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 with Substantive Changes:

10A NCAC 15 .0201	PURPOSE AND SCOPE
10A NCAC 15 .0208	OUT-OF-STATE RADIATION MACHINES AND RADIATION GENERATING DEVICES
10A NCAC 15 .0211	INDIVIDUAL RESPONSIBLE FOR RADIATION PROTECTION REQUIREMENTS AND RESPONSIBILITIES
10A NCAC 15 .0212	RADIATION MACHINES AND RADIATION GENERATING DEVICES THAT DO NOT MEET RULE REQUIREMENTS

Rule Readoption with Substantive Changes:

10A NCAC 15 .0202	EXEMPTIONS
10A NCAC 15 .0203	APPLICATION FOR REGISTRATION PROCESS: GENERAL REQUIREMENTS FOR ALL FACILITIES, RADIATION MACHINES, AND SERVICES PROVIDED IN NORTH CAROLINA
10A NCAC 15 .0204	FACILITY RESPONSIBILITIES
10A NCAC 15 .0205	SERVICE PROVIDER RESPONSIBILITIES
10A NCAC 15 .0206	TRAINING AND EDUCATIONAL REQUIREMENTS TO PROVIDE SERVICES
10A NCAC 15 .0207	ADDITIONAL REQUIREMENTS TO PROVIDE SERVICES
10A NCAC 15 .0209	ISSUANCE OF NOTICE OF REGISTRATION
10A NCAC 15 .0210	MODIFICATIONS: REVOCATION TERMINATION OF REGISTRATIONS
10A NCAC 15 .0213	CLINICAL STUDIES, RESEARCH, AND SCREENING REQUIREMENTS

*See text in Appendix

Rulemaking Authority G.S. 104E-7; 104E-9(8); 104E-12; 104E-13; 104E-19(a); 104E-20
21 CFR 1020.30(d)

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 .0200 of Chapter 15 regulate all registrants who use radiation machines, radiation generating devices (RGDs), and who provide radiological services 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 .0200 had four rules, .0201, .0208, .0211, and .0212 that were determined to be "Necessary Without Substantive Public Interest" and will be amended with this rulemaking action. Nine rules, Rules 10A NCAC 15 .0202 - .0207, .0209, .0210, and .0213 were determined to be "Necessary with Substantive Public Interest" and will be readopted 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 1020.30(d)[1] are proposed for incorporation by reference, including subsequent amendments and editions. The federal regulations are being incorporated by reference into Rule 10A NCAC 15 .0205(f)(2)(A).

Introduction

The North Carolina Department of Health and Human Services (DHHS), Division of Health Service Regulation (DHSR), and Radiation Protection Section (RPS) regulate the use of radiation machines and Radiation Generating Devices (RGDs) by any individual or entity in possession of one of these radiation sources in North Carolina (NC). As part of the readoption process, these proposed amendments and readoptions 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 of existing requirements to remove ambiguity, make technical corrections, remove unnecessary rules, and update terminology. Additions to current rule language are to clarify existing requirements and to align with common industry standards that are largely considered requirements under the current Rules. The Radiation Protection Section intends that the proposed amendments and readoptions simplify compliance and reduce the time stakeholders, registrants, and agency staff spend interpreting rules. There may be an additional cost for stakeholders and registrants to meet some requirements that will increase current safety requirements for radiation workers and NC citizens.

Additionally, the amendments and readoptions align the rules with current practices and the Conference of Radiation Control Program Directors Suggested State Regulations - Part B[2]. The Radiation Protection Section also incorporates the suggestions of The Radiation Protection Commissions, 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 such as state prisons and educational institutions. State governments may use RGDs for security screening, research, or other applications. This includes DHHS agency staff.

[1] Code of Federal Regulations: (CFR) (21 CFR) retrieved from: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J

[2] Conference of Radiation Control Program Directors: (CRCPD), retrieved from https://online.flippingbook.com/view/892080394/

2. Local Government: The local level includes county jails, educational institutions, health departments, and law enforcement that use radiation machines or RGDs. Their applications may overlap with those of state governments.
3. Private Sector: This includes any business or industry that uses radiation machines or RGDs.

Rule Changes and Anticipated Impacts
A brief description of each rule is provided below.

10A NCAC 15 .0201 - 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 that radiation generating devices are included in this Rule.
- Paragraph (b) strikes through the definition of facility. The definition of facility was relocated to Rule .0103 of this Chapter. The new language clarifies to whom this Rule applies.
- Paragraph (c) specifically lists out the other Sections to which all registrants are also subject.
- Proposed new language in Paragraph (d) through (i) was added to clarify the Sections that regulate various modalities.

The proposed changes will provide additional clarity and reduce ambiguity to the regulated community, which may result in incremental improvements to compliance. The agency expects no economic impact.

10A NCAC 15 .0202 – EXEMPTIONS
The proposed readoption changes are detailed below.

- Subparagraph (b)(1) adds language that provides clarity that all radioactive materials are exempt from the requirements of this Section.
- Subparagraph (b)(2) language is relocated from existing Rule .0202(b).
- Paragraph (c) strikes through existing language regarding domestic television receivers as being exempt. These types of receivers are outdated; as such, this exemption is no longer needed. The proposed new language relocated the existing Rule .0106(a) of this Chapter to this rule.

The proposed changes will provide additional clarity to the regulated community which may result in incremental improvements to compliance. The agency expects no economic impact.

10A NCAC 15 .0203 - APPLICATION FOR REGISTRATION PROCESS: GENERAL REQUIREMENTS FOR ALL FACILITIES, RADIATION MACHINES, AND SERVICES PROVIDED IN NORTH CAROLINA
The proposed readoption renames the rule title from "Application: Registration: Radiation Machines: Facilities" to "Application for Registration Process: General Requirements for All Facilities, Radiation Machines, And Services Provided In North Carolina".

- Paragraph (a) clarifies who must apply for registration with the agency.
- Subparagraph (b)(1) clarifies how all application forms must be completed and how to submit the forms to the agency.
- Subparagraph (b)(2) adds language that clarifies incomplete forms will not be processed.
- Subparagraph (b)(3) clarifies that the agency may require additional information after submission of an application. Examples of additional information that is requested by the agency are information to ensure the accuracy of control model numbers and information about new x-ray equipment technology.

- Subparagraph (b)(4) lists the web address where application forms can be found.
- Paragraph (c) through (g) proposes new language to clarify existing requirements of information the registrant or potential registrant is to enter on the form, as required by the Administrative Rule Style Guide.
- Paragraph (h) relocates language in existing Rules .0209 and .0210(b) of this Section and adds new language that is considered a current requirement and aligns with Suggested State Regulations -Part B[3]. Combining this information into one Rule removes ambiguity as to whom these requirements apply by informing all registrants that they must meet this requirement.
- Subparagraph (h)(1) is relocated from existing Rule .0209 titled "Report of Changes". The proposed change of adding this requirement to this rule removes ambiguity by clarifying that all registrants must notify the agency when a change to the Notice of Registration occurs.
- Subparagraph (h)(2) proposes new language that removes ambiguity and clarifies what is considered a current requirement for when a registrant terminates all activities at the facility.
- Subparagraph (h)(3) proposes new language that removes ambiguity and clarifies what is considered a current requirement that a registration is not transferrable as part of a change of ownership.
- Subparagraph (h)(4) proposes new language that removes ambiguity and clarifies what is considered a current requirement for sources of radiation because of bankruptcy, foreclosure, or state auction.
- Subparagraph (h)(5) is relocated from existing Rule .0806(b) and updates terminology of

The agency expects the proposed changes to Rule .0203 will reduce the time registrants and stakeholders spend to achieve compliance by having requirements for all registrants 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 submitted to the agency and whoever provides guidance to inquiries from registrants regarding compliance issues.

10A NCAC 15 .0204 – FACILITY RESPONSIBILITIES

The proposed readoption renames the rule title from "Prohibited Services and Installation" to "Facility Responsibilities". The proposed readoption does not remove the existing requirements a facility must meet; rather, it removes ambiguity by clarifying the existing language.

- Paragraph (a) proposes new language providing clarity regarding completing and submitting the required agency forms.
- Paragraph (b) is relocated from existing Rule .0603(b), of this Chapter. The Radiation Protection Commission requested this change.
- Subparagraph (b)(1) is relocated from existing Rule .0603(b), of this Chapter. The proposed new language to this existing requirement clarifies when a Shielding Design needs to be submitted to the agency for acknowledgment.
- Subparagraph (b)(2) provides new language to clarify what information needs to be submitted to the agency for review by the agency.
- Subparagraph (b)(3) provides new language to clarify that a radiation machine shall not be installed until DHHS has acknowledged receipt of their shielding design. In accordance with 10A NCAC 15 .0603(b), a registrant is already required to have shielding designs reviewed by a qualified expert and to submit recommendations of the expert to the agency. However, DHHS staff have found this to be an area of high noncompliance. As such, this proposed clarification is likely to improve compliance by emphasizing the duty of the registrant to have shielding designs reviewed PRIOR to installation.
- Subparagraph (b)(4) provides language a radiation machine shall not be replaced until a service provider confirms that the existing shielding design meets the requirements. It also

[3] Conference of Radiation Control Program Directors: (CRCPD), retrieved from https://online.flippingbook.com/view/892080394/

requires that documentation of this confirmation be maintained by the applicant. While already allowed under the current rules, this proposed language will emphasize that an existing shielding design might be adequate without having to pay for a new shielding design. In practice, this improved clarity could result in an unquantifiable cost savings for some registrants.

- Subparagraph (b)(5) provides new language that removes ambiguity and provides clarification for when a radiation machine is replaced.
- Subparagraph (b)(6) exempts bone densitometry, dental handheld, mammography, and mobile/portable radiographic machines used in more than two locations from needing shielding designs. Based on feedback from stakeholders, committee, and working group members, the requirement to have an acknowledged shielding design for bone density, dental handheld, and mammography machines was considered unnecessary Due to historical data of the low radiation output, most states no longer require a shielding design for bone density or 2D mammography radiation machines. Since the inception of 3D mammography machines, the agency has required a shielding design to be performed. Over the last 10 years, data has shown that the radiation output of 3D mammography is similar to that of 2D mammography. Portable radiation machines are manufactured to move from room to room and historically have not required a shielding design unless the machine is "routinely" used in 1 or 2 rooms. When a portable machine is used in more than 2 rooms, a shielding design is not required. Due to the well-documented low radiation output of these particular machines, not requiring a shielding design for these circumstances does not pose an increased risk to the public or staff. Exempting these machines from needing a shielding design could result in cost savings to facilities and time savings for the agency staff that reviews shielding designs.
- Paragraph (c) proposes new language to remove ambiguity and clarify registration requirements and the timeframe to submit registration documents for facilities using radiation machines, including those used for mobile services, research, and industrial radiography. The additional language aligns with the current requirement to register with the agency.
- Paragraph (d) is relocated from existing Rule .0208 of this Section. This requirement is specifically for facilities and not service providers.
- Paragraph (e) and (f) are current requirements in the existing Rule.

Most of the changes proposed in this rule are not a change from existing rule requirements and standards of practice but simply clarify registration requirements for radiation machines and 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 registration requirements. These proposed changes meet existing requirements and therefore the agency expects minimal to no economic impact for registrants currently using radiation machines or RGDs.

The change is expected to result in a cost reduction for registrants who acquire new radiation machines in the future. Currently, registrants are required to submit shielding designs for bone density, dental handheld, and mammography machines. A shielding design is estimated to cost a registrant between $400 - $1,200.[4] In the last 5 years, the average number of shielding designs received by DHHS for the three modalities was 266 per year. Under the proposed rule, registrants will no longer be required to submit shielding designs for bone density, dental handheld, and mammography machines. Assuming the average number of shielding designs received remains about the same in the future, the total annual cost savings to registrants is estimated to be between $106,400 (266 designs x $400 per design) to $319,200 (266 designs x $1,200 per design) per year. Based on the current usage of bone density, dental handheld, and mammography machines in the various sectors,these savings will be spread across private (~86%), state government (~2%), and local government (~12%) registrants.

[4] The estimated cost range of $400 - $1,200 for a shielding design was obtained from a registered service provider. The cost of a shielding design varies by modality and type of installation.

The time it takes agency staff to process a shielding design averages two (2) hours. Assuming the average number of shielding designs received is 266 per year, the agency estimates a time savings of approximately $17,024 per year ($32/hr x 266 shielding designs x 2 hours)[5].

The agency expects the other proposed clarifying changes to Rule .0204 to result in a reduction of time registrants and stakeholders spend to achieve compliance by having all registration requirements for facilities located in one Rule. The agency expects the changes to simplify and possibly increase overall compliance with this Rule. The changes will result in unquantifiable, minimal time savings for agency staff who review documentation submitted to the agency and provide guidance to registrant inquiries regarding compliance issues. Increased compliance should also result in incremental improvements to operator and public safety from radiation exposure.

10A NCAC 15 .0205 – SERVICE PROVIDER RESPONSIBILITIES

The proposed readoption renames the rule title from "Application for Registration of Services" to "Service Provider Responsibilities". The proposed readoption does not remove the existing requirement for service providers but clarifies existing language and updates terminology.

- Subparagraph (e) lists all the services for which a person who is engaged in the business of furnishing or offering to furnish these services would make them subject to the registration requirements. All but one of the services listed in Subparagraph (e) are services currently listed in Paragraph (d) of the existing rule. Proposed Part (e)(1) includes new language that adds "manufacturer training for the use of radiation machines or radiation generating devices" to the list of services. The Radiation Protection Commission requested this addition due to the emergence of new technologies. Subparagraph (e)(10) also introduces the term "radiation protection expert."
- Paragraph (f) is clarifying that a general health or medical physicist shall review and sign all work performed by a radiation protection expert. This is considered required under current Rules.
- Paragraph (g) is relocated from existing Rule .0206(b) regarding reports of installation. This requirement is specifically for service providers, not facilities.
- Paragraph (h) is relocated from existing Rule .0206(a) regarding report of sale and installation. This requirement is specifically for service providers, not facilities. The proposed addition of new language in the rule clarifies existing requirements including the information the service provider must enter on the form, as required by the Administrative Rule Style Guide.
- Paragraph (i) is relocated from existing Rule .0210(a) regarding prohibited activities. This requirement is specifically for service providers, not facilities.
- Paragraph (j) is relocated from existing Rule .0210(c) regarding prohibited activities. This requirement is specifically for service providers, not facilities.
- Paragraph (k) adds language for required records. Additional rule language is based upon existing industry standards and is a current requirement.
- Paragraph (l) adds language for required records and is considered a current requirement.

The agency expects the proposed clarifying changes to Rule .0205 to result in an unquantifiable, minimal benefit in the form of time savings to service providers. Specifically, service providers may spend less time understanding the requirements. The agency expects the changes to simplify and possibly increase overall compliance with this Rule. The changes may also result in unquantifiable time savings for agency staff who review documentation submitted to the agency, increase safety for facility staff using the equipment, increase patient safety, and provide guidance to registrant inquiries regarding compliance issues.

[5]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).

10A NCAC 15 .0206 – TRAINING AND EDUCATIONAL REQUIREMENTS TO PROVIDE SERVICES
The proposed readoption renames the rule title from "Reports of Installation" and relocates "Training and Educational Requirements for Equipment Services" from existing Rule .0214 of this Section into this Rule.

- Subparagraph (a)(1) is relocated from existing Rule .0214(a)(1) and adds new language to include registered service providers who provide manufacturer training for use of radiation machines/radiation generating devices in the Class 1 category. Providers in the Class 1 category must be "knowledgeable, familiar, and comply with the rules which govern the possession, installation, and use of radiation machines in North Carolina." The language aligns with industry standards and is considered a requirement in the current rule.
- Subparagraphs (a)(3) to (a)(8) is relocated from existing Rule .0214(a)(3) to (a)(8).
- Subparagraph (a)(9) proposes new language that updates the requirements to align with industry standards and the Suggested State Regulations Part A. The proposed new language removes language in existing Rule .0214(a)(9)(A). The Radiation Protection Commission requested this change.
- Subparagraph (a)(10) proposes new language that provides the qualifications for a "radiation protection expert." The Radiation Protection Commission requested this change.
- Paragraph (b) proposes new language with an effective date for persons that do not meet the requirements of Paragraph (a)(9) of this Rule. This new language aligns with the Suggested State Regulations and does not increase requirements for currently registered service providers. Existing service providers for this class can continue to perform services on their current registration that are in good standing.
- Paragraph (c) is relocated from the current Rule .0214(d).

The changes proposed in Rule .0206 are not changes from existing requirements and standards of practice. However, they clarify existing requirements for persons who provide radiological services in NC. The agency does not broaden the scope of regulation by adding rule language, only intending to reduce the burden on registrants and stakeholders who must comply with this Rule by clarifying requirements for service providers. The agency expects the changes to simplify compliance resulting in an unquantifiable, minimal increase in compliance with this Rule. The agency expects no economic impact.

10A NCAC 15 .0207 – ADDITIONAL REQUIREMENTS TO PROVIDE SERVICES
The proposed readoption renames the rule title from "Issuance of Notice of Registration" to "Additional Requirements to Provide Services".

The change is for administrative purposes, by relocating the existing rule, with no change from existing requirements. Therefore, the agency expects no economic impact.

10A NCAC 15 .0208 - OUT-OF-STATE RADIATION MACHINES AND RADIATION GENERATING DEVICES
The proposed amendment renames the rule title from "Prior Notification of Transfer" to "Out of State Radiation Machines and Radiation Generating Devices".

- Paragraph (a) is relocated from existing Rule .0211(a) with no changes made to the rule.
- Paragraph (b) is relocated from existing Rule .0211(b). The proposed change to language is for clarification. The Paragraph now has three Subparagraphs instead of two for ease of reading and comprehension. The rule language clarifies registration requirements for out of state radiation machines and RGDs for temporary use in NC.
- Paragraph (c) is a proposed new paragraph containing new rule language clarifying the documentation to be maintained for agency review. The existing rule has the reporting requirements of notifying the state five days prior to entering the state yet most service providers from out of state do not maintain the required documentation for agency review during inspection.
- Paragraph (d) is a proposed new paragraph containing new rule language removing ambiguity

to clarify the agency's authority to inspect out of state radiation machines or RGDs used in the state.

The changes proposed in Rule .0208 are no change from existing requirements for out of state machines and RGD used in NC temporarily. The agency does not broaden the scope of regulation with new rule language, while intending to reduce the burden on registrants and stakeholders who must comply with this Rule, by clarifying registration requirements, maintaining documentation, and performing inspections. The agency expects this clarification may result in an unquantifiable increase in compliance.

10A NCAC 15 .0209 - ISSUANCE OF NOTICE OF REGISTRATION

The proposed readoption renames the rule title from "Report of Changes" to "Issuance of Notice of Registration" relocated from Rule .0207.

The change is for administrative purposes, by relocating the existing rule, with no change from existing requirements. Therefore, the agency expects no economic impact.

10A NCAC 15 .0210- MODIFICATIONS: REVOCATION TERMINATION OF REGISTRATIONS

The proposed readoption renames the rule title from "Other Prohibited Activities" to "Modifications: Revocation: Termination of Registrations" relocated from Rule .0212.

The change is for administrative purposes, by relocating the existing rule, with no change from existing requirements. Therefore, the agency expects no economic impact.

10A NCAC 15 .0211 - INDIVIDUAL RESPONSIBLE FOR RADIATION PROTECTION REQUIREMENTS AND RESPONSIBILITIES

The proposed amendment renames the rule title from "Out of State Radiation machines" to "Individual Responsible for Radiation Protection Requirements and Responsibilities".

- Paragraph (a) proposes new language to remove ambiguity and clarify the qualifications a person must have to be designated as an individual "responsible for radiation protection" on the application form. The provision in current Rule .0203(a)(2) that requires the designation of an individual on the application form responsible for radiation protection is proposed to be relocated to Rule .0211(a). Language is added to specify the training, education, and experience required for a person to carry out the job duties of the requested registration.
- Paragraph (b) proposes new language to remove the ambiguity of what responsibilities the individual responsible for radiation protection can oversee.

The changes proposed in Rule .0211 are not changes from existing requirements regarding training necessary to carry out the responsibilities and job duties for the individual designated as responsible for radiation protection. The agency staff routinely guides registrants who inquire about who can be designated as the individual responsible for radiation protection, what type of training is required, and the responsibilities they can perform. Additionally, the agency has a guidance document posted on the agency website for further clarification. The new language aligns with the industry standard of care and aligns with Suggested State Regulations -Part B[6]. The agency does not broaden the scope of regulation with new rule language but desires to reduce the burden on registrants and stakeholders who must comply with this Rule by removing ambiguity and providing clarification. The changes may result in unquantifiable time savings for agency staff who provide guidance to inquiries from registrants regarding compliance issues and for registrants seeking guidance for clarity. Historically, registrants have not had to require staff to receive additional training due to a licensed practitioner designated as the individual responsible, or by having someone on staff who has

[6] Conference of Radiation Control Program Directors: (CRCPD), retrieved from https://online.flippingbook.com/view/892080394/

received the necessary training to be considered qualified. Therefore, the agency expects minimal to no economic impact.

10A NCAC 15 .0212 - EMERGING TECHNOLOGIES THAT DO NOT MEET RULE REQUIREMENTS

The proposed amendment renames the rule title from "Modifications: Revocation: Termination of Registrants" to Emerging Technologies That Do Not Meet Equipment Requirements".

- Paragraph (a) proposes new language, specific to machines and RGDs considered new technology or that do not meet equipment requirements under existing rule language. Subparagraphs (a)(1) through (a)(7) contain the information to be submitted for review before a machine or 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 (b) is a proposed new paragraph containing new rule language clarifying when the agency will respond to the request and that, based on the information submitted, additional information may be requested to determine if the RGD is allowed for use in this state.

The changes proposed in Rule .0212 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. These proposed changes meet existing requirements of when a user or manufacturer must submit information for review. The agency does not broaden the scope of regulation by adding rule language but rather seeks to reduce the burden on registrants and stakeholders who must comply with this Rule by clarifying the information that shall be submitted to the agency for review. Adding the 90-day timeframe gives the regulated community when to expect a response from the agency. This shouldn't create a new burden on the community. The agency is already doing this in practice. Therefore, the agency expects minimal to no economic impact.

10A NCAC 15 .0213- CLINICAL STUDIES, RESEARCH, AND SCREENING REQUIREMENTS

The proposed readoption renames the rule title from "Additional Requirements: Registered Services" to "Clinical Studies, Research, and Screening Program Requirements"

- Paragraph (a) proposes new language of the requirement of agency acknowledgment prior to the initiation of clinical studies, research, or screening programs using radiation machines on humans in the state.
- Paragraph (b) proposes new language clarifying the requirement of submitting a request to waive the requirement that no individual shall be exposed to the useful beam except for healing arts purposes and the exposures shall be authorized by a licensed practitioner.
- Paragraph (c) proposes new language, specific to information that must be submitted to the agency before conducting clinical studies, research, or screening in the state using radiation machines on humans.
- Subparagraph (c)(1) proposes new language and is specific to programs that have received IRB approval. The information requested is a federal requirement, 21 CFR 56[7], which provides the standards for IRBs for clinical investigations that support applications for research using products regulated by the FDA, which the program must receive to initiate the program. The agency is requesting the information that was submitted to the FDA and the approval received from the FDA to confirm approval of the clinical study, research, or screening program.
- Subparagraph (c)(2) is specific to programs that have not received IRB approval. The information requested is considered a current requirement, aligns with industry standards of care, and aligns with Suggested State Regulations -Part B[8].

[7] Code of Federal Regulations (CFR): retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56
[8] Conference of Radiation Control Program Directors: (CRCPD), retrieved from https://online.flippingbook.com/view/892080394/

- Paragraph (d) 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 the use of the RGD is allowed.

The changes proposed in Rule .0213 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. These proposed changes meet existing requirements for what information must be submitted to the agency for review prior to conducting a clinical study, research, or screening program. The agency does not broaden the scope of regulation with the addition of rule language but seeks to reduce the burden on registrants who must comply with this Rule by clarifying the requirements to conduct clinical studies, research, or screening programs. Therefore, the agency expects an increase in compliance by removing ambiguity and clarifying a current requirement. Additionally, the agency expects minimal to no economic impact.

See Table 1, Summary of Impacts on following page.

Table 1: Summary of Annual Quantified and Unquantified Impacts by Rule

Rule #	State *DHSR agency staff*		State *Law enforcement, educational, and government facilities with RGDs* Local *County law enforcement and educational facilities with RGDs* Private *Privately-owned facilities with Radiation Machines & RGDs* *Service Providers*	
	Cost	**Benefit**	**Cost**	**Benefit**
.0201 .0202 .0203	None	Minimal time savings and incremental improvements in compliance due to increased clarity.	None	Minimal time savings and incremental improvements to compliance due to increased clarity.
.0204	None	$17,024 (time savings) to DHSR staff from reviewing fewer shielding designs. *$32/hr x 2 hrs/plan 266 plans/yr* Minimal time savings from improved clarity/compliance.		$106,400 - $319,200 (cost savings) for registrants from not needing to pay for shielding design. *266 shielding designs/yr x shielding design cost range of $400 - $1,200 per design* *The percentage of the 266 shielding designs per facility type breaks down as follows:* *State: 2%* *Local: 12%* *Private: 86%* Minimal time savings and incremental improvements in compliance due to increased clarity.
.0205 .0206 .0207 .0208 .0209 .0210 .0211 .0212 .0213	None	Minimal time savings and incremental improvements in compliance due to increased clarity.	None	Minimal time savings and incremental improvements in compliance due to increased clarity.
Estimated Annual Total Impact*	None	$17,024 (time savings) + additional unquantified time savings for DHSR staff.	None	$106,400 - $319,200 (cost savings) + unquantified time savings for registrants, spread across state government, local government, and privately owned facilities.
*Increased compliance should also result in incremental improvements to operator and public safety which could reduce the potential for unnecessary radiation exposure. These benefits were unquantifiable.				

Appendix

10A NCAC 15 .0201 is proposed for amendment as follows:

SECTION .0200 - REGISTRATION OF RADIATION MACHINES: FACILITIES AND SERVICES

Codifier's Note: 10 NCAC 03G .2300 was transferred to 15A NCAC 11 .0200 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3. 7

10A NCAC 15 .0201 PURPOSE AND SCOPE

(a) This Section provides for the registration of radiation ~~machines,~~ machines, radiation generating devices, ~~radiation machine~~ facilities, and persons providing other radiological services.

(b) ~~For purposes of this Section, "facility" means the location at which one or more radiation machines are installed or located within one building, vehicle, or under one roof and are under the same administrative control~~. A person who acquires, owns, possesses, or receives a radiation machine or radiation generating device before receiving a notice of registration in accordance with Rule .0209 of this Section is subject to the requirements of this Chapter.

(c) In addition to the requirements of this Section, all registrants are subject to the provisions in ~~of the other sections~~ Sections .0100, .1000, .1100, and .1600 of this Chapter.

(d) ~~Special requirements for registration of particle accelerators are provided in Section .0900 of this Chapter and are in addition to the requirements of this Section.~~ Registrants using radiation machines for human and veterinary use are subject to the requirements in Section .0600 of this Chapter.

(e) ~~In addition to the requirements of this Section, all registrants are subject to the annual fee provisions contained in Section .1100 of this Chapter.~~ Registrants using radiation machines for non-human use at educational facilities, for forensic medicine, or by service providers for demonstration purposes are subject to the requirements of Section .0600 of this Chapter.

(f) Registrants using industrial radiographic machines are subject to the requirements of Section .0500 of this Chapter.

(g) Registrants using ionizing radiation generating devices are subject to the requirements of Section .0800 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-9(8); 104E-19(a);*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; July 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0201 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended Eff. May 1, 2025.

10A NCAC 15 .0202 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0202 EXEMPTIONS

(a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Section provided that the dose equivalent rate average over an area of ~~ten~~ 10 square centimeters does not exceed 0.5 mrem per hour at five centimeters from any accessible surface of the equipment when any external shielding is removed. The production, testing, or factory servicing of such equipment are not exempt.

(b) ~~Radiation machines while in transit or storage incident thereto are exempt from the requirements of this Section.~~ The following are exempt from the requirements of this Section:

(1) all radioactive materials; and

(2) radiation machines while in transit.

(c) ~~Domestic television receivers are exempt from the requirements of this Section.~~ The agency may, upon application, grant individual exemptions or exceptions from the requirements of these Rules if it will not result in a radiation dose that exceeds the limits prescribed in these Rules for the protection of public health, safety, or property.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0202 Eff. February 1, ~~2015.~~ 2015;
Readopted May 1, 2025.

10A NCAC 15 .0203 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0203 ~~**APPLICATION: REGISTRATION: RADIATION MACHINES: FACILITIES**~~ **APPLICATION FOR REGISTRATION PROCESS: GENERAL REQUIREMENTS FOR ALL FACILITIES, RADIATION MACHINES, AND SERVICES PROVIDED**

~~(a) Each person having an unregistered radiation machine or facility shall:~~

~~(1) apply for registration of such facility and each radiation machine within 30 days following initial operation of that facility and each radiation machine. Application for registration shall be completed on agency forms and shall contain all information required by the forms and accompanying instructions. The registration of the first radiation machine at a facility constitutes registration of the facility itself.~~

~~(2) designate on the application form an individual who shall be responsible for radiation protection.~~

~~(b) Agency forms described in Subparagraph (a)(1) of this Rule require the following and other information:~~

~~(1) name, address and telephone number of the radiation machine facility;~~

~~(2) name of the person responsible for radiation protection in the facility;~~

~~(3) name, training and experience of the person designated in Subparagraph (a)(2) of this Rule;~~

~~(4) the manufacturer, model number, serial number and type of each radiation machine located within the facility;~~

~~(5) the date of the application and the signatures of the persons specified in Subparagraphs (b)(2) and (3) of this Rule.~~

(a) A person with an unregistered facility, radiation machine, radiation generating device, or an unregistered service provider, shall apply for registration with the agency. After submitting the required application forms prescribed by the agency in this Rule, registration of the first radiation machine, radiation generating device, or registration of services provided, constitutes registration of the facility or service provider.

(b) All application forms in this Rule shall be completed by meeting the following requirements:

(1) The individual with administrative control of a radiation machine, radiation generating device, or that is responsible for providing services shall ensure application forms, required by the agency in this Rule, meet the following requirements:

(A) are accurate, complete, and contain all the information required by the application forms and accompanying instructions; and

(B) submitted to the agency at the e-mail address on the application for registration forms or mailed to the address in Rule .0111 of this Chapter.

(2) Incomplete application forms or application forms submitted without the requested documentation to provide services, will not be processed.

(3) The agency may require additional information at any time after submission of the application to determine if the notice of registration should be issued or denied.

(4) Application forms can be found at https://radiation.ncdhhs.gov/Xray/applic.htm.

(c) A Business Application form shall be submitted prior to the operation of a facility or providing services in this state and the following additional requirements shall be met:

(1) The application shall be submitted by any person:

(A) with one or more radiation machines at a facility; or

(B) that plans to engage in services listed in Subparagraphs (f) and (g) of this Rule.

(2) The application form requires the following:

(A) indication if the application is for a new facility, a change of ownership, when a facility moves, or to update information by marking the corresponding checkbox;

(B) the legal business name, facility physical address, phone number, type of business, days and hours of operation;

(C) the name, title, mailing address, phone, and e-mail address of business manager;

(D) the name of the individual on-site who is responsible for radiation protection. The training and experience qualifying him or her to perform the job duties and responsibilities in Rule .0211 of this Section, shall be documented on the application;

(E) the name, title, mailing address, phone, and e-mail address for the invoice contact;

(F) description of facility use;

(G) description of service provider equipment;

(H) dated and signed by the owner or the individual with administrative control; and

(I) identify equipment forms included with the application form by marking the corresponding checkbox.

(d) Equipment application forms shall be submitted in accordance with Rule .0204(c)(1) through (5) of this Section, for the type of radiation machine or radiation generating device in use or the service provided. The following additional requirements shall be met:

(1) The application shall be submitted by any person:

(A) with one or more unregistered radiation machines or radiation generating devices at a facility; or

(B) that is engaged in leasing or performing demonstrations using an unregistered radiation machine or radiation generating device.

(2) The application requires the following information:

(A) registration number;

(B) equipment location; manufacturer, model, serial number, number of tubes, install date, modality, application, type, and use;

(C) location of equipment not in use;

(D) installer information; and

(E) shall be dated and signed by the individual with administrative control. The individual with administrative control can delegate a responsible person or persons within the organization to sign when amendments are made to this form by notifying the agency in writing.

(e) A Delete X-Ray Equipment form shall be submitted when a facility disposes of a radiation machine or radiation generating device. The agency form requires the following information:

(1) registration number, facility name, and physical address;

(2) identify if the application is for a new facility, for a change of ownership, a facility moves, or to update information;

(3) equipment location; manufacturer, model, serial number;

(4) identify the reason for deleting the equipment;

(5) the recipient of the equipment, to the individual or business name, physical and e-mail address, and phone number; and

(6) dated and signed by the owner or the individual with administrative control of the radiation machine or radiation generating device.

(f) A Company Service application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (C) of this Paragraph and the following additional requirements shall be met:

(1) The application shall be submitted by any person engaged in:

(A) direct sales, transfer, leasing, or demonstration of radiation machines or radiation generating devices;

(B) providing individual monitoring devices; and

(C) radiation survey equipment calibration.

(2) The application requires the following information:

(A) registration number;

(B) business name, facility physical address;

(C) identify if the application is for a new service provider, for a change of ownership, if a facility moves, or to update information;

(D) identify each class and modality of services requested to be provided in the state;

(E) submit the requirements listed on the agency form for each class and modality requesting to provide services in the state;

(F) list any class or modality not listed on this form;

(G) description of service provider equipment used for output measurements and surveys; and

(H) signature of the individual with administrative control.

(g) A Company Employee Services application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (H) of this Paragraph and the following additional requirements shall be met:

(1) The application shall be submitted by any person engaged in providing the following services:

(A) area radiation surveys for diagnostic radiographic and fluoroscopy facilities;

(B) equipment surveys and shielding designs for radiation generating devices;

(C) general health physics consulting services to perform dose estimates, radiation output measurements, radiation safety program development, and radiation safety program training;

(D) installation or service repair of radiation machines or radiation generating devices;

(E) qualified expert consulting services for CT and mammography radiation machines;

(F) radiation protection expert;

(G) shielding designs for diagnostic radiographic and fluoroscopy facilities; and

(H) therapeutic facility and shielding design, area radiation survey, or calibration.

(2) The application requires the following information:

(A) name of the employee to be registered;

(B) start date if the employee is being added and the stop date if the employee is being removed from the registration;

(C) business registration number, name, physical address, and contact e-mail;

(D) identify class and modality of services to be provided;

(E) training and experience to submit for each class of services to be provided;

(F) the date and signature of the employee applying for registration;

(G) the date and signature of the individual with administrative control; and

(H) any additional information the agency determines to be necessary for evaluation of the application for registration.

(h) The following general requirements apply to all facilities and services provided in North Carolina.

(1) The registrant shall notify the agency when any change will render the information in an application for registration or notice of registration no longer accurate.

(2) A registrant that terminates all activities of radiation machines, radiation generating devices, or providing services shall meet the following requirements within 30 days:

(A) request termination of the notice of registration in writing by the owner or the individual with administrative control;

(B) submit to the agency, a delete a radiation machine or radiation generation device form, in accordance with Paragraph(e) of this Rule; and

(C) pay any outstanding fees pursuant to Rule .1100 of this Chapter.

(3) A registrant shall not transfer the registration as part of a change of ownership.

(4) A person who takes possession of a radiation machine or radiation generating device because of bankruptcy, foreclosure, or state auction may possess the machine or device when the following additional requirements are met:

(A) The machine or device shall be posted stating that the new owner is responsible for registering with the agency if used in this state.

(B) If the machine or device is energized, it shall only be energized by someone registered in accordance with this Section and only to demonstrate that it is operable for sale or transfer.

(5) No person shall in any advertisement refer to the fact that his or her facility is registered with the agency pursuant to the provisions of Rule .0204 or .0205 of this Section, and no person shall state or imply that under such registration any activities have been approved by the agency.

History Note: *Authority G.S. 104E-7; 104E-12; 104E-20;*
Eff. February 1, 1980;
Amended Eff. May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0203 Eff. February 1, ~~2015.~~ 2015;
Readopted May 1, 2025.

10A NCAC 15 .0204 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0204 ~~PROHIBITED SERVICES AND INSTALLATION~~ FACILITY RESPONSIBILITIES

~~(a) Except as provided in Paragraph (b) of this Rule or otherwise authorized in writing by the agency, each person registered pursuant to Rule .0203 of this Section shall prohibit any person from furnishing equipment services described in Rule .0205(d) of this Section to his facility until such person provides evidence that he is currently registered with the agency as a provider of such services in accordance with Rule .0205 of this Section.~~

~~(b) No person registered pursuant to the provisions of Rule .0203 of this Section shall perform any services listed in Rule .0205(d) of this Section in his facility unless such person satisfies the applicable requirements in Rules .0205, .0213, and .0214 of this Section and has received written authorization from the agency to perform such services.~~

(a) All forms in this Rule shall be completed in accordance with Rule .0203 of this Section and any accompanying instructions.

(b) Shielding design requirements:

(1) Prior to construction for all new installations of radiation machines for human or veterinary use and prior to structural modification of existing installations, an applicant, shall have the floor plans, shielding specifications, and equipment arrangement reviewed by a registered service provider. Prior to replacing a radiation machine, a registered service provider shall review the shielding plan acknowledged by the agency. The service provider shall provide documentation to the registrant if the existing shielding design, acknowledged previously by the agency, meets the requirements of this Chapter.

(2) The service provider shall submit the shielding design and the agency shielding design review form to the agency for review. The agency form shall include the following information:

(A) facility and service provider name, registration number, e-mail and physical address, and phone number;

(B) equipment location, manufacturer, status, kVp, mA, mA min per week, facility type; and

(C) proposed date of installation.

(3) The radiation machine shall not be installed until the applicant has received acknowledgment of the shielding design from the agency.

(4) A radiation machine shall not be replaced until a registered service provider confirms and documents that the existing shielding design, acknowledged previously by the agency, meets the requirements of this Chapter. The documentation provided to the registrant from the service provider shall be maintained for agency review.

(5) The acknowledgment of such plans shall not preclude the requirement for additional modifications should a subsequent analysis of operating conditions indicate the possibility of a dose that exceeds the limits in Rule .1601 of this Chapter.

(6) Shielding designs are not required to be submitted for any of the following:

(A) bone densitometers;

(B) dental handheld radiation machines;

(C) mammography; or

(D) mobile or portable radiographic machines used in one or two locations.

(c) Facility registration

(1) Radiation machines for human or veterinary use shall meet the following requirements within 30 days of initial use:

(A) have a shielding design acknowledged by the agency in accordance with Paragraph (b) of this Rule; and

(B) submit an equipment application in accordance with Rule .0203 (d) of this Section.

(2) Mobile services using radiation machines or radiation generating devices shall meet the following requirements prior to use:

(A) submit a shielding design in accordance with Paragraph (a) of this Rule for fixed radiation machines used in a vehicle or trailer, except out-of-state fixed radiation machines used in a vehicle or trailer shall submit a shielding design with the equipment application in Part B of this Subparagraph and maintain documentation in accordance with .0208(d) of this Section for agency review;

(B) submit an equipment application in accordance with Rule .0203 (d) of this Section;

(C) submit a copy of operating and safety procedures to protect patients, operators, and the public from radiation that exceeds doses in Rule .1601 of this Chapter;

(D) receive a notice of registration from the agency; and

(E) the individual with administrative control shall ensure that radiation machines or radiation generating devices are operated in accordance with (c)(4)(B) or (c)(5)(B).

(3) Radiation machines for clinical studies, research, and screenings shall meet the following requirements prior to use:

(A) submit a request in accordance with Rule .0213 of this Section; and

(B) receive a notice of acknowledgment and conditions from the agency to conduct the study.

(4) Radiation generating devices in Section .0800 of this Chapter shall meet the following requirements prior to the use of the radiation generation device:

(A) submit an equipment application in accordance with Rule .0203(d) of this Section; and

(B) the individual with administrative control shall ensure operators are qualified in accordance with Rule .0800 of this Chapter to use the radiation generating device indicated on the equipment application.

(5) Industrial radiography radiation machines in Section .0500 of this Chapter shall meet the following requirements prior to use:

(A) submit an equipment application in accordance with Rule .0203(d) of this Section; and

(B) the individual with administrative control shall ensure operators are qualified in accordance with Section .0500 of this Chapter to use the machines indicated on the equipment application.

(d) Persons registered pursuant to Paragraph (c) of this Rule shall notify the agency, using the Delete Radiation Machine or Radiation Generating Devices form, prior to the transfer of a registered radiation machine or radiation generating device to another person required to be registered pursuant to Paragraph (c) of this Rule.

(e) Persons registered pursuant to .0203(c) of this Rule shall prohibit any person from furnishing services described in Rule .0205(d) of this Section, at his or her facility, until such person provides evidence they are currently registered with the agency as a provider of such services in accordance with Rule .0205 of this Section.

(f) No person registered pursuant to the provisions of Paragraph (c) of this Rule shall perform any services listed in Rule .0205(d) of this Section in his or her facility unless such person meets the requirements in Rules .0205 and .0206 of this Section and has received written authorization from the agency to perform such services.

History Note: *Authority G.S. 104E-7; 104E-9(a)(3); 104E-12;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0204 Eff. February 1, ~~2015.~~ 2015;
Readopted May 1, 2025.

10A NCAC 15 .0205 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0205 ~~APPLICATION FOR REGISTRATION OF SERVICES~~ SERVICE PROVIDER RESPONSIBILITIES

(a) Each person who is engaged in the business of ~~installing or offering to install radiation machines and machine components or is engaged in the business of~~ furnishing or offering to furnish any ~~equipment~~ services listed in Paragraph ~~(d)~~ (e) of this Rule in this ~~state, to any agency licensee or registrant,~~ state or any agency registrant shall apply for registration of such services with the agency prior to furnishing or offering to furnish any of these services.

(b) ~~Application~~ Applications for registration shall be completed ~~on appropriate form(s) provided by the agency~~ in accordance with Rule .0203 of this Section and contain all information required by the agency as indicated on the form and accompanying instructions. ~~This information shall include:~~

~~(1) the name, address and telephone number of:~~

~~(A) the individual or the company to be registered;~~

~~(B) the owner(s) of the company;~~

~~(2) the description of the services to be provided;~~

~~(3) the name, training and experience of each person who provides services specified in Paragraph (d) of this Rule;~~

~~(4) the date of the application and the signature of the person responsible for the company; and~~

~~(5) any additional information the agency determines to be necessary for evaluation of the application for registration.~~

(c) Each person applying for registration ~~under~~ pursuant to Paragraph (a) of this Rule shall certify that he or she has read and understands the requirements of the rules in this ~~Chapter.~~ Chapter by signing the company or employee services application.

~~(d) For the purpose of this Section, equipment services include:~~

~~(1) direct sale and transfer of radiation machines and machine components to end users;~~

~~(2) installation or servicing of radiation machines and associated radiation machine components;~~

~~(3) diagnostic radiographic facility and shielding design;~~

~~(4) diagnostic fluoroscopic facility and shielding design;~~

~~(5) diagnostic area radiation survey, e.g., shielding evaluation;~~

~~(6) radiation instrument calibration;~~

~~(7) therapeutic facility and shielding design, area radiation survey or calibration;~~

~~(8) personnel dosimetry services; and~~

~~(9) general health physics consulting, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, non-healing arts facility and shielding design and area radiation surveys.~~

(d) Applicants for registration of services are subject to the requirements of Rules .0206 and .0207 of this Section.

~~(e) Applicants for registration of services are subject to the applicable requirements of Rules .0213 and .0214 of this Section.~~

(e) For purposes of this Section, services include:

(1) area radiation surveys and shielding evaluations for diagnostic radiographic and fluoroscopy facilities;

(2) direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices;

(3) general health and medical physics consulting to include the following services:

(A) equipment surveys and shielding designs for radiation generating devices;

(B) dose estimates;

(C) radiation output measurements;

(D) radiation safety program development; and

(E) radiation safety program training.

(4) installation or service repair to include the following:

(A) radiation machines and machine components, including the making of diagnostic radiation output measurements; or

(B) radiation generating devices to include equipment surveys.

(5) manufacturer training for the use of radiation machines or radiation generating devices;

(6) providing individual monitoring devices;

(7) a radiation protection expert;

(A) developing radiation safety programs;

(B) performing output measurements; and

(C) providing radiation safety program training.

(8) radiation survey equipment calibrations;

(9) shielding designs for diagnostic radiographic and fluoroscopy facilities; and

(10) therapeutic facility and shielding design, area radiation survey, or calibration.

(f) Persons registered pursuant to Subparagraph(e)(7) of this Rule shall have all surveys, reports, or other work performed, reviewed and signed by a general health or medical physicist registered in accordance with this Rule.

(g) Report of installation

(1) Persons, registered pursuant to Paragraph (a) of this Rule, who sell, lease, transfer, lend, dispose of, or install radiation machines in this state shall, within 15 days after each calendar quarter, notify the agency at XrayNORS@dhhs.nc.gov or the address in accordance with Rule .0111 of this Chapter of the following:

(A) whether any radiation machines were installed, transferred, or disposed of during the calendar quarter;

(B) the name and address of persons who received radiation machines during the calendar quarter;

(C) the manufacturer, model, and serial number of each radiation machine transferred or disposed of; and

(D) the transfer date of each radiation machine.

(2) The information specified in Parts (g)(1)(A) through (D) of this Rule may be omitted from the quarterly reports when the following requirements are met:

(A) for any diagnostic x-ray system that contains certified components when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is submitted to the agency; or

(B) for radiation machines for non-human use and radiation generating devices, when a report of sale and installation pursuant to Paragraph (h) of this Rule is submitted to the agency.

(h) A report of sale and installation of radiation generating devices shall include the following information:

(1) facility registration number, street address, city, state, and telephone number;

(2) service provider registration number, company name, street address, city, state, and telephone number;

(3) identify if the radiation machine or the radiation generating device was sold or installed by checking the corresponding checkbox;

(4) identify the system type by checking the corresponding checkbox;

(5) room location, date of sale or installation;

(6) manufacturer, serial number, and control model number;

(7) the seller's signature or signature of the individual responsible for installation; and

(8) the date signed.

(i) No person registered pursuant to Paragraph (a) of this Rule for x-ray sales or installations shall make, sell, lease, transfer, lend, assemble, or install radiation machines, radiation machine components, or radiation generating devices unless such machines and devices when placed in operation shall meet the requirements of these Rules.

(j) No person registered pursuant to Rule .0205 of this Section shall install radiation machines that are subject to provisions of Section .0600 of this Chapter unless the registrant first determines that the agency has issued a written acknowledgment of a shielding design in accordance with Rule .0204(b) of this Section.

(k) Tests performed at the time of installation for fluoroscopy machine output measurement and radiation generating devices equipment surveys, demonstrating the requirements of these Rules are met, shall be provided to the registrant at the time of installation.

(l) Records of any routine maintenance, repair, alterations, or reassembly of radiation machines or radiation generating devices shall:

(1) include the date that the service was performed and a legible signature of the person performing the service; and

(2) be provided to the registrant when the service is provided.

History Note: *Authority G.S. 104E-7; 104E-12; 104E-20;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0205 Eff. February 1, ~~2015.~~ 2015;
Readopted May 1, 2025.

10A NCAC 15 .0206 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0206 ~~REPORTS OF INSTALLATION~~ TRAINING AND EDUCATIONAL REQUIREMENTS TO PROVIDE SERVICES

~~(a) Persons, registered pursuant to Rule .0205 of this Section, who sell, lease, transfer, lend, dispose of, assemble or install radiation machines in this state shall, within 30 days after each calendar quarter, notify the agency at the address in Rule .0111 of this Chapter, of:~~

~~(1) whether any radiation machines were installed, transferred, or disposed of during the calendar quarter;~~

~~(2) the name and address of persons who received radiation machines during the calendar quarter;~~

~~(3) the manufacturer, model and serial number of each radiation machine transferred or disposed of;~~

~~(4) the date of transfer of each radiation machine.~~

~~(b) The information specified in Subparagraphs (a)(2), (3) and (4) of this Rule may be omitted from the quarterly reports required in (a) of this Rule for any diagnostic x-ray system which contains certified components when a copy of the assembler's report prepared in compliance with 21 CFR 1020.30(d) is submitted to the agency.~~

(a) A person registered to provide services pursuant to Rule .0205 of this Section shall be qualified by reason of education, training, and experience to provide the services for which registration is requested. The following are the minimum qualifications for specific types of services:

(1) Class I - direct sales, transfer, leasing, lending, demonstration, or manufacturer training for the use of radiation machines or radiation generating devices: The applicant shall certify all persons providing services are knowledgeable, familiar, and comply with the rules which govern the possession, installation, and use of radiation machines in North Carolina.

(2) Class II - installation or service to verify performance associated with the installation or service:

(A) manufacturer's equipment school for service, maintenance, and installation for the type of radiation machine used for dental hand-held, intraoral, and extra-oral, medical diagnostic, or medical fluoroscopic or equivalent training;

(B) training in basic principles of radiation protection; and

(C) three months of experience in the installation and service of radiation machines and machine components services are requested.

(3) Class III –shielding design for diagnostic radiographic facilities:

(A) training in basic principles of radiation protection;

(B) training in shielding design for each modality registering to provide services; and

(C) one year of experience in diagnostic radiographic facility and shielding for the specific type of machine application.

(4) Class IV - shielding design for diagnostic fluoroscopic facilities:

(A) training in basic principles of radiation protection;

(B) training in shielding design for each modality registering to provide services; and

(C) one year of experience in diagnostic fluoroscopic facility and shielding for the specific type of machine application.

(5) Class V - area radiation surveys and shielding evaluation for diagnostic radiographic and fluoroscopy facilities:

(A) training in basic principles of radiation protection;

(B) training in shielding evaluation for each modality registering to provide services; and

(C) one year of experience performing area radiation surveys for the specific type of machine application.

(6) Class VI - radiation instrument calibration: The applicant must possess a current radioactive materials license or registration authorizing radiation instrument calibration.

(7) Class VII - therapeutic facility and shielding design, area radiation survey, or calibration:

(A) certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics;

(B) certification by the American Board of Medical Physics; or

(C) have a master's degree in physics, biophysics, radiological physics, or health physics, one year of full-time training in therapeutic radiological physics, one year of full-time experience in a therapeutic facility including personal calibration and spot-check of at least one machine, submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed, submit a copy of all forms, reports, and documents that will be supplied to customers; and submit one sample of each specific type of therapy modality service provided.

(8) Class VIII – providing individual monitoring dosimetry: The applicant must hold current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology or use NVLAP-accredited dosimetry.

(9) Class IX - general health or medical physics consulting shall be performed by a person meeting one of the following requirements:

(A) certified by the American Board of Health Physics in health physics in the appropriate field or specialties for services provided;

(B) certified by the American Board of Medical Physics;

(C) certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, x-ray and radium physics; or

(D) hold a master’s or doctorate in physics, medical physics, other physical science, engineering, or applied mathematics, from an accredited college or university and have 40 hours of practical training or supervised experience in x-ray physics.

(10) Class X - radiation protection expert:

(A) having education and experience equivalent to a graduate or a master's degree from an accredited college or university in radiation protection, radiation safety, biology, chemistry, engineering, physics, or a closely related physical or biological science; and

(B) acquired competence in radiation protection, by receiving special studies, training, and practical experience. Such special studies and training must have been sufficient in the above sciences to provide the understanding, ability, and competency.

(b) Any person registered to provide Class IX services prior to the effective date of this rule and holding a baccalaureate degree in physical science of physics, chemistry, or radiologic science, engineering or related field, and having two years of progressive experience in medical or health physics or two years of graduate training in medical or health physics is exempt from the requirements in Subparagraphs (a)(9)(A) through (D) of this Rules, provided he or she is in good standing with the agency.

(c) The agency shall initiate action to terminate the registration of any person who fails to meet the requirements of this Rule.

History Note: *Authority G.S. 104E-7; ~~104E-12;~~ 104E-13;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0206 Eff. February 1, ~~2015.~~ 2015;
Readopted May 1, 2025.

10A NCAC 15 .0207 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0207 ~~ISSUANCE OF NOTICE OF REGISTRATION~~ ADDITIONAL REQUIREMENTS TO PROVIDE SERVICES

~~(a) The agency shall issue a notice of registration upon a determination that an applicant:~~

~~(1) is qualified by reason of education, training or experience in the use and hazards of radiation sources described in the application for registration;~~

~~(2) has facilities and equipment which meet the requirements in these Rules;~~

~~(3) has established a radiation protection program, appropriate to the registered activities, which assures compliance with radiation protection requirements in these Rules; and~~

~~(4) meets the applicable requirements in this Chapter.~~

~~(b) The agency may, by registration condition or order, when not in conflict with any law, waive any requirement in these Rules or impose requirements with respect to the registrant's receipt, possession, use and transfer of radiation machines as the agency deems appropriate or necessary for compliance with the rules in this Chapter. Such additional requirements are subject to appeal under 15A NCAC 1B .0200.~~

~~(c) The agency may refuse to grant a registration required in Rules .0203 and .0205 of this Section to any applicant who does not possess adequate qualifications or equipment or satisfy the applicable requirements in this Chapter; provided that, before any order is entered denying an application for registration, the agency shall give notice and grant a hearing as provided in G.S. 150B.~~

(a) A person applying for registration of diagnostic area radiation survey, diagnostic radiation output measurements, or therapeutic calibration services pursuant to Rule .0205 of this Section shall meet the following additional requirements:

(1) The applicant shall have radiation survey and radiation measurement equipment appropriate to the services requested for authorization.

(2) The applicant shall ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated at least every 12 months by a person registered to provide such services pursuant to Rule .0205 of this Section, except as provided in Subparagraph (a)(3) of this Rule. The agency may approve less frequent calibration of equipment used, provided the applicant satisfies to the agency that the proposed frequency and procedures will provide equivalent or better assurance of proper calibration.

(3) The applicant may perform the equipment calibrations required in Subparagraph (a)(2) of this Rule provided that:

(A) such calibrations are current and traceable to the National Institute of Standards and Technology;

(B) calibration procedures are approved by the agency;

(C) radiation sources used for such calibration are licensed or registered as required by the rules in this Chapter; and

(D) the equipment is labeled to indicate the date of calibration and records of the calibration are maintained.

(4) The applicant shall submit:

(A) a description of the procedures that will be used in performing area radiation surveys including a list of all guides and references to the employed;

(B) a copy of all forms, reports, and documents that will be supplied to customers;

(C) samples of three different types of surveys;

(D) samples of three reports of diagnostic radiation output measurements; and

(E) samples of three therapeutic kV imaging calibration reports.

(b) A person applying for registration of diagnostic radiographic, fluoroscopic, and therapeutic facility and shielding design services shall meet the following additional requirements:

(1) The applicant shall submit examples of the facility and shielding design which will be provided to registrants.

(2) The applicant shall submit examples of the calculations, which will be performed as part of the facility and shielding design, along with any guides, occupancy factor rationales, and workload estimation rationales, that will be used.

(3) The applicant shall ensure that the facility and shielding design services provided to registrants of the agency meet the requirements in this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0207 Eff. February 1, 2015.
Readopted May 1, 2025.

10A NCAC 15 .0208 is proposed for amendment as follows:

10A NCAC 15 .0208 ~~PRIOR NOTIFICATION OF TRANSFER~~ OUT-OF-STATE RADIATION MACHINES AND RADIATION GENERATION DEVICES

~~(a) Persons registered pursuant to Rule .0203 of this Section shall notify the agency in writing prior to transfer of a registered radiation machine to another person required to be registered pursuant to Rule .0203(a) of this Section. This Rule does not prohibit transfer without prior notification to sales and service companies registered pursuant to Rule .0205 of this Section.~~

~~(b) The notification shall include:~~

~~(1) the name and address of the transferee, and~~

~~(2) the manufacturer, model number and serial number of the radiation machine to be transferred.~~

(a) No person shall bring any radiation machine or radiation generating device into the state, for any temporary use, unless such person has given a written notice to the agency at least five working days prior to use in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine or radiation generating device will be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he or she may, upon application to the agency, obtain permission to proceed sooner.

(b) A person bringing a radiation machine or radiation generating device into this state, for any temporary use, shall meet the following requirements:

(1) complete the registration process in accordance with Rule .0203 and .0204 of this Section prior to beginning operations in this state;

(2) supply the agency with other information the agency may reasonably request; and

(3) comply with the Rules of this Chapter.

(c) The out of state registrant shall maintain, in possession of the radiation machine or radiation generating device when used in this state, the following:

(1) the current notice of registration from this agency;

(2) a copy of the notice submitted to the agency in accordance with Paragraph (a) of the Rule;

(3) the shielding design, if required, in accordance with Rule .0204(c)(2)(A) of this Section; and

(4) a copy of the out of state registrant's operating and safety procedure.

(d) An inspection may be conducted by an authorized representative of the agency on any radiation machine or radiation generating device used in this state.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0208 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;

1 *Amended May 1, 2025.*

10A NCAC 15 .0209 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0209 ~~REPORT OF CHANGES~~ ISSUANCE OF NOTICE OF REGISTRATION

~~Any registrant shall notify the agency in writing when any change will render the information contained in the application for registration or notice of registration no longer accurate.~~

(a) The agency shall issue a notice of registration upon a determination that an applicant:

(1) is qualified by reason of education, training, or experience in the use and hazards of radiation sources described in the application for registration;

(2) has facilities and equipment which meet the requirements in these Rules;

(3) has established a radiation protection program, appropriate to the registered activities, which assures compliance with radiation protection requirements in these Rules; and

(4) meets the applicable requirements in this Chapter.

(b) The agency may, by registration condition or order, when not in conflict with any law, waive any requirement in these Rules or impose requirements with respect to the registrant's receipt, possession, use, and transfer of radiation machines or radiation generating devices as the agency deems appropriate or necessary for compliance with the rules in this Chapter.

(c) The agency may refuse to grant a registration required in Rules .0203, .0204, and .0205 of this Section to any applicant who does not possess adequate qualifications or equipment or satisfy the applicable requirements in this Chapter; provided that, before any order is entered denying an application for registration, the agency shall give notice and grant a hearing as provided in G.S. 150B.

History Note: *Authority G.S. 104E-7; ~~104E-12;~~*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0209 Eff. February 1, ~~2015.~~ 2015;
Readopted May 1, 2025.

10A NCAC 15 .0210 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0210 ~~OTHER PROHIBITED ACTIVITIES~~ MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRATIONS

~~(a) No person registered pursuant to Rule .0205 of this Section for x-ray sales or installations shall make, sell, lease, transfer, lend, assemble, or install radiation machines or equipment used in connection with such machines unless such machines and equipment when placed in operation shall meet the applicable requirements of these Rules.~~

~~(b) No person, in any advertisement, shall refer to the fact that he or his facility is registered with the agency pursuant to the provisions of Rule .0203 or .0205 of this Section and no person shall state or imply that any activity under such registration has been approved by the agency.~~

~~(c) No person registered pursuant to Rule .0205 of this Section shall install radiation machines which are subject to provisions of Section .0600 of this Chapter unless the registrant first determines that the agency has issued written acknowledgement of receipt of any facility and shielding design required in Rule .0603 of this Chapter.~~

(a) The terms and conditions of all registrations are subject to amendment, revision or modification and all registrations are subject to suspension or revocation by reason of:

(1) rules adopted pursuant to provisions of the Act; or

(2) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.

(b) Any registration may be revoked, suspended, or modified in whole or in part:

(1) for any material false statement in the application or in any statement of fact required by provisions of this Section;

(2) because of conditions that would warrant the agency to refuse to grant a registration on original application revealed by:

(A) the application;

(B) any statement of fact;

(C) any report, record, inspection, or other means; or

(3) for violations of, or failure to observe any of the terms and conditions of the Act, the registration, the rules of this Chapter, or the order of the agency.

(c) Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a registrant, the agency shall:

(1) call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and

(2) provide an opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.

(d) Before any order is entered suspending, revoking, or modifying a registration, the agency shall give notice and grant a hearing as provided in Chapter 150B of the North Carolina General Statutes.

(e) The agency may terminate a registration upon written request submitted by the registrant to the agency.

History Note: *Authority G.S. 104E-7; ~~104E-20;~~ 104E-13;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0210 Eff. February 1, ~~2015.~~ 2015;
Readopted May 1, 2025.

10A NCAC 15 .0211 is proposed for amendment as follows:

10A NCAC 15 .0211 ~~OUT-OF-STATE RADIATION MACHINES~~ INDIVIDUAL RESPONSIBLE FOR RADIATION PROTECTION REQUIREMENTS AND RESPONSIBILITIES

~~(a) No person shall bring any radiation machine into the state, for any temporary use, unless such person has given a written notice to the agency at least five working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine is to be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he may, upon application to the agency, obtain permission to proceed sooner.~~

~~(b) The person in Paragraph (a) of this Rule shall:~~

~~(1) comply with all applicable rules in this Chapter, including registration pursuant to Rule .0203 of this Section; and~~

~~(2) supply the agency with such other information as the agency may reasonably request.~~

(a) A person applying for registration shall designate an individual responsible for radiation protection on the Business Application form pursuant to Rule .0203(c) of this Section. The individual shall be qualified by reason of education, training, and experience commensurate with the registration requested. The following are the minimum qualifications that must be met to carry out the job duties:

(1) training in basic radiation protection principles;

(2) completed educational courses relating to ionizing radiation;

(3) know potential radiation hazards and emergency precautions; and

(3) training and experience in and knowing the proper use of the type of equipment used.

(b) The individual shall be responsible for the following:

(1) Establishing and overseeing operating and safety procedures:

(A) that maintain radiation exposures as low as reasonably achievable (ALARA); and

(B) to review the procedures annually, or when changes occur to ensure the procedures are current.

(2) Ensuring individual monitoring devices are used in accordance with these Rules by occupationally exposed personnel and records of monitoring results shall be:

(A) reviewed;

(B) maintained; and

(C) notifications are made in accordance with Section .1601 of this Chapter.

(3) Ensuring that personnel are complying with:

(A) this Chapter;

(B) the conditions of the notice of registration; and

(C) the operating and safety procedures of the registrant.

(4) Knowing:

(A) the management policies and administrative procedures of the registrant; and

(B) keeping management informed of the registrant's radiation protection program.

(5) Investigating and reporting to the agency:

(A) known or suspected radiation exposure to an individual; or

(B) radiation levels that exceed the limits in this Chapter.

(6) Assuming control and having the authority to carry out corrective actions including stopping operations in emergencies or unsafe conditions.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0211 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended May 1, 2025.

10A NCAC 15 .0212 is proposed for amendment as follows:

10A NCAC 15 .0212 ~~**MODIFICATIONS: REVOCATION: TERMINATION OF REGISTRANTS**~~ **RADIATION MACHINES AND RADIATION GENERATING DEVICES THAT DO NOT MEET EQUIPMENT REQUIREMENTS**

~~(a) The terms and conditions of all registrations are subject to amendment, revision or modification and all registrations are subject to suspension or revocation by reason of:~~

~~(1) rules adopted pursuant to provisions of the Act; or~~

~~(2) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.~~

~~(b) Any registration may be revoked, suspended or modified in whole or in part:~~

~~(1) for any material false statement in the application or in any statement of fact required by provisions of this Section;~~

~~(2) because of conditions which would warrant the agency to refuse to grant a registration on original application revealed by:~~

~~(A) the application;~~

~~(B) any statement of fact;~~

~~(C) any report, record, inspection or other means; or~~

~~(3) for violations of, or failure to observe any of the terms and conditions of the Act, the registration, the rules of this Chapter, or order of the agency.~~

~~(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, prior to the institution of proceedings for modification, revocation or suspension of a registrant, the agency shall:~~

~~(1) call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and~~

~~(2) provide an opportunity for the registrant to demonstrate or achieve compliance with all lawful requirements.~~

~~(d) Before any order is entered suspending, revoking or modifying a registration, the agency shall give notice and grant a hearing as provided in Chapter 150B of the North Carolina General Statutes.~~

~~(e) The agency may terminate a registration upon written request submitted by the registrant to the agency.~~

(a) Radiation machines that are not able to meet the equipment requirements of these Rules shall not be sold, installed, or used prior to the agency completing a review of information regarding the radiation machine and determining if the use of the radiation machine is allowed. The user or manufacturer of the radiation machine shall submit the following to the agency for review:

(1) an equipment application form in accordance with .0204(c) of this Section;

(2) the manufacturer manual;

(3) description of intended use;

(4) operator training provided to the end user;

(5) an independent equipment survey to include the following:

(A) all equipment settings available to the operator;

(B) output at the highest setting;

(C) leakage radiation around the radiation machine;

(6) an area survey to include the following:

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

(B) the survey instrument used; and

(C) the name and legible signature of the person who performed the survey; and

(7) the hazard level associated with the use of the RGD.

(b) After receiving the information in Paragraph (a) of this Rule, the agency will respond to the applicant in writing within 90 days. Upon review, the agency may require additional information to determine if use of the radiation machine is allowed.

History Note: *Authority G.S. 104E-7; ~~104E-13;~~ 104E-20;*
Eff. June 1, 1989;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0212 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Amended May 1, 2025.

10A NCAC 15 .0213 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0213 ~~ADDITIONAL REQUIREMENTS: REGISTERED SERVICES~~ CLINICAL STUDIES, RESEARCH, AND SCREENING PROGRAM REQUIREMENTS

(a) ~~An applicant for registration of diagnostic area radiation survey, diagnostic radiation output measurements or therapeutic calibration services pursuant to Rule .0205 of this Section shall meet the following additional requirements:~~

~~(1) The applicant shall have adequate radiation survey and radiation measurement equipment appropriate to the services requested for authorization.~~

~~(2) The applicant shall ensure that the equipment in Subparagraph (a)(1) of this Rule is calibrated at least every 12 months by persons registered to provide such services pursuant to Rule .0205 of this Section, except as provided in Subparagraph (a)(3) of this Rule. The agency may approve less frequent calibration of equipment used for therapy calibration, provided the applicant satisfies the agency that the proposed frequency and procedures will provide equivalent or better assurance of proper calibration.~~

~~(3) The applicant may perform the equipment calibrations required in Subparagraph (a)(2) of this Rule provided that:~~

~~(A) such calibrations are currently traceable to the National Institute of Standards and Technology;~~

~~(B) the calibration procedures are approved by the agency;~~

~~(C) the radiation sources used for such calibration are licensed or registered as required by the rules in this Chapter; and~~

~~(D) the equipment is labeled to indicate the date of calibration and records of the calibration are maintained.~~

~~(4) The applicant shall submit:~~

~~(A) a description of the procedures that will be used in performing area radiation surveys including a list of all guides and references to the employed;~~

~~(B) a copy of all forms, reports and documents that will be supplied to customers;~~

~~(C) samples of three different types of surveys;~~

~~(D) samples of three reports of diagnostic radiation output measurements; and~~

~~(E) samples of three therapeutic calibration reports.~~

~~(b) An applicant for registration of services pursuant to Rule .0205 of this Section who proposes to provide diagnostic radiographic, fluoroscopic and therapeutic facility and shielding design services shall meet the following additional requirements:~~

~~(1) The applicant shall submit examples of the facility and shielding design which will be provided to clients.~~

~~(2) The applicant shall submit examples of the calculations which will be performed as part of the facility and shielding design along with any guides, occupancy factor rationales, and workload estimation rationales which will be used.~~

~~(3) The applicant shall ensure that the facility and shielding design services provided to licensees and registrants of the agency satisfy the applicable requirements in this Chapter.~~

(a) Persons proposing to conduct clinical studies, research, or screenings on humans may not initiate a program without receiving acknowledgment from the agency.

(b) A person shall provide to the agency a request to waive the requirements of Rule .0603(a)(1)(G) of this Chapter and receive an acknowledgment to initiate the program from the agency prior to conducting a clinical study, research, or screenings. Clinical studies and research programs that have received approval through an Institutional Review Board (IRB) are not exempt from meeting the requirements of this Section.

(c) A person requesting a waiver shall submit the following for agency review:

(1) Programs with an IRB approval:

(A) the study protocol submitted to the IRB;

(B) the IRB approval; and

(C) qualifications for radiation machine operators.

(2) Programs without an IRB approval:

(A) the registrant or applicant's business name, street address, city, state, and zip code;

(B) person(s) name proposing the research activity;

(C) a business address where all research activities will be conducted;

(D) contact name, telephone number, and e-mail address;

(E) copy of the informed consent provided to the subjects;

(F) machine model and serial number to be used;

(G) start and end date of the research program;

(H) description of the population to be examined in the program;

(I) purpose of the research program;

(J) diseases or conditions for which the examinations will be used in diagnosing;

(K) description of the X-ray procedure proposed in the program, the number of exposures, the number of procedures, total time involvement period for each subject;

(L) an evaluation of any known alternative methods not involving ionizing radiation that could achieve the goals of the screening program and reasons why these methods are not used instead of the x-ray examinations;

(M) name of the NC licensed practitioner who will supervise the program;

(N) name of the NC licensed practitioner(s) who will interpret images;

(O) qualifications for radiation machine operators;

(P) qualifications for the person who will supervise the radiation machine operators;

(Q) description of the methods used to advise the subjects and their physicians of the research program results;

(R) description of the quality control program;

(S) an evaluation by a medical physicist of the x-ray system to be used in the program. The evaluation by the medical physicist shall include a measurement of patient exposures from the x-ray examinations to be performed;

(T) description of the procedures for the retention or disposition of the images and other records pertaining to the X-ray exams; and

(U) plans for the radiation machine once the program is completed.

(d) After receiving the information in Paragraph (c) of this Rule, the agency will respond to the applicant in writing within 60 days. The agency may require additional information to complete the review.

(e) Nothing in this Rule relieves registrants from complying with the other requirements of this Chapter.

History Note: *Authority G.S. 104E-7;*
Eff. June 1, 1989;
Amended Eff. June 1, 1993;
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