulations -Part H. The Suggested State Regulations are documents that the Conference of Radiation Control Programs Directors (CRCPD) maintain and that are intended to provide the framework for uniformity of radiation control laws and regulations among states. The current version of Suggested State Regulations -Part H, SSRCR Volume I - July 2016 has expanded its scope to include the evolution of RGDs used for security purposes only. The Radiation Protection Section has based the proposed amendments on the same federal regulations, technical articles, reports, and standards that were reviewed and considered in the development of the current version of Suggested State Regulations. See H-Rationale-2016 *(pg. 20)*[1], for a listing of annotations of materials referenced.

The proposed amendments reorganize the rules, resulting in a shift of rule titles and numbers for easier reading. Subject area content was also reorganized for improved comprehension. Changes include clarification to existing requirements to remove ambiguity, technical corrections, and updated terminology. Additions to current rule language are to clarify existing requirements, are based on common industry standards that align with Suggested State Regulations and are considered requirements under the current Rules. The amendments will make it easier for stakeholders, registrants, and agency staff to interpret and apply the requirements of this Rule. Additionally, the amendments align the rules with current practices, Suggested State Regulations, the American National Standards Institute (ANSI) standards, International Electrotechnical Commission (IEC) standards, and Federal requirements. The Radiation Protection Section also incorporates the suggestions of Radiation Protections Xray Surveillance Advisory Committee and Working Group members.

Scope of Analysis

The impacts estimated in this analysis are based on data obtained from the registration database maintained for the Radiation Protection Section – Radiology Compliance Branch. This analysis includes the three types of entities registered with the Radiation Protection Section– Radiology Compliance Branch.

1. State Government: This includes entities like state prisons, law enforcement agencies, and educational institutions. State governments may use RGDs for security screening, research, or other applications.
2. Local Government: at the local level, including county jails, local law enforcement, and educational institutions, also use RGDs. Their applications may overlap with those of state governments.
3. Private Sector: Various industries, such as food and beverage manufacturing and processing centers, fall under the private sector category. They employ RGDs for specific applications related to their industries, such as quality control in manufacturing processes.

Data in Table 1 details the number of registered facilities ("registrants") and the number of registered RGDs. Compared to the data from 2015, there has been a significant increase in the number of registered entities in local government and the private sector, while the number of state government entities has experienced a decrease. A similar trend is observed in the number of registered RGD X-ray tubes. It is crucial to note that this shift does not necessarily reflect an actual change in the numbers for state and local registered registrants and RGDs. A change of database structure occurred after the 2015 analysis, introducing more detailed Excel sheet logs containing registrant and RGD data. The decline in the number of state government registrants and RGDs is attributed to details contained in the new database's Excel sheet logs, resulting in the reclassification of some entities as local government registrants. However, the increase in numbers within the private sector accurately signifies the growth of registrants and RGDs in NC.

[1] Conference of Radiation Control Program Directors: (CRCPD), retrieved from https://www.crcpd.org/page/SSRCRs_flipbook

Table 1. Number of Registered Registrants and RGDs X-Ray Tubes (2015 Compared to 2023)

# of Registrants								# of RGD's X-Ray Tubes							
State		Local		Private		**Total**		State		Local		Private		**Total**	
2015	2023	2015	2023	2015	2023	2015	2023	2015	2023	2015	2023	2015	2023	2015	2023
51	38	31	96	417	473	**499**	**607**	169	161	44	98	944	1025	**1157**	**1284**

Data in Table 2 details the number of registered facilities ("registrants") and the number of registered RGDs subject to new rule requirements listed in the Rule # column.

Table 2. Number of Affected Registrants and Devices by proposed New Rule Requirements

Rule #	**# of Registrants**				**# of Registered RGD's**			
	State	Local	Private	**Total**	State	Local	Private	**Total**
.0805(e)	3	36	10	**49**	3	40	15	**58**
.0806(h)	0	0	51	**51**	0	0	98	**98**
.0806(i)	1	0	10	**11**	1	0	15	**16**
.0807(a)	2	19	4	**25**	28	15	7	**50**
.0807(b)	2	39	0	**41**	2	40	0	**42**

Rule Changes and Anticipated Impacts

A brief description of each rule is provided below.

SECTION .0800 – RADIATION GENERATING DEVICES

The proposed amendment is to rename Section .0800 rules to "Radiation Generating Devices". This replaces the previous title of "Requirements for Non-Human Use of Radiation Generating Devices". This Section now aligns with allowing human screening for public safety and security purposes only.

This proposed change will not have an economic impact.

10A NCAC 15 .0801 - PURPOSE AND SCOPE

The proposed amendment will remove ambiguity and clarify rule language to make it easier for registrants, the public, and stakeholders to comply with the rules.

- Paragraph (a) clarifies the provision of other Sections by listing out Sections .0100, .0200, .1011, and .1600.
- Paragraph (b) language was added to clarify industrial radiographic operations of electronic radiation machines are no longer in Rule .0807 of this Section.
- Paragraph (c) was added to clarify the purpose and provide examples of the types of RGDs regulated in this Section. Some of the examples were relocated from the existing Rule .0802(25) of this Section.

The proposed changes will provide additional clarity to the regulated community which may result in incremental improvements to compliance.

10A NCAC 15 .0802 – DEFINITIONS
The proposed amendments are detailed below.

- The following existing definitions have been updated to clarify rule language, update outdated terminology, and reflect current practices. “Analytical RGD equipment”, “Mobile RGD”, “Portable RGD”, and “Radiation generating device (RGD)”.
- The following definitions are used in existing rules but were not previously defined. These terms have been added to clarify existing rule language. “Accessible surface”, “Emergency procedure”, “Interlock”, “Safety device”, and “Warning device”.
- The following existing definition has been renamed from an existing definition to clarify amended rule language in Rule .0806 of this Section. “X-ray gauge” renamed to “Gauging device”.
- The following existing definition has been renamed to clarify amended rule language in Rule .0807. “Bomb detection RGDs” renamed to “Security screening device”.
- The following definitions have been added for the purpose of clarifying amended rule language in Rule .0807 of this Section: “General-use system”, “Inspection zone”, “Limited-use system”, “Screening”, “and “Security screening system”.
- The following definitions have been removed from this Rule because all requirements for industrial radiographic operations of electronic radiation machines have been relocated to Section .0500 of this Chapter: “Industrial radiography” and “Permanent radiographic installation”.
- The following definition has been removed because it is unnecessary: “Hybrid gauge”.

The proposed changes will provide additional clarity to the regulated community which may result in incremental improvements to compliance.

10A NCAC 15 .0803 - PERSONNEL REQUIREMENTS
The proposed amendment renames the rule title from “Equipment Requirements” to “Personnel Requirements” and relocates the “Personnel Requirements” from the existing Rule .0806 of this Section.

- Paragraph (a) clarifies current language relocated from existing Rule .0806(a)(2) for “records of training that demonstrate the requirements” to “document the scope of training and instruction required”. This change clarifies that the registrant shall document instruction and training provided to individuals that operate RGDs. Documentation of training is considered a requirement under the existing rule to confirm operators have received instruction and training; therefore, the agency does not expect the change to result in an economic impact. Additionally, documentation is the most effective way to establish fulfillment of training requirements that have been met. The agency expects incrementally increased compliance from registrants and stakeholders by knowing that documentation along with demonstration of training and instruction is a requirement.
- Paragraph (b) reorganizes requirements and removes ambiguity of current rule language relocated from existing Rule .0806(a)(1) of this Section. The Radiation Protection Commission’s X-ray Advisory Committee and Working Group Members requested the reference to .1003 be removed. The reference to Rule .1003 of this Chapter was removed and the subject areas contained therein are relocated into Subparagraphs (b)(1), (b)(2), and (b)(3) of this proposed rule amendment. Effective 10/1/2023, Rule .1003 of this Chapter was repealed and readopted in current Rule .1001(a)(6). The proposed addition to rule language in the Subparagraphs remove ambiguity by clarifying subject area requirements contained in the current Rule .1001(a)(6) of this Chapter. The subject areas are basic principles of radiation protection, use of the RGD, and operating and emergency procedures.

- Subparagraph (b)(1) clarifies current rule language, from existing Rule .0806(a)(1), referencing Rule .1003 of this Chapter, regarding basic principles of radiation protection. The proposed additions remove ambiguity by clarifying current subject area requirements contained in the current Rule .1001(a)(6) of this Chapter. The additional language is based on industry standards and aligns with language, for radiation hazards and safety training, found in 10 CFR 835.901[2], the American National Standards Institute (ANSI) standard ANSI/HPS N13.36-2001[3], and the Suggested State Regulations-Part H[4]. The agency expects the change to improve safety for workers and the public by ensuring basic training and instruction are provided to operators of RGDs. Based on documentation reviewed during inspections, agency staff has observed registrants provide unnecessary training that exceeds the scope of training necessary for the RGD in use and is likely due to ambiguity in the existing Rule. The agency expects the proposed changes are likely to result in a small, but unquantifiable time and cost savings to registrants in the form of reduced time spent providing unnecessary training.
- Subparagraph (b)(2) clarifies current rule language relocated from existing Rule .0806(a)(1), referencing Rule .1003 of this Chapter, regarding persons receiving instruction for RGDs in use. The proposed additions remove ambiguity by clarifying current subject area requirements contained in the current Rule .1001(a)(6) of this Chapter. The additional language is based on industry standards and aligns with language found in the Suggested State Regulations-Part H for training for each RDG in use. The improved clarity could result in incremental improvement to compliance. Improved compliance with training requirements could result in improved safety for workers and the public.
- Subparagraph (b)(3) This proposed Subparagraph refers to the proposed amendment in Rule .0804 for operating and emergency procedures requirements. This is a new statement regarding where operating and emergency procedure requirements are in this Section and is for clarification purposes only.
- Paragraph (c) is relocated from existing Rule .0806(a)(2) regarding maintaining records of instruction and training for each operator for agency review. This amendment provides clarity to existing language. Maintaining records is an existing requirement; therefore, the agency does not expect this to result in an economic impact.
- Paragraph (d) is relocated from existing Rule .0806(a)(2) regarding operators demonstrating instruction and training requirements have been met. The proposed additional language removes ambiguity by clarifying existing language. Operators demonstrating an understanding of safe operating procedures and safe use of the RGD is an existing requirement; therefore, the agency does not expect this to result in an economic impact.
- Paragraph (e) is relocated from existing Rule .0806(b) and updates terminology of "personnel monitoring equipment" to "individual monitoring devices" to align terminology in current Rule .1601(a)(24) of this Section.
- Subparagraph (e)(1) is relocated from existing Rule .0806(b)(1) and the verbiage "without safety devices is unnecessary" and has been removed.
- Subparagraph (e)(2) is relocated from existing Rule .0806(b)(2).

As a whole, the proposed changes to Rule .0803 may result in a reduction in the time registrants and

[2] Code of Federal Regulations: (CFR) (10 CFR 835.907)
https://www.ecfr.gov/current/title-10/chapter-III/part-835/subpart-J/section-835.901

[3] American National Standards Institute ANSI, retrieved from
https://global.ihs.com/search_res.cfm?&rid=HPS&input_doc_number=%28ANSI%29%20STANDARD%20ANSI%2FHPS%20N13%2E36&input_doc_title=

[4] Conference of Radiation Control Program Directors: (CRCPD), retrieved from https://www.crcpd.org/page/SSRCRs_flipbook

stakeholders spend to achieve compliance from having all personnel requirements located in one Rule. The agency expects the changes to simplify and increase overall compliance with this Rule regarding personnel requirements. The changes may result in unquantifiable time savings for agency staff who review documentation of instruction and training during inspections and who provide guidance to inquiries from registrants regarding compliance issues.

10A NCAC 15 .0804 – OPERATING REQUIREMENTS

The proposed amendment renames the rule title from "Area Requirements" and relocates the "Operating Requirements" of the existing Rule .0806 of this Section into this Rule.

- Paragraph (a) is relocated from existing Rule .0805(a) and refers to where personnel requirements are in the proposed amendment in Rule .0803 of this Section.
- Paragraph (b) is relocated from existing Rule .0805(b). Paragraph (c) relocates and combines the reference to normal operating procedures from existing Rule .0805(b) of this Sections and the reference referring to operating and emergency procedures from existing Rule .0806(a)(1) of this Section. The proposed amendment adds "manufacturer or supplier of the RGD" language to the rule. Standard practice is for manufacturers or suppliers of RGDs to provide manuals, which contain operating and emergency procedures, to end users at the time of purchase of an RGD. Operating and emergency procedures are a current requirement and standard; it is likely most registrants currently meet the requirement, but it is unknown to what extent.
- Paragraph (d) is relocated from existing Rule .0806(a)(1), referencing Rule .1003 of this Chapter, regarding operating and emergency procedures. Subparagraphs (d)(1), (d)(2), and (d)(3) proposed additions remove ambiguity by clarifying current subject area requirements contained in the current Rule .1001(a)(6) of this Chapter. The additional language is based on industry standards and aligns with language for operating requirements found in the Suggested State Regulations-Part H.
- Paragraph (e) is a proposed paragraph that adds requirements specific to open beam and portable handheld RGDs. Additional rule language in Subparagraphs (e)(1) and (e)(2) in this proposed Rule amendment is based upon existing industry standards and aligns with language found in the Suggested State Regulations -Part H. This will not result in an additional cost because the addition simply employs procedures for use in a safe manner and is based upon sound radiation protection principles to minimize dose to occupational workers and members of the public. The agency expects an increase in compliance for registrants and stakeholders who must comply with the rule because the rule will be easier to follow due to clarifying requirements specific to open beam and portable handheld RGDS.
- Paragraph (f) is relocated from existing Rule .0806(a)(1) and (a)(2) regarding maintaining records of operating and emergency procedures for each operator for agency review. This amendment provides clarity to existing language. Maintaining records is an existing requirement; therefore, the agency does not expect this to result in an economic impact.
- Paragraph (g) is a proposed paragraph that adds equipment alignment procedures requirements. Additional rule language is based upon existing industry standards and aligns with language found in the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021[5].

[5] American National Standards Institute ANSI, retrieved from https://global.ihs.com/search_res.cfm?&rid=HPS&input_doc_number=%28ANSI%29%20STANDARD%20ANSI%2FHPS%20N43%2E2&input_doc_title=

- Paragraph (h) is a proposed paragraph that adds special equipment alignment procedures requirements. Additional rule language is based upon existing industry standards and aligns with language found in the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021.
- Paragraph (i) is relocated from existing Rule .0805(f) regarding Safety devices. The proposed amendment separates the requirements into Subparagraphs for easier reading and to improve comprehension. Additional rule language in this proposed change is considered required under current Rule, is based upon existing industry standards, and aligns with language found in the Suggested State Regulations-Part H.
- Part (i)(1)(A) is relocated from existing Rule .0805(f). The proposed changes correct verbiage and adds rule language to clarify what actions registrants are required to take in the event a safety device fails annual testing.
- Part (i)(1)(B) is a proposed paragraph that adds requirements for the information to be included in testing records.
- Part (i)(1)(C) is relocated from existing Rule .0805(f) regarding retention of testing records. The proposed amendment changes the retention time from "3 years" to "for agency review during inspection".
- Part (i)(2)(A) is relocated from existing Rule .0805(d) regarding procedures for bypassing safety devices. The proposed changes updates terminology and corrects rule references in the existing rule.
- Part (i)(2)(B) is relocated from existing Rule .0805(d) regarding written approval for bypassing safety devices.
- Part (i)(2)(C) is relocated from existing Rule .0805(f) regarding signage to post on the RGD when bypassing a safety device.
- Paragraph (h) is relocated from existing Rule .0805(e) regarding requirements when an individual modifies components of an RGD.

As a whole, the proposed changes to Rule .0804 may result in a reduction in the time registrants and stakeholders spend to achieve compliance from having all operating requirements located in one Rule. The agency expects the changes to simplify and increase overall compliance with this Rule. The changes may result in unquantifiable time savings for agency staff who review documentation of instruction and training during inspections and who provide guidance to inquiries from registrants regarding compliance issues.

10A NCAC 15 .0805 - AREA REQUIREMENTS

The proposed amendment renames the rule title from "Operating Requirements" and relocates the "Area Requirements" of the existing Rule .0804 of this Section into this Rule.

- Paragraph (a) is relocated from existing Rule .0804(c) and clarifies what is considered a radiation area.
- Subparagraph (a)(1) is relocated from existing Rule .0804(c) and refers to posting of the area. This amendment clarifies the wording for radiation area posting requirements. The proposed amendment aligns with current Rule .1601(a)(35) and the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021. This will not result in an economic impact.
- Subparagraph (a)(2) is a proposed Subparagraph that adds clarification to the types of supervision acceptable for a radiation area. Additional rule language in Subparagraphs (a)(2) in this proposed Rule amendment is based upon existing industry standards, aligns with language found in the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021, and is considered required under current Rules.

- Paragraph (b) is relocated from existing Rule .0804(a) regarding dose limits for individual members of the public.
- Subparagraph (b)(1) is a proposed Subparagraph that clarifies visibly separating the area meeting when the area meets this requirement. The proposed change updates terminology, corrects the rule, aligns with industry standard, language found in the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021, and is considered required under current Rules.
- Subparagraph (b)(2) is a proposed Subparagraph that clarifies posting requirements for an area meeting this requirement. The proposed change updates terminology, corrects the rule, aligns with industry standard, language found in the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021, and is considered required under current Rules.
- Paragraph (c) is relocated from existing Rule .0804(a) regarding local components and dose limits for individual present in the area.
- Paragraph (d) is relocated from existing Rule .0804(b)(1) regarding radiation surveys.
- Subparagraph (d)(1)(A) is relocated from existing Rule .0804(b)(3)(A) regarding radiation survey instrument measurement capabilities.
- Subparagraph (d)(1)(B) is relocated from existing Rule .0804(b)(3)(C) regarding radiation survey instrument calibration frequency.
- Part (d)(2)(A) is relocated from existing Rule .0804(b)(1)(A). Terminology is corrected from "radiation survey" to "equipment survey". A radiation survey in accordance with Rule .0603(b)(1)(A) of the Chapter determines radiation levels in adjacent areas. An equipment survey determines radiation levels in any area surrounding local components of an RGD. Terminology is updated from "within 30 days of initial use" to "prior to initial use". These changes align with industry standards, language found in the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021, and the Suggested State Regulations-Part H.
- Part (d)(2)(B) is relocated from existing Rule .0804(b)(1)(B).
- Part (d)(2)(C) is relocated from existing Rule .0804(b)(1)(C).
- Part (d)(2)(D) is a proposed Subparagraph. The proposed Subparagraph clarifies that a survey is required if there is a primary beam when any local component of the RGD is disassembled or removed. This change aligns with industry standards, language found in the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021, and in the Suggested State Regulations-Part H. The change is not expected to result in an economic impact.
- Subparagraph (d)(3) is relocated from existing Rule .0804(b)(2) regarding procedures differing from this Rule.
- Paragraph (e) is a proposed paragraph that adds language for area requirements for radiographic and fluoroscopic non-healing arts equipment and security screening systems. Additional rule language in Subparagraphs (e)(1) and (e)(2) in this proposed Rule amendment is based upon existing industry standards and aligns with language found in the American National Standards Institute (ANSI) Standard N43.17-2009[6] and the American National Standards Institute (ANSI) Standard N43.5-2013[7]. Table 2 indicates the number of registrants affected by the proposed rule amendment.
- Subparagraph (e)(1) is a proposed paragraph that adds requirements to submit a floor plan

[6] American National Standards Institute ANSI, retrieved from https://global.ihs.com/search_res.cfm?&rid=HPS&input_doc_number=%28ANSI%29%20STANDARD%20ANSI%2FHPS%20N43%2E17&input_doc_title=

[7] American National Standards Institute ANSI, retrieved from https://global.ihs.com/search_res.cfm?&rid=HPS&input_doc_number=%28ANSI%29%20STANDARD%20ANSI%2FHPS%20N43%2E5&input_doc_title=

meeting the requirements of this Rule to the agency. The agency expects the proposed amendment to result in a time cost to agency staff that will review the floor plan equipment arrangement. A minimal economic impact in the form of time spent preparing and submitting the floor plan is expected for very few registrants in the regulated community, local and state government.

An Excel sheet is maintained to track the number of waiver requests for state, local, and private registrants and the number of RGD's meeting this requirement. Over the last 5 years, there have been approximately 30 new registrants that have installed 34 RGDs, averaging around 7 RGDs per year. Assuming this trend continues in the future, there would be about seven RGDs per year which would be required to submit a floor plan to the agency. This is based on the 26 local government registrants installing 27 RGDs and 4 registrants from the private sector installing 7 RGDs. Future estimates are based on past waiver requests and assuming the number is expected to increase as more people utilize new technology.

The agency anticipates it would take approximately 2 hours to review and process a floor plan from start to finish. If the numbers over the next 5 years were to increase, averaging 10 new RGD installs per year, the estimated annual time cost is estimated to be close to $640per year ($32/hr x 10 floor plans x 2 hours)[8]. A member of the Working Group regulated by the Rule reported room drawing cost $500 to $1,000. If the numbers over the next 5 years were to increase, averaging 10 per year, the total annual cost of obtaining floor plans, from an individual registered with the agency to perform class IX services as a general health physics consultant, would be between $5,000 - $10,000 per year. The agency expects improved safety for operators of RGDs and the public. This is based on the agency reviewing floor plans for RGD equipment arrangement prior to installation that may result in a decrease in exposure to operators and the public.

- Subparagraph (e)(2) is a proposed paragraph that adds rule language regarding compliance with dose limits of Section .1600 of this Chapter. This amendment adds rule language to clarify the information that shall be included in the survey record. Surveys are considered required under current Rules for radiographic and fluoroscopic non-healing arts equipment, aligning with survey requirements in Rule .0603(c) of this Chapter and required as a condition set forth in the waiver that allows use of security screening systems for public safety and security purposes. This change is expected to result in a cost reduction for local and state government registrants that acquire security screening systems because registrants will not have to purchase the American National Standards Institute (ANSI) Standard N43.17-2009 to comply. Currently, registrants are required to purchase the Standard at the current price ($50 - $80).

- An Excel sheet is maintained to track the number of waiver requests for state, local, and private registrants, and the number of RGD's meeting this requirement. In the last 5 years, 39 local government agencies have requested a waiver for use of a security screening system and 26 local government agencies have registered the RGDs. Future estimates are based on past waiver requests and assuming the number is expected to increase more people utilizing new technology. If the numbers over the next 5 years were to increase, 10 per year, the total annual cost savings from not having to obtain the ANSI standard is estimated to be between $500 to $800 per year.

[8] Hourly rate was calculated using NC OSHR: Total Compensation Calculator for an Environmental Health Specialist with 10 years of service earning an annual salary of $42,000 ($67,335 total compensation).

- Subparagraph (e)(3) is a proposed Subparagraph removing ambiguity by adding language for when a new survey is required.
- Subparagraph (e)(4) is a proposed Subparagraph clarifying records must be maintained for agency review.

As a whole, the proposed changes to Rule .0805 will clarify and update the rules to align with current practices and industry standards. This could result in incremental improvements to compliance and safety. There are likely to be costs to a small number of registrants for obtaining a floor plan for radiographic and fluoroscopic non-healing arts equipment and security screening systems. Agency staff will also likely realize a small time cost for reviewing floor plans. There may also be modest cost savings to a small number of state and local government registrants from not having to purchase the ANSI Standard.

10A NCAC 15 .0806 - EQUIPMENT REQUIREMENTS

The proposed amendment renames the rule title from "Personnel Requirements" and relocates "Equipment Requirements" of the existing Rule .0804 of this Section into this Rule.

- Paragraph (a) is relocated from existing Rule .0803(a) and .0803(b) regarding certified and certifiable cabinet x-ray systems. This paragraph has proposed Subparagraphs (a)(1) through (a)(4) detailing the applicable areas of the CFR and are for clarification purposes only.
- Paragraph (b) is proposed new language that provides the web address where copies of 21 CFR 1020.40 may be obtained at no charge.
- Paragraph (c) is relocated from existing Rule .0803 regarding equipment requirements for all RGDs. The proposed changes reorganize equipment requirements for all RGDS and include corrections to clarify existing language, so the rules are easier to understand. The changes align with manufacturing and industry standards and with language found in American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and in the Suggested State Regulations-Part H. This rule change does not require any additional actions by registrants or agency staff. The agency expects an increase in compliance from having requirements for all RGD located in one paragraph.
- Subparagraph (c)(1) is relocated from existing Rule .0803(e) regarding warning devices. This requirement removes "on open beam analytical RGDs" to clarify warning devices shall be labeled and the purpose of the device identified is applicable to all RGDs.
- Subparagraph (c)(2) is relocated from existing Rule .0803(k) regarding warning lights. The proposed changes add "of a fail-safe design" to clarify existing language. The change aligns with language found the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and in the Suggested State Regulations-Part H.
- Part (c)(2)(A) is relocated from existing Rule .0803(k)(1) regarding location of warning lights. The proposed change from existing language "near switch" to "within sight" and removed removes "or" when transitioning to the next Part. These changes align with the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and are more applicable to how the device is installed. The agency expects the change to result in cost savings to registrants by not having to place unnecessary labels in addition to labels of RGDs commercially manufactured RGD to meet this standard. The agency expects the change may result in small improvements to compliance during inspections.
- Part (c)(2)(B) relocated from existing Rule .0803(k)(2) regarding warning lights shall be in a conspicuous location.
- Part (c)(2)(C) relocated from existing Rule .0803(k)(2) regarding warning lights visible from all instrument access areas.

- Subparagraph (c)(3) is relocated from existing Rule .0803(l) regarding activation of warning lights.
- Subparagraph (c)(4) is relocated from existing Rule .0803(d)(2) This requirement removes "on open beam analytical RGDs" to clarify each shutter shall be equipped with a "shutter open" warning light or device of fail-safe device is applicable to all RGDs.
- Subparagraph (c)(5) is relocated from existing Rule .0803(j)(2) regarding location of label. The proposed change corrects the existing language "near any exit port" to "near any switch". The change aligns the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and is more applicable to how the device is installed. The agency expects the change to result in cost savings to registrants by not having to place unnecessary labels in addition to labels placed for the RGD during installation that is according to industry standards. The agency expects the change to result in increased compliance during inspections.
- Subparagraph (c)(6) is relocated from existing Rule .0803(m)(2) regarding x-ray tube source housing. The proposed changes add "of a fail-safe design" to clarify existing language. The change aligns with language found the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and in the Suggested State Regulations-Part H.
- Subparagraph (c)(7) is relocated from existing Rule .0803(n)(2) regarding high voltage generator housing. The proposed updates existing language to align with language found the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and in the Suggested State Regulations-Part H.
- Paragraph (d) is relocated from existing Rule .0803 regarding equipment requirements for open-beam RGDs. The proposed changes reorganize additional equipment requirements for open-beam RGDS and include corrections to clarify existing language, so the rule is easier to understand. The changes align with manufacturing and industry standards and with language found in the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and in the Suggested State Regulations-Part H. This rule change does not require any additional actions by registrants or agency staff. The agency expects an increase in compliance from having all open-beam RGD additional requirements located in one paragraph.
- Subparagraph (d)(1) is relocated from existing Rule .0803(g) regarding open-beam RGD ports.
- Subparagraph (d)(2) is relocated from existing Rule .0803(f) regarding open-beam RGD shutters at unused ports. The proposed change includes terminology to clarify existing requirements.
- Subparagraph (d)(3) is relocated from existing Rule .0803(m)(1) regarding open-beam RGD x-ray tube source housing leakage radiation.
- Subparagraph (d)(4) is relocated from existing Rule .0803(c) regarding open-beam RGD safety devices. The proposed change adds "or interlock" to clarify existing language. The change aligns with language found the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and in the Suggested State Regulations-Part H.
- Subparagraph (d)(5) is relocated from existing Rule .0803(i) regarding an exemption from the requirement of a safety device.
- Paragraph (e) is a proposed new requirement to reflect the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 and the Suggested State Regulations-Part H for enclosed beam RGDs. Subparagraphs .0806(e)(1) to (e)(2) adds additional equipment requirements specific to enclosed RGDs. Most enclosed RGDs in use are commercially manufactured to meet these standards.
- Paragraph (f) is a proposed new requirement to reflect the American National Standards Institute (ANSI) standard ANSI/HPS N43.2-2021 for Bimodal beam RGDs. Subparagraphs

.0806(f)(1) to (f)(3) adds additional equipment requirements specific to RGDs that can override interlocks between enclosed and open-beam operation. Most Bimodal RGDs in use are commercially manufactured to meet these standards.

- Paragraph (g) is relocated from existing Rule .0803(h). The proposed new requirement adds rule language for equipment requirements specific to portable x-ray fluorescence RGDs in Subparagraphs (g)(1) through (g)(3). The proposed additions to rule language clarifies existing rule language, is based upon existing industry standards, and aligns with language found in the International Standard IEC 62495[9] for portable x-ray fluorescence analyzers and is considered required under current Rules. The reference to "devices shall be constructed according to International Standard IEC 62495" has been removed since most portable x-ray fluorescence RGDs in use are commercially manufactured to meet these standards. The existing rule language incorporated, by reference, the International Standard IEC 62495 and can be downloaded for $115. The agency expects the new requirement to result in cost savings for registrants because the proposed Rules include the main equipment requirements. However, the cost savings are difficult to quantify because it is unknown how many registrants have purchased the International Standard IEC 62495 or would purchase the standard were to remain incorporated by reference.
- Subparagraph (g)(2) is relocated from existing Rule .0803(j)(1) regarding a visible and legible label requirement.
- Paragraph (h) is a proposed new requirement to reflect American National Standards Institute (ANSI) standard ANSI/HPS 43.8-2008[10]. Subparagraphs .0806(h)(1) to (h)(8) adds additional equipment requirements specific to gauging devices, clarifies existing rule language, is based upon existing industry standards, aligns with language found in the American National Standards Institute (ANSI) standard ANSI/HPS 43.8-2008 and is considered required under current Rules. Most gauging devices in use are commercially manufactured to meet these standards.
- Paragraph (i) is a proposed new requirement to reflect American National Standards Institute (ANSI) standards. Subparagraphs .0806(i)(1) to (i)(8) adds additional equipment requirements specific to for radiographic and fluoroscopic non-healing arts equipment, clarifies existing rule language, is based upon existing industry standards, aligns with language found in the American National Standards Institute (ANSI) Standard N43.5-2013[11]. Most radiographic and fluoroscopic non-healing arts equipment in use are manufactured to meet these standards. It is likely that most registrants in possession of and using this type of equipment currently meet the proposed requirements, but it is unknown to what extent. The agency expects the new requirement to have a minimal economic impact on registrants if the equipment in use does not meet these requirements.
- Paragraph (j) is a proposed new requirement regarding secured access to and operation of RGDs. The change aligns with language found in the Suggested State Regulations-Part H. Most registrants in possession of RGDs currently meet the proposed requirement. If the requirement is not met, the secured access requirement can be met using engineering controls, usually at no additional cost to registrants.

The changes proposed in Rule .0806 are not changes from existing requirements and standard of practice;

[9] International Standard IEC, retrieved from https://webstore.iec.ch/publication/7108

[10] American National Standards Institute ANSI, retrieved from https://global.ihs.com/search_res.cfm?&rid=HPS&input_search_filter=HPS&input_doc_number=N43%2E8&input_doc_title=&org_code=HPS

[11] American National Standards Institute ANSI, retrieved from https://global.ihs.com/search_res.cfm?&rid=HPS&input_search_filter=HPS&input_doc_number=N43%2E5&input_doc_title=&org_code=HPS

rather, they are clarifications of existing equipment requirements for RGDs. The agency does not broaden the scope of regulation with the addition of rule language but seeks to reduce the burden on registrants and stakeholders who must comply with this Rule by clarifying equipment requirements for RGDs. Most commercially manufactured RGDs meet current industry standards. The agency expects the economic costs to be minimal if RGDs maintained and used by the registrant meet current industry standards. The proposed changes may result in a reduction in the time registrants and stakeholders spend to achieve compliance by having all equipment requirements specific to the RGD in use better organized in the Rule *(e.g., Certified and certifiable cabinets, all RGDs, open-beam RGDs, and enclosed RGDs).* The agency expects the changes to simplify and increase overall compliance with this Rule.

10A NCAC 15 .0807 - SECURITY SCREENING EQUIPMENT REQUIREMENTS FOR GOVERNMENT USE ONLY

The proposed amendment renames the rule title from "Permanent Radiographic Installations and Industrial Radiography RGDs" to "Security Screening Equipment Requirements for Government Use Only". All permanent radiographic installations and industrial radiography RGDs requirements have been relocated to Section .0500 rule amendments 10A NCAC 15 .0501 with a proposed effective date of 5/1/24.

- Paragraph (a) is relocated from existing Rule .0808 of this Section regarding requirements for bomb detection RGDs. The proposed changes remove ambiguity by adding rule language for requirements specific to security screening devices in Subparagraphs (a)(1) through (a)(4). The proposed change to rule language simplifies existing rule language, is based upon existing industry standards, and aligns with language found in the American National Standards Institute (ANSI) Standard N43.17-2009 and the Suggested State Regulations-Part H. Table 2 indicates the number of registrants affected by the proposed rule amendment.
- Paragraph (b) is a proposed new paragraph that removes ambiguity by adding rule language for requirements specific to security screening systems in Subparagraphs (b)(1) through (b)(12). The agency became aware, in 2014, of local detention centers purchasing systems use to search for contraband. The agency began granting waivers from 10A NCAC 15 .0603(a)(1)(G), which prohibits use of radiation on individuals for non-healing arts purposes, in February 2015, and based the conditions of use on the American National Standards Institute (ANSI) Standard N43.17-2009. The current waivers granted contains the ANSI standard sections so registrants can easily reference for compliance. The proposed additions to rule language are considered required conditions in the waivers granted in accordance with 10A NCAC 15 .0108, aligns with language found in the American National Standards Institute (ANSI) Standard N43.17-2009, and the Suggested State Regulations-Part H.

The changes proposed in this rule are not a change from existing rule requirements and standard of practice but clarify equipment requirements for security screening devices and systems. The agency does not broaden the scope of regulation with the addition of rule language but seeks to reduce the burden on registrants and stakeholders who must comply with this Rule by clarifying equipment requirements. These proposed changes meet existing requirements and therefore the agency expects minimal to no economic impact for registrants currently utilizing security screening devices.

This change is expected to result in a cost reduction for local and state government registrants that acquire security screening systems in the future as registrants will not have to purchase the American National Standards Institute (ANSI) Standard N43.17-2009 to meet compliance. Currently, registrants are required to purchase the standard at the current price between $50 - $80. In the last 5 years, 39 local government agencies have requested a waiver for use of a security screening system and 26 have registered the RGDs. If the

number of security systems in use continues to increase over the next 5 years on average of 10 per year, the total annual cost savings from not having to obtain the ANSI standard is estimated to be between $500 to $800 per year.

The amount of time it takes agency staff to process a waiver request for a security system averages three (3) hours. If the number of security systems in use continue to increase over the next 5 years to average 10 per year, the agency anticipates a time savings of at least $960 per year ($32/hr x 10 security systems x 3 hours)[12]. State and local government registrants will save time if they no longer have a need to prepare waiver requests for submission. The amount of time it takes for the registrants to prepare waiver requests for submission to the agency is unknown and is likely quite variable among registrants.

Lastly, the proposed changes to Rule .0807 should simplify the rule and increase overall compliance. This may result in unquantifiable time savings for agency staff who review documentation of instruction and training during inspections and who provide guidance to inquiries from registrants regarding compliance issues.

10A NCAC 15 .0808 - OTHER EQUIPMENT REQUIREMENTS

The proposed amendment renames the rule title from "Applicable Rules for Bomb Detection RGDs" to "Other Equipment Requirements".

- Paragraph (a) is a proposed new paragraph specific to RGDs that are considered new technology or that do not meet equipment requirements in existing rule language. Subparagraphs (a)(1) through (a)(8) contain the information to be submitted for review before an RGD can be marketed for sale, installed, or used in NC. This is required under current rules when a user or manufacturer of an RGD does not meet equipment requirements in existing rules.
- Paragraph (a) is a proposed new paragraph containing new rule language clarifying the time in which the agency will respond to the request and that based on the information submitted, additional information may be requested if use of the RGD is allowed.

The changes proposed in Rule .0808 are not changes from existing requirements for information to be submitted for agency review. The agency, in accordance with 10A NCAC 15 .0108, can determine any conditions to include in a waiver or in accordance with 10A NCAC 15 .0106 grant an exemption. The agency does not broaden the scope of regulation with the addition of rule language but seeks to reduce the burden on registrants and stakeholders who must comply with this Rule by clarifying equipment requirements. These proposed changes meet existing requirements for when a user or manufacturer must submit information for review. Therefore, the agency expects minimal to no economic impact.

Summary

Table 3: Summary of Annual Quantified and Unquantified Impacts by Rule (as compared to the regulatory baseline)

[12] Hourly rate was calculated using NC OSHR: Total Compensation Calculator for an Environmental Health Specialist with 10 years of service earning an annual salary of $42,000 ($67,335 total compensation).

Rule #	**State** *Law enforcement, educational, and government facilities with RGDs, & DHSR agency staff*		**Local** *County law enforcement and educational facilities with RGDs*		**Private** *Privately-owned facilities with RGDs*	
	Cost	*Benefit*	*Cost*	*Benefit*	*Cost*	*Benefit*
.0801	None	Minimal time savings from improved clarity/compliance.	None	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.	None	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.
.0802	None	Minimal time savings from improved clarity/compliance.	None	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.	None	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.
.0803	None	Minimal time savings from improved clarity/compliance.	None	Small, unquantifiable time and cost savings from not providing unnecessary training. Incremental improvements to safety due to increased compliance.	None	Small, unquantifiable time and cost savings from not providing unnecessary training. Incremental improvements to safety due to increased compliance.
.0804	None	Minimal time savings from improved clarity/compliance.	Possible, but unlikely minimal cost if operators need to purchase operating and emergency procedures manual.	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.	Possible, but unlikely minimal cost if operators need to purchase operating and emergency procedures manual.	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.

Rule #	**State** *Law enforcement, educational, and government facilities with RGDs, & DHSR agency staff*		**Local** *County law enforcement and educational facilities with RGDs*		**Private** *Privately-owned facilities with RGDs*	
	Cost	*Benefit*	*Cost*	*Benefit*	*Cost*	*Benefit*
.0805	$640 (time cost) to DHSR staff to review floor plans ($32/hr x 10 plans x 2 hrs per plan)	$150-$240 from not having to purchase ANSI Standards (3 registrants x ANSI Standards cost range $50-$80) Minimal time savings from improved clarity/compliance.	$3,500-$7,000 for obtaining floor plans (7 floor plans/yr x room drawing cost range $500-$1,000)	$350-$560 from not having to purchase ANSI Standards (7 registrants x ANSI Standards cost range $50-$80)	$1,500-$3,000 for obtaining floor plans (3 floor plans/yr x room drawing cost range $500-$1,000)	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.
.0806	None	Minimal time savings from improved clarity/compliance	Possible, but unlikely, cost if RGDs in use do not meet current industry standards.	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.	Possible, but unlikely, cost if RGDs in use do not meet current industry standards.	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.
.0807	None	$960 (time savings) for DSHR staff to review and approve waivers ($32/hr x 10 waivers x 3 hrs per waiver) Minimal time savings from improved clarity/compliance Savings for ANSI Standard already accounted for in Rule .0805.	None	Unquantifiable time savings from not preparing waivers. Minimal time savings from improved clarity/compliance. Savings for ANSI Standard already accounted for in Rule .0805.	None	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.

Rule #	**State** *Law enforcement, educational, and government facilities with RGDs, & DHSR agency staff*		**Local** *County law enforcement and educational facilities with RGDs*		**Private** *Privately-owned facilities with RGDs*	
	Cost	*Benefit*	*Cost*	*Benefit*	*Cost*	*Benefit*
.0808	None	Minimal time savings from improved clarity/compliance	None	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.	None	Minimal time savings and incremental improvements to safety due to increased clarity and compliance.
Estimated Annual Total Impact	$640 time cost (DHSR staff time)	$150 - $240 for ANSI Standard $960 time savings (DHSR staff time) Minimal, unquantified time savings	$3,500-$7,000 for floor plans Minimal unquantified costs	$350 - $560 for ANSI Standard Minimal unquantified time and cost savings	$1,500 - $3,000 for floor plans Minimal unquantified costs	Minimal unquantified time and cost savings

Appendix

10A NCAC 15 .0801 is proposed for amendment as follows:

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

10A NCAC 15 .0801 PURPOSE AND SCOPE

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

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

(c) RGDs used for the purpose of elemental analysis, microstructural analysis, quality assurance, quality control, research and development, gauging and measurement, or other nondestructive testing and evaluation addressed in this Section include but are not limited to:

(1) analytical RGDs;

(2) cabinet x-ray systems;

(3) electron beam device below 1MeV;

(4) electron microscopes;

(5) ion implantation equipment, low energy;

(6) gauging devices;

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

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0801 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended Eff. October 1, 2024.

10A NCAC 15 .0802 is proposed for amendment as follows:

10A NCAC 15 .0802 DEFINITIONS

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

~~(2)~~(3) "Analytical RGD equipment" means equipment that uses electronic means to generate ionizing radiation for the purpose of examining the microstructure of materials, ~~i.e.~~ using but not limited to x-ray diffraction, x-ray fluorescence, and x-ray spectroscopy.

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

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

(5) "Certified bomb technician" means a member of an accredited bomb squad who has 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 an RGD utilized in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed. These systems shall be certified in accordance with 21 CFR 1010.2 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 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) "Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected exposure of an individual exceeding administrative or regulatory limits. This procedure shall include the names and telephone numbers of individuals to be contacted as well as directives for processing individual monitoring devices.

~~(12)~~(13) "Fail-safe characteristics" means a design feature that causes the radiation beam to terminate, port shutters to close, or otherwise prevents emergence of the primary beam, 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.

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

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

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

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

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

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

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

~~(16)~~(19) "Ion implantation equipment, low-energy" means any enclosed device operating below 1MeV used to accelerate elemental ions and implant them in other materials.

~~(17)~~(20) "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.

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

~~(18)~~(22) "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)~~(23) "Mobile RGD" means RGD equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

~~(20)~~(24) "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)~~(25) "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)~~(26) "Portable RGD" means RGD equipment designed to be ~~carried.~~ hand-carried.

~~(24)~~(27) "Primary beam" means radiation that passes through an aperture of the source assembly housing by a direct path from the radiation source.

~~(25)~~(28) "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~~ may be used as a:

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

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

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

~~(D) hybrid gauging devices;~~

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

~~(F) baggage scanners;~~

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

~~(H) permanent radiographic installations.~~

~~(26)~~(29) "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.

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

~~(27)~~(31) "Scattered radiation" means radiation, other than leakage radiation, that during passage through matter, has been deviated in direction or has been modified by a decrease in energy.

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

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

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

~~(28)~~(35) "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)~~(36) "Source" means the point of origin of the radiation, such as the focal spot of an x-ray tube.

~~(30)~~(37) "Stationary RGD" means RGD equipment that is installed or placed in a fixed location.

~~(31)~~(38) "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.

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

~~(32)~~(40) "X-ray generator" means the part of an x-ray system that provides the accelerating (high) voltage and current for the x-ray tube.

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

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0802 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;

Amended Eff. October 1, 2024.

10A NCAC 15 .0803 is proposed for amendment as follows:

10A NCAC 15 .0803 ~~EQUIPMENT REQUIREMENTS~~ PERSONNEL REQUIREMENTS

~~(a) Certified cabinet x-ray systems shall meet the requirements of 21 CFR 1020.40 as incorporated by reference in Rule .0117(a)(3) of this Chapter.~~

~~(b) All certified and certifiable cabinet x-ray systems shall:~~

~~(1) be constructed so that, the radiation emitted from the system shall not exceed an exposure of 0.5 milliroentgen (mR) in one hour at any point five centimeters outside the external surface; and~~

~~(2) have a fail-safe interlock that prevents irradiation when the cabinet, chamber, or coupled chambers are open.~~

~~(c) Open-beam analytical RGD systems shall be equipped with a safety device that prevents the entry of any portion of an individual's body into the primary x-ray beam path that causes the beam to be shut off upon entry into its path.~~

~~(d) Open-beam analytical RGDs shall be provided with a visible and legible indication of:~~

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

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

~~(e) Warning devices on open-beam analytical RGDs shall be labeled so that their purpose is identified. On open-beam analytical RGDs installed after February 1, 1980, warning devices and lights shall have fail-safe characteristics.~~

~~(f) Unused ports on radiation source housings for open-beam RGDs shall be secured in the closed position in a manner that will prevent unintended opening.~~

~~(g) Each port on the radiation source housing on open-beam analytical RGDs installed after February 1, 1980 and designed to accommodate interchangeable components shall be equipped with a shutter that cannot be opened unless a collimator or a component coupling is connected to the port.~~

~~(h) Portable open-beam analytical RGDs that shall be manufactured to be used hand-held without safety devices are exempt from the requirements of Paragraph (c) of this Rule and shall be constructed according to International Standard IEC 62495 that is incorporated by reference and includes subsequent amendments. This standard can be downloaded for one hundred twenty one dollars ($121.00) at the following website: http://webstore.ansi.org/FindStandards.aspx?SearchString=IEC+62495+Ed.+1.0+en%3a2011&SearchOption=0&PageNum=0&SearchTermsArray=null%7cIEC+62495+Ed.+1.0+en%3a2011%7cnull.~~

~~(i) A registrant may apply to the agency, as defined in Rule .0104 of this Chapter, for an exemption from the requirement of a safety device. This request shall include:~~

~~(1) a description of the safety devices;~~

~~(2) the reason safety devices cannot be used; and~~

~~(3) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.~~

~~(j) Analytical RGDs shall be provided with a visible and legible label(s) bearing the radiation symbol and the words:~~

~~(1) "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar meaning, near the exit port to identify the location of the beam; and~~

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

~~(k) Warning lights labeled with the words "X-RAYS ON," or other words having similar meaning, shall be located:~~

~~(1) near any switch that activates the high voltage to energize an x-ray tube; or~~

~~(2) in a conspicuous location near the radiation source housing and radiation beam(s) and visible from all instrument access areas.~~

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

~~(m) Each x-ray tube housing shall be:~~

~~(1) constructed that when all shutters are closed the leakage radiation measured at a distance of five centimeters from its surface is not capable of producing an exposure in excess of 2.5 millirem (mrem)/ (25 microsieverts µSv) in one hour; and~~

~~(2) if the tube housing is the primary shielding for the x-ray tube, does not produce x-rays when the housing is opened or disassembled.~~

~~(n) Each x-ray generator shall be supplied with a protection cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing an exposure in excess of 0.25 mrem/2.5µSv in one hour.~~

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

(a) The registrant shall document the scope of training and instruction required for the RGD they possess in accordance with the rules of this Section.

(b) No individual shall be permitted to operate or maintain RGDs unless the individual has received instruction in the basic principles of radiation protection, training provided by the manufacturer for the specific RGD in use, and instruction in the operating and emergency procedures. Instruction and training shall include but is not limited to:

(1) Basic principles of radiation protection:

(A) radiation fundamentals;

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

(C) units of radiation dose and measurements;

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

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

(F) declared pregnancy policy;

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

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

(2) Device specific training for each RGD:

(A) hands-on training for proper use;

(B) radiation hazards associated with use;

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

(D) procedures to prevent unauthorized use; and

(E) agency rules regarding use.

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

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

(d) Individuals who will be operating the RGD shall be able to demonstrate an understanding in safe operating procedures and use of the RGD.

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

(1) operating open-beam RGDs; and

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

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0803 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended Eff. October 1, 2024.

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

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

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

~~(b) Survey Requirements~~

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) Normal operating and emergency procedures shall include but are not limited to the following:

(1) safe use of the RGD;

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

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

(e) Open beam and portable handheld RGDs

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

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

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

(C) available to all individuals operating the RGD.

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

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

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

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

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

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

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

(i) Safety Devices

(1) Testing

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

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

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

(2) Bypassing

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

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

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

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

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

(2) shutters;

(3) collimators; or

(4) beam stops.

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0804 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended Eff. October 1, 2024.

10A NCAC 15 .0805 is proposed for amendment as follows:

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

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

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

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

~~(d) No individual shall bypass a safety device unless the person has obtained the approval of the person responsible for radiation safety or the RSO. This process shall be incorporated into the radiation protection program by the RSO, as set forth in Rule .1603(a), and the operating procedures as set forth in Rule .0603(a)(1)(B). The written approval, as granted by the RSO, shall include an expiration date. When a safety device has been bypassed, a legible sign bearing the words "SAFETY DEVICE NOT WORKING" or words having a similar meaning shall be placed on the radiation source housing and the control panel during the bypassing period.~~

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

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

~~(2) shutters;~~

~~(3) collimators; or~~

~~(4) beam stops~~

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

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

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

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

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

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

(A) door interlocks;

(B) entry monitors; or

(C) engineering controls.

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

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

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

(c) The local components of RGDs shall be located and arranged to include sufficient shielding or access control to ensure no radiation levels exist in any area surrounding the local components that result in a dose to an individual to present in excess of the dose limits in Rule .1601(a)(15) of this Chapter.

(d) Surveys shall be performed for each RGD, as set forth in Rule .1601(a)(50) of this Chapter, to show compliance with Paragraph (c) of this Rule.

(1) Radiation survey instruments shall be:

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

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

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

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

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

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

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

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

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

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

(A) the proposed location of the system;

(B) direction of the useful beam;

(C) adjacent areas; and

(D) location of the operator.

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

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

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

(C) survey instrument used; and

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

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

(4) Records of the floor plan with equipment arrangement and survey shall be available for agency review during inspection.

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

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

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

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

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

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

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

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

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

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

(1) 21 CFR 1020.40(a) Applicability;

(2) 21 CFR 1020.40(b) Definitions;

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

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

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

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

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

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

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

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

(C) visible from all instrument access areas.

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) A useful beam control system shall be provided whenever the useful beam is accessible, and the radiation levels exceed one hundred mrem per hour (100 mrem/hr) (1 mSv/hr) at five centimeters from any accessible surface or five mrem per hour (5 mrem/h) (.05 mSv/h) at thirty centimeters (30 cm). The useful beam controls may include, but are not limited to, a moving shutter, a moving source, or a high voltage power supply.

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

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

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

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

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

(A) ANSI device classification;

(B) name of manufacturer;

(C) model; and

(D) serial number.

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

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

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

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

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

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

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

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

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

(3) The controls shall be:

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

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

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

(A) yellow or amber in color;

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

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

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

(A) red in color; and

(B) permanently marked.

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

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

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

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

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

10A NCAC 15 .0807 is proposed for amendment as follows:

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

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

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

~~(1) .0501;~~

~~(2) .0502;~~

~~(3) .0506;~~

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

~~(5) .0522;~~

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

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

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

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

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

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

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

~~(13) .0525.~~

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

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

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

(A) establish a visible barrier;

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

(C) if the operator is unable to maintain visual control of the area during operation of the RGD, an additional means to control the area shall be provided.

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

(A) date and time of use;

(B) location of use; and

(C) operator of the RGD.

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

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

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

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

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

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

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

(6) An inspection zone shall be:

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

(B) visibly marked; and

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

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

(A) the individual being scanned;

(B) the inspection zone; and

(C) any access areas.

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

(A) upon installation;

(B) every 12 months; and

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

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

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

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

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

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

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

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

(11) Records of each individual scanned at the same facility shall be maintained for agency review during inspection.

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

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

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

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

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

10A NCAC 15 .0808 is proposed for amendment as follows:

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

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

~~(1) .0501;~~

~~(2) .0502;~~

~~(3) .0509;~~

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

~~(5) .0522;~~

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

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

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

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

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

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

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

~~(13) .0525.~~

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

(1) equipment form for application;

(2) manufacturer manual;

(3) description of use;

(4) operator training;

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

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

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

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

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

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

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