Fiscal Impact Analysis of
Permanent Rule Amendment

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

Contact Persons Shanah Black, DHSR Rule-Making Coordinator: (919) 855-3811
Louis Brayboy, Radiation Protection Interim Section Chief: (919)814-2304
Denise Cloninger, Radiology Compliance Branch Manager: (919) 814-2330
Regina Kissinger, Healing Arts Health Physicist Supervisor: (919) 814-2335
James Albright, Environmental Programs Consultant: (919) 814-2251 (cell: (919) 604-4037)

Impact Summary

Federal Government:	No Impact
State Government:	Minimal Benefit
Local Government:	No Impact
Regulated Community:	Minimal Benefit
Substantial Impact:	No Impact

Rules without Changes

Rule Readoption:

10A NCAC 15 .0101	SCOPE
10A NCAC 15 .0102	COMPLIANCE WITH LAWS

Rules with Proposed Changes

Rule Readoption with Substantive Changes:

10A NCAC 15 .0103	DEFINITIONS
10A NCAC 15 .0104	INCORPORATION BY REFERENCE
10A NCAC 15 .0105	DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENCY
10A NCAC 15 .0106	INSPECTIONS AND TESTS
10A NCAC 15 .0107	IMPOUNDING
10A NCAC 15 .0108	ENFORCEMENT
10A NCAC 15 .0109	RECORDS
10A NCAC 15 .0110	PROHIBITED USES
10A NCAC 15 .0112	PETITIONING FOR RULE MAKING
10A NCAC 15 .0306	SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS
10A NCAC 15 .0311	PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL
10A NCAC 15 .0313	EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

Rule amendment:

10A NCAC 15 .1001	NOTICES, INSTRUCTIONS, AND REPORTS TO EMPLOYEES

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION

Rules Proposed for Repeal

Rule Repeals Through Readoption: 10A NCAC 15 .0114; .0115; .0116; .0117; .0118; .0316; .0345; .0346

Rule Repeal: 10A NCAC 15 .0323

*See text in Appendix

Rulemaking Authority G.S. 104E-2, 104E-7; 104E-7(a); 104E-7(a)(2); 104E-10; 104E-10(b); 104E-7; 104E-11; 104E-12; 104E-12(a); 104E-14; 104E-15(a); 104E-24; 104E-25(5)(b); 150B-19(5)(b); 150-B-21.6

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 Sections .0100, .1000, and .1600 of Chapter 15 apply to all persons who acquire, possess, receive, transfer of use any source of radiation in the state. Rules in Section .0300 of Chapter 15 regulate licensing of radioactive materials 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, Fourteen rules, Rules 10A NCAC 15 .0101 - .0110, .0112, .0306, .0311 and .0313 were determined to be "Necessary with Substantive Public Interest" and will be readopted with this rulemaking action. Eight rules, Rules 10A NCAC 15 .0114 - .0118, .0316, .0345, and .0346 were determined to be "Necessary with Substantive Public Interest" and will be readopted through repeals with this rulemaking action.

Two Rules, 10A NCAC 15. 1001 and .1601, are being amended during this rulemaking to account for changes being made during this rulemaking to the definitions Rule, 10A NCAC 15 .0103. Both of these rules were readopted prior to this rulemaking.

One Rule, previously readopted, is being repealed during this rulemaking because it becomes redundant after this rulemaking.

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 1000, 21 CFR 1002, 21 CFR 1003, 21 CFR 1010 and 21 CFR 1020[1] are incorporated by reference, including subsequent amendments and editions. The federal regulations are being incorporated by reference into Rules 10A NCAC 15 .0104(a)(1) (A) - (V).

Introduction

The North Carolina Department of Health and Human Services (DHHS), Division of Health Service Regulation (DHSR), Radiation Protection Section (RPS) regulates the use of use of radioactive materials and radiation machines in the State of North Carolina (NC). As part of the readoption process, these proposed 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 to existing requirements to remove ambiguity, make technical corrections, and update terminology. Additions to current rule language are to clarify existing requirements. The Radiation Protection Section intends the proposed rules for readoption to maintain current safety requirements for radiation workers and NC citizens.

With regard to the radioactive materials rules, Section 274 of the Atomic Energy Act of 1954, as amended, authorized the United States Nuclear Regulatory Commission (USNRC) to enter into an agreement with the states for the discontinuance of regulatory authority over some uses of radioactive materials and delegation of that regulatory authority to the states. The USNRC kept regulatory authority over activities such as nuclear power generation and common defense of the nation. North Carolina assumed responsibility for regulating the use of radioactive materials from the USNRC in 1964 by signing the "Agreement" and thus became what is known as an "Agreement State." In accordance with the Agreement, the USNRC assigns compatibility categories to different regulations.

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

Scope of Analysis

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

1. State Government: This includes entities like state educational institutions, hospitals, law enforcement agencies, and prisons.
2. Local Government: This includes educational institutions, county jails, county health departments, and local law enforcement.
3. Regulated Community – Private Sector: Various industries, such as food and beverage manufacturing and processing centers, fall under the private sector category. They employ RGDs for specific applications related to their industries, such as quality control in manufacturing processes.

Rule Changes and Anticipated Impacts

A description of each rule is provided below.

10A NCAC 15 .0103 - DEFINTIONS

The proposed rule readoption renames the rule title from "Intentional Exposures" and relocates the "Definitions" of the existing Rule 10A NCAC 0104 of Section .0100 to this Rule. The "Intentional Exposure" requirement has been removed from this Section due to being redundant and Rule .1601 of Section .1600 of this Chapter. The definitions being struck from the existing rule and that are not being readopted in this Rule, are now incorporated by reference in Section .0300 and apply to the same regulated community. The remaining definitions have been reorganized into paragraphs and subparagraphs providing clarity to the regulated community. Additionally common rules for licensees and registrants are combined while rules specific to licensees and registrants are now delineated.

- Paragraph (a) includes definitions common to licensees and registrants.
- Subparagraph (a)(5) is an added definition for the purpose of clarifying each month.
- Subparagraph (a)(6) has been renamed from existing Rule .0104(179) of this Section for the purpose of clarification. "Year" renamed to "Calendar Year".
- Subparagraph (a)(8) is an added definition to clarify the acronym "CFR" currently in 10A NCAC 15.
- Subparagraph (a)(14) is an added definition for clarification purposes.
- Paragraph (b) is a new paragraph containing definitions specific to registrants and the proposed rule changes are detailed below.
    - The following definitions have been updated to correct and clarify existing rule language. "Registrant" and "Registration".
    - The following definitions are used in existing rule language but were not previously defined. These terms have been added to clarify existing rule language, update outdated terminology and reflect current practices. "Clinical study", "Consulting", "Healing arts", "Individual responsible for radiation protection", "Install or installation", :"Licensed Practitioner", "Registered", "Service", and "Service provider".
- Paragraph (c) is a new paragraph relocating "Other definitions" from existing Rule .0105 so the definitions and the reference to other definitions will be in one Section.
- Paragraph (d) is a new paragraph containing definitions specific to licensees and the proposed rule changes are detailed below.

The proposed changes are not expected to result in an economic impact. The agency does expect the proposed changes to result in an unquantifiable reduction in the amount of time the regulated community and agency staff spend determining the applicable rules to achieve compliance while maintaining safety for radiation workers and

the states' citizens. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0104 – INCORPORATION BY REFERENCE

The proposed rule readoption renames the rule title from "Definitions" and relocates "Incorporation by Reference" of the existing Rule .0117 of this Section to this Rule. The "Incorporated by Reference" rules being struck from the existing rule that are not being readopted in this Rule, are now incorporated by reference by the rules in Sections .0200, .0300, and .0600 and apply to the same regulated community. There will be no change to the requirements the regulated community must meet because of this proposed rule change.

Paragraph (a)(1) incorporates several Sections of 21 CFR Subchapter J, including subsequent amendments and editions. This technical correction will provide clarity and increase comprehension of the proposed rule change while maintaining current safety and performance standards.

Paragraph (a)(2) incorporates the Agreement between the United States Atomic Energy Commission and the State of North Carolina. The Atomic Energy Commission is the forerunner to the USNRC.

Paragraph (b) informs licensees and registrants of the website addresses where copies of the federal documents incorporated by reference in Paragraph (a) of this Rule can be obtained.

The changes are not expected to result in an economic impact. The regulatory requirements remain unchanged in the proposed rule. The agency does expect the proposed changes to simplify and clarify this rule result in an unquantifiable reduction in the amount of time the regulated community and agency staff spend determining the applicable CFRs to achieve compliance. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0105 – DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENCY

The proposed rule change renames the rule title from "Other Definitions" and relocates "Designation of Authorized Representative of the Agency" of the existing Rule .0112 of this Section to this Rule.

- Paragraph (b) provides clarity when a public employee authorized by and designated by the agency to conduct tests or surveys will be conducted with an authorized representative of the agency.

The only change of note to this rule is administrative in nature that removes ambiguity and provides clarification to the regulated community. This will not impact the regulated community, stakeholders, or agency staff.

10A NCAC 15 .0106 – INSPECTIONS AND TESTS

The proposed rule change renames the rule title from "Exemptions". The following two rules are relocated and combined into this one rule. "Inspections" of the existing Rule .0107 and "Tests" of the existing Rule .0116 of this Section.

- Paragraph (a) is relocated from existing Rule .0107, "Inspections". The existing rules language is updated to clarify when inspection will be performed, during hours of operation. Additionally, this rule separates requirements into Subparagraphs for easier reading and to improve comprehension.
- Paragraph (a)(1) is a proposed paragraph that adds rule language to clarify who from the agency will do the inspection, what will be inspected, and the location(s) where inspections are performed.
- Paragraph (a)(2) is a proposed paragraph that adds rules language to clarify what must be

available to the agency. Additionally, a correction from existing language of these Rules to Rules in this Chapter, clarifying records shall be maintain for agency review, not just the records in this Section.

- Paragraph (b) is relocated from existing Rule .0116 of this Section.

The existing rule for both inspections and tests was combined because the tests in current rule are performed during an inspection. Combining the two rules into one rule will result in easier reading and better comprehension. There will be no change to the requirements the regulated community must meet because of this proposed rule change. This will not impact the regulated community, stakeholders, or agency staff.

10A NCAC 15 .0107 - IMPOUNDING

The proposed rule change renames the rule title from "Inspections" and relocates "Impounding" of the existing Rule .0109 of this Section to this Rule. There will be no change to the requirements the regulated community must meet because of this proposed relocation of the rule. This will not impact the regulated community, stakeholders, or agency staff.

10A NCAC 15 .0108 - ENFORCEMENT

The proposed rule change renames the rule title from "Additional Requirements" to "Enforcement". The requirement in existing Rule .0108(a) has been removed because it is a redundant rule in Rule .0207.

The changes proposed in Rule .0108 add rule language of when persons are subject to administrative penalties pursuant to G.S. 104E-24 of the North Carolina Radiation Protection Act. The agency does not broaden the scope of regulation with the addition of the rule language but seeks to remove ambiguity by clarifying the current provision of G.S 104E-24 for licensees, registrants, and stakeholders who must comply with the rules of 10A NCAC 15. The proposed changes will provide additional clarity to the regulated community which may result in incremental improvements to compliance. An improvement in compliance would result in a cost reduction for persons subject to administrative penalties being accessed. Furthermore, the agency expects additional clarity to result in opportunity savings for agency staff with anticipated incremental improvements to compliance. The changes are difficult to quantify, but the agency does expect a minimal benefit to the regulated community and agency.

10A NCAC 15 .0109 – RECORDS

The proposed rule change renames the rule title from "Impounding" and relocates "Records" of the existing Rule .0115 of this Section to this Rule.

- Paragraph (a) this proposed rule separates requirements into paragraphs and subparagraphs for easier reading and to improve comprehension.
- Subparagraph (a)(2) is a new Subparagraph that adds rule language for operator training. Operator training is an existing requirement.

There will be no change to the requirements the regulated community must meet because of this proposed rule change. The proposed changes will provide additional clarity to the regulated community which may result in incremental improvements to compliance by maintaining required records. This will not result in an economic impact to the regulated community, stakeholders, or agency staff.

10A NCAC 15 .0110 – PROHIBITED USES

The proposed rule change removes outdated technology, includes new technology, adds rule language to remove ambiguity of existing requirements when radiation machines or sources of radiation are used for

demonstration or training purposes.

- Item (1) adds rule language to clarify prohibiting use of radiation machines or sources of radiation when adequate shielding is not provided. Demonstration or training is used increasingly more in areas where multiple persons are present.
- Item (2) adds rule language to clarify that only dental hand-held radiation machines authorized for use by the agency may be used.

There will be no change to the requirements the regulated community must meet because of this proposed rule change. The agency does not expand the scope of regulation with the addition of the rule language but seeks to clarify the requirements for registrants and stakeholders who must comply with dose limits of 10A NCAC 15 .1601. The proposed changes will provide additional clarity to the regulated community for new technology of handheld radiation machines, which may result in a reduction in the cost for a person who may be unaware that only dental hand-held radiation machines authorized for use by the agency may be used. The changes are difficult to quantify, but the agency does expect a minimal benefit to the regulated community.

10A NCAC 15 .0112 – PETITIONING FOR RULEMAKING

The proposed rule change renames the rule title from "Designation of Authorized Representative of the Agency to "Petitioning for Rulemaking". The previous language in Rule .0112 has been removed from the Rule.

The changes made in Rule .0112 are administrative in nature and provide instructions for submitting petitions for rulemaking to the agency. Rule .0112 instructs our licensees and registrants in the petitioning for rulemaking process and follows the guidance for rulemaking petitions pursuant to G.S. 150B-20 of the Administrative Procedure Act. The agency does not broaden the scope of regulation with the addition of rule language but seeks to remove ambiguity by clarifying the petitioning for rulemaking process for persons wishing to submit a petition for rule making for the adoption, amendment, or repeal of a Rules in 15A NCAC 10. This Rule is explanatory in purpose, therefore, the agency expects no economic impact.

10A NCAC 15 .0306 Specific Licenses: Sealed Sources in Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The amended rule removes the explanation of what a specific license and a general license are from the existing rule and is reorganized into Paragraphs with subdivisions where appropriate to improve readability. The text in this Rule is identical to the text in Rule .0323.

- Paragraph (a) incorporates the regulations in 10 CFR 34 by reference, including subsequent amendments and editions.

- Paragraph (b) is an administrative addition to the Rule to clarify where applications for radioactive materials licenses are sent, to specify in Rule the information required on the application form and provides a web address where the application forms may be obtained. Paragraph (b) imposes no new requirements on licensees, and the information the agency requires to be on a form is required to be in rule by G.S. 150B-18 (referencing G.S. 150B-2(8a): this addition "describes the procedure or practice requirements of an agency."). This administrative addition to the Rule is anticipated to have a negligible impact.

- Paragraph (c) requires licensees to submit reports of leaking sealed sources to the agency and where those reports should be sent.

- Paragraph (d) requires licensees to report source disconnects and leak tests of industrial devices that indicate that the protective guide inside the camera is failing to the agency. A source disconnect occurs when the

connection between the guiding cable and the radioactive source fails. This is an emergency because the source cannot be retracted into the shielded device if the connection fails. Industrial radiography devices are shielded using depleted uranium. The presence of depleted uranium in a leak test indicates that there is a contamination hazard to workers using that device and the device should be removed from service. Although these reports are required by 10 CFR 34.101, they are not specifically spelled out in the federal regulation, and this clarifies the reporting requirements.

- Paragraph (e) is administrative in nature and instructs the licensed community how to apply for exemptions from the rules.

The regulations in 10 CFR 34 that are being incorporated by reference apply to the same regulated parties currently subject to the requirements in Section .0300 of 10A NCAC Chapter 15 and are identical to the requirements being struck from .0323. There will be no change to the requirements the regulated community must meet because of this proposed rule change.

None of the proposed changes to Rule 10A NCAC 15 .0306 impose burdens on the regulated community that are not already required by Rule .0323 of Chapter 15, or require any changes to the operations of federal, state or local government. As stated earlier, the purpose of this rulemaking is to move the requirements of 10 CFR Part 34 so they are found between the requirements of 10 CFR Part 33 and Part 35, and to make it easier and quicker for the licensed community to find these requirements. The amount of effort expended to locate the Rule and the time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .0311 Packaging and Transportation of Radioactive Material

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes the general license for luminous safety devices containing tritium or promethium-147 and is reorganized into Paragraphs with subdivisions where appropriate to improve readability.

- Paragraph (a) incorporates 10 CFR 71 by reference, including subsequent amendments and additions as stated in (a)(1) through (a)(41).

- Subparagraph (a)(1), (a)(3) through (a)(26), and (a)(29) through (a)(41) simply list the regulations incorporated in Paragraph (a) without any changes.

- Subparagraphs (a)(2) and (a)(27) instructs licensees where to submit communications and reports to the state.

- Subparagraph (a)(28) states that only the NRC can issue certificates of compliance for transportation packages, and delegates the state as the responsible party for reviewing quality assurance plans.

- Paragraph (b) is an administrative addition to the Rule to clarify how to apply for an exemption from the Rule. There is no form, and only limited information is required to apply for an exemption. This administrative addition to the Rule is anticipated to have a negligible impact.

- Paragraph (c) provides an address where copies of 10 CFR 71 can be obtained for no cost to our regulated community.

None of the proposed changes to Rule 10A NCAC 15 .0311 will impose additional burdens on the regulated community or require any changes to the operations of federal, state or local government. The regulatory requirements remain unchanged in the proposed rule from those existing in Rules .0104, .0111, .0114, .0117, from Section .0100 of Chapter 15 and .0344, from Section .0300 of Chapter 15. The only changes of note to this Rule are administrative changes that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance and reviewing license applications. The amount of time saved will be negligible and will not represent a significant financial benefit;

however, it is noted here for completeness.

10A NCAC 15 .0313 Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters under Section 274
The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes General License for the possession of radioactive material.

- Paragraph (a) incorporates 10 CFR 150 by reference including subsequent amendments and editions as listed in (a)(1) through (a)(8). All of the requirements of 10 CFR Part 150 are incorporated by reference in 10A NCAC 15 .0117, and this Rule makes no changes to those requirements.

- Paragraph (a)(3) removes the term “foreign obligations” from the definitions in 10 CFR 150.3 where it appears. The term "foreign obligations” falls under the regulatory resonsiblity of the NRC.

- Paragraph (a)(4) instructs that communications or reports required by the Rule be sent to the agency unless otherwise instructed by the agency.

- Paragraph (b) gives the web address where copies of the regulations in 10 CFR 150 can be obtained free of charge.

None of the proposed changes to Rule 10A NCAC 15 .0313 will impose additional burdens on the regulated community or require any changes to the operations of federal, state or local government. The regulatory requirements remain unchanged in the proposed rule from those existing in Rules .0111 and .0117 from Section .0100 of Chapter 15. The only change of note to this Rule is an administrative change instructing licensees where to get copies of Part 150 that will provide clarity to the regulated community thereby making compliance with the rule easier. This should translate into less time spent by the regulated community on the license application process as well as less time spent by regulatory staff providing technical assistance and reviewing license applications. The amount of time saved will be negligible and will not represent a significant financial benefit; however, it is noted here for completeness.

10A NCAC 15 .1001 Notices, Instructions, and Reports to Employees
The Radiation Protection Commission is proposing to amend this rule. The proposed rule amendment changes the rule citation references for terms found in Parts (a)(3)(A) through (F) of this Rule to reflect changes made to Rule .0103 of Section .0100 of Chapter 15 during this rulemaking. The agency expects no discernable fiscal impact due to these Rule changes.

10A NCAC 15 .1601 Standards for Protection Against Radiation
The Radiation Protection Commission is proposing to amend this rule. The proposed rule amendment changes the rule citation references for terms found in Parts (a)(3)(A) through (D) of this Rule to reflect changes made to Rule .0103 of Section .0100 of Chapter 15 during this rulemaking. The agency expects no discernable fiscal impact due to these Rule changes.

Summary

The proposed rule changes are largely for the purpose of updating the rules to clarify existing requirements, to remove ambiguity, comply with federal regulations regarding incorporating by reference, perform technical corrections, reorganize the rules for easier reading and comprehension, and update terminology. None of the proposed changes will result in additional burdens to the regulated community, nor will they result in changes to operations for local, state, or federal government.

Appendix

10A NCAC 15 .0101 is proposed for readoption as follows:

CHAPTER 15 – RADIATION PROTECTION

SECTION .0100 – GENERAL PROVISIONS

10A NCAC 15 .0101 SCOPE

(a) Except as otherwise specifically provided these Rules apply to all persons who receive, possess, use, transfer, own or acquire any source of radiation within the State of North Carolina.

(b) Nothing in these Rules shall apply to any person to the extent any person is subject to regulation by the United States Nuclear Regulatory Commission.

(c) Regulation by the State of North Carolina of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended" under provisions of Public Law 86-373, as amended, and 10 CFR Part 150.

History Note: *Authority G.S. 104E-2; ~~104E-7, 104E-10104E-7(a)(2);~~ 104E-7; 104E-10; 104E-12(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2201 Eff. January 4, 1990;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0101 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2015.

10A NCAC 15 .0102 is proposed for readoption as follows:

10A NCAC 15 .0102 COMPLIANCE WITH LAWS

Nothing in these Rules shall relieve any person of responsibility for complying with other pertinent North Carolina laws and rules.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2202 Eff. January 4, 1990;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0102 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0103 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0103 ~~INTENTIONAL EXPOSURE~~ DEFINITIONS

~~Nothing in Sections .0100 to .1000 of this Chapter shall be interpreted as limiting the intentional exposure of patients to radiation for the purposes of medical diagnosis and therapy.~~

(a) As used in the Rules of this Chapter, persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed under the rules in Sections .0300, .0900, .1200, and 1300 of this Chapter, the following definitions apply:

(1) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.

(2) "Agency" means the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.

(3) "Authorized representative" means an employee of the agency.

(4) "Annually" means either:

(A) at intervals not to exceed twelve (12) consecutive months; or

(B) once per year at the same time each year (completed during the same month each year over a period of multiple years).

(5) “Calendar month” means January, February, March, April, May, June, July, August, September, October, November, or December.

(6) “Calendar year” means the period of time between 12:00:00 am January 1 to 11:59:59 pm December 31.

(7) “Calibration” means the determination of the reading or response of an instrument to known radiation values over the range of the instrument, or the strength of a source of radiation relative to a standard.

(8) “CFR” means Code of Federal Regulations.

(9) "Commission" has the meaning as defined in G.S. 104E-5(5), except as stated in Paragraph (c) of this Rule.

(10) "Department" has the meaning as defined in G.S. 104E-5(6) except as stated in Paragraph (c) of this Rule.

(11) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

(12) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

(13) "Inspection" means an examination or observation by an authorized representative of the agency to determine compliance with rules, orders, requirements, and conditions of the agency or the Commission.

(14) “Monthly” means once every calendar month.

(15) “Natural radioactivity" means radioactivity of naturally occurring nuclides.

(16) “Person” has the same meaning as defined in G.S. 104E-5(11).

(17) "Quarterly" means four time per calendar year, and:

(A) at intervals not to exceed 13 weeks; or

(B) once per month during the months of January, April, July, and October; or

(C) once per month during the months of February, May, August, and November; or

(D) once per month during the months of March, June, September, and December.

(18) "Radiation" except as otherwise defined in Section .1400 of this Chapter, has the meaning as defined in G.S. 104E-5(12).

(19) "Radiation dose" means dose.

(20) "Semiannually" means twice per calendar year at six (6) month intervals.

(21) "SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.

(22) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

(23) "State" means the State of North Carolina.

(24) "These Rules" means Chapter 11 of this Title.

(b) As used in the Rules of this Chapter, persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following definitions shall apply:

(1) "Assembler" means any person engaged in the business of assembling, installing, or replacing one or more components of a radiation machine, x-ray system, or subsystem. The term includes the owner of radiation machines, x-ray systems, or subsystems and their employees or agent who assembles components of the machines, systems, or subsystems used in a facility.

(2) "Clinical study" means human use of a radiation machine for research and development. The terms "clinical investigation", "clinical research", "research", and "study" also means "clinical study".

(3) "Consulting" means providing professional technical advice on radiological matters by an expert registered with the agency in accordance with Rule .0205 of this Section.

(4) "Facility" means the location at which one or more radiation machines or sources of radiation are installed or located within one building, at one address or vehicle, and are under the same administrative control.

(5) "Healing arts" means the art or science of diagnostic examination using a source of radiation in the diagnosis or treatment of human or animal diseases.

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

(7) "Install or installation" means the assembly, placement, initial calibration, operational testing, or other actions that allow a radiation machine to be used in a new location or after being moved from one location to another.

(8) "Licensed practitioner" means a person authorized to order diagnostic exams that use radiation machines for diagnosing or treatment of human or animal diseases. The person shall be:

(A) a physician in accordance with Subparagraph (9) of this Rule; or

(B) licensed by the appropriate licensing board in North Carolina pursuant to G.S. Chapter 90 to provide professional services in chiropractic, dentistry, podiatry, and veterinary medicine.

(9) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 1.

(10) "Radiation machine" has the same meaning as defined in G.S. 104E-5(13).

(11) "Registrant" means any person who is registered with the agency, after completing the registration process, in accordance with Rule .0203 of this Chapter.

(12) "Registration" means the process of registration, with the agency, by completing and submitting agency forms in accordance with Rules .0203 and .0205 of this Chapter.

(13) "Registered" means a facility or service provider that has completed the registration process in accordance with Rules .0203 and .0205 of this Chapter and has been issued a Notice of Registration in accordance with Rule .0207 of this Chapter.

(14) "Research and development" means:

(A) theoretical analysis, exploration, or experimentation; or

(B) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

(15) "Service" means calibration, conversion, repair, routine maintenance, or other testing performed on a radiation machine, x-ray system or subsystem, or source of radiation, other than those actions taken during installation.

(16) "Service Provider" means any person engaged in equipment services included in Rule .0205(d) of this Chapter.

(c) Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1000, .1200, .1300, .1400, .1600, and .1700 of this Chapter.

(d) To reconcile differences between the Rules of this Chapter and the incorporated sections of Federal regulations and to effectuate their joint enforcement, the following words and phrases shall be substituted for the language of the Federal regulations:

(1) With the exception of 10 CFR 30.4 and in the definition of Special Nuclear Material, a reference to ''NRC'' or ''Commission'' means the "Agency.

(2) A reference to ''NRC or agreement state" means the "Agency or agreement state.

(3) In 10 CFR 40.4 and 70.4, in the definition of "Special Nuclear Material", the sentence "and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material", remains preserved as implemented by G.S. 104E-5.(16).

(4) In 10 CFR 30.18(d), 30.32(g), 31.5(b)(1)(ii), 31.5(c)(3)(ii), 31.5(c)(8)(i), 31.6, 31.7(a), 31.10(a), 1.10(b)(1), 31.12(c)(4), 32.13, 32.51(a), 32.51(c), 32.56, 32.59, 32.72(b)(5)(ii), 40.13(c)(10), 40.22(e), 40.25(b), 40.25(d)(3), 40.54, 40.55(c), (c)(1), (d)(1)(ii), (d)(2) and (d)(3), where a reference is made to "an Agreement State", it means "an Agreement State or the NRC".

(5) In 10 CFR 31.6 where the words "any non-agreement state" or "offshore waters" are used, substitute the words "State of North Carolina,".

(6) In 10 CFR 70.19(a)(1) and 70.19(c)(3), the term "Commission or the Atomic Energy Commission" remains and does not mean the Agency or have the same definition shown in G.S. 104E-5(5). In 10 CFR 70.42(b)(1) the word "Department" means the "U.S. Department of Energy".

(7) "Written directive," except as defined in Rule .0307 of this Chapter, means an order in writing for a specific patient or human research subject dated and signed by an authorized user prior to the administration of radiation therapy through the use of a licensed accelerator that contains the patient or human research subject's name and the following information:

(A) total dose;

(B) dose per fraction;

(C) treatment site, and

(D) number of fractions.

History Note: *Authority G.S. 104E-7; 104E-7(a); 10 CFR 20.1003;*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2203 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0103 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0104 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0104 ~~DEFINITIONS~~ INCORPORATION BY REFERENCE

~~As used in these Rules, the following definitions apply.~~

~~(1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).~~

~~(2) "Accelerator produced material" means any material made radioactive by use of a particle accelerator.~~

~~(3) "Act" means North Carolina Radiation Protection Act as defined in G.S. 104E-1.~~

~~(4) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).~~

~~(5) "Adult" means an individual 18 or more years of age.~~

~~(6) "Agency" means the, North Carolina Department of Health and Human Services, Division of Health Service Regulation, Radiation Protection Section.~~

~~(7) "Agreement state" has the meaning as defined in G.S. 104E-5(2).~~

~~(8) "Air-purifying respirator" means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.~~

~~(9) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.~~

~~(10) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed radioactive material, exist in concentrations:~~

~~(a) in excess of the derived air concentrations specified in Appendix B to 10 CFR 20.1001 - 20.2401; or~~

~~(b) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake or 12 DAC hours.~~

~~(11) "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the rules of this Chapter as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.~~

~~(12) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in an effective dose equivalent of five rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. The ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix B to 10 CFR 20.1001 - 20.2401.~~

~~(13) "Annually" means either:~~

~~(a) at intervals not to exceed 12 consecutive months; or~~

(b) once per year at the same time each year (completed during the same month each year over a period of multiple years).

(14) "Assigned protection factor (APF)" means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. APF can be divided into the ambient airborne concentrations to estimate inhaled air concentrations.

(15) "Atmosphere-supplying respirator" means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere and includes supplied-air respirators and self-contained breathing apparatus units.

(16) "Authorized representative" means an employee of the agency, or an individual outside the agency when the individual is so designated by the agency under Rule .0112 of this Section.

(17) "Authorized user" means an individual who is authorized by license or registration condition to use a source of radiation.

(18) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that are not under the control of the licensee or registrant. "Background radiation" does not include sources of radiation regulated by the agency.

(19) "Becquerel" is the SI unit of radioactivity. One becquerel is equal to one disintegration per second (s^{-1}).

(20) "Bioassay" or "radiobioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

(21) "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal or interstitial application.

(22) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(23) "Byproduct material" has the meaning as defined in G.S. 104E-5(4), and in addition includes:

(a) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(b) Any discrete source of Radium-226 that is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity;

(c) Any material that:

(i) has been made radioactive by use of a particle accelerator; or

(ii) is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; and

(d) Any discrete source of naturally occurring radioactive material, other than source material, that:

(i) the US Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would poses a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) is extracted or converted after extraction for use in a commercial, medical, or research activity.

(24) "Class", "lung class" or "inhalation class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times as follows:

CLASSIFICATION OF INHALED MATERIAL

Class	Clearance half-time
Class D (Day)	less than 10 days
Class W (Weeks)	10 days to 100 days
Class Y (Years)	greater than 100 days

(25) "Clinical procedures manual" means a collection of procedures governing the medical use of radioactive material not requiring a written directive that describes each method by which the licensee performs clinical procedures and includes other instructions and precautions. Each clinical procedure, including the radiopharmaceutical dosage and route of administration, shall be approved in writing by an authorized user prior to inclusion in the manual. The radiation safety officer shall ensure that the manual includes the approved procedure(s) for all clinical procedures using radioactive material not requiring a written directive performed at the facility.

(26) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(27) "Commission" has the meaning as defined in G.S. 104E-5(5).

(28) "Committed dose equivalent" (HT,50) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(29) "Committed effective dose equivalent" (HE,50) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues (HE,50 = ΣwTHT,50).

(30) "Consortium" means an association of medical use licensees and a PET radionuclide production facility that jointly own or share in the operation and maintenance costs of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The consortium's PET radionuclide production facility must be located at an educational institution, federal or medical facility.

(31) "Constraint" or "dose constraint" means a value above which specified licensee actions are required.

(32) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

(33) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(34) "Curie" is the special unit of radioactivity. One curie is equal to 3.7 x 1010 disintegrations per second = 3.7 x 1010 becquerels = 2.22 x 1012 disintegrations per minute.

(35) "Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(36) "Decommission" means to remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for either unrestricted use and termination of the license or for restricted use and termination of the license.

(37) "Deep dose equivalent" (Hd), which applies to external whole body exposure, is the dose equivalent at a tissue depth of one cm (1000 mg/cm2).

(38) "Demand respirator" means an atmosphere supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(39) "Department" has the meaning as defined in G.S. 104E-5(6).

(40) "Depleted uranium" means the source material uranium in which the isotope uranium 235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

(41) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of ALI. DAC values are given in Table 1, Column 3, of Appendix B to 10 CFR 20.1001 - 20.2401).

(42) "Derived air concentration-hour" (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of five rems (0.05 Sv).

(43) "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

(44) "Disposable respirator" means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(45) "Distinguishable from background" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using measurement technology, survey and statistical techniques as defined in 10 CFR 20.1003.

(46) "Dose" or "radiation dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other Items of this Rule.

(47) "Dose equivalent" (HT) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

(48) "Dose limits" (see "Limits" defined in this Rule).

(49) "Dosimetry processor" means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

(50) "Effective dose equivalent" (HE) is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factors (wT) applicable to each of the body organs or tissues that are irradiated (HE = ΣwTHT).

(51) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(52) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(53) "Equipment services" means the selling, installation, rebuilding, conversion, repair, inspection, testing, survey or calibration of equipment which can affect compliance with these Rules by a licensee or registrant.

(54) "Exposure" means being exposed to ionizing radiation or to radioactive material.

(55) "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

(56) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

(57) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(58) "Eye dose equivalent" (See "Lens dose equivalent" as defined in this Rule).

(59) "Filtering facepiece" or "dust mask" means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(60) "Fit factor" means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(61) "Fit test" means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(62) "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using sources of radiation.

(63) "Gray" (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of one joule/kilogram (100 rads).

(64) "Helmet" means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(65) "High dose rate remote afterloader" (HDR) means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(66) "High radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

(67) "Hood" means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(68) "Hospital" means a facility that provides as its primary functions diagnostic services and intensive medical and nursing care in the treatment of acute stages of illness.

(69) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.

(70) "Individual" means any human being.

(71) "Individual monitoring" means:

(a) the assessment of dose equivalent by the use of devices designed to be worn by an individual;

(b) the assessment of committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(c) the assessment of dose equivalent by the use of survey data.

(72) "Individual monitoring devices" or "individual monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

(73) "Inhalation class" (see "Class" defined in this Rule).

(74) "Inspection" means an examination or observation by the agency to determine compliance with rules, orders, requirements and conditions of the agency or the Commission.

(75) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(76) "Lens dose equivalent" (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 cm (300 mg/cm2).

(77) "License," except where otherwise specified, means a license issued pursuant to Section .0300 of this Chapter.

(78) "Licensee" means any person who is licensed by the agency pursuant to Section .0300 of this Chapter.

(79) "Licensing state" means any state designated as such by the Conference of Radiation Control Program Directors, Inc. Unless the context indicates otherwise, use of the term Agreement State in this Chapter includes licensing state with respect to naturally occurring and accelerator produced radioactive material (NARM).

(80) "Limits" or "dose limits" means the permissible upper bounds of radiation doses.

(81) "Loose-fitting facepiece" means a respiratory inlet covering that is designed to form a partial seal with the face.

(82) "Lost or missing licensed radioactive material" means licensed radioactive material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

(83) "Low dose rate remote afterloader" (LDR) means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

(84) "Lung class" (see "Class" as defined in this Rule).

(85) "Manual brachytherapy" means a type of brachytherapy in which the brachytherapy seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

(86) "Medical event" means an event that meets the criteria in Rule .0364 of this Chapter.

(87) "Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

(88) "Medium dose rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

(89) "Member of the public" means any individual except when that individual is receiving an occupational dose.

(90) "Minor" means an individual less than 18 years of age.

(91) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

(92) "Monitoring," "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

(93) "Natural radioactivity" means radioactivity of naturally occurring nuclides.

(94) "Negative pressure respirator" means a tight-fitting respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside of the respirator.

(95) "Nonstochastic effect" or "deterministic effect" means health effects, the severity of which vary with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect.

(96) "NRC" means the United States Nuclear Regulatory Commission or its authorized representatives.

(97) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or registrant or other person. Occupational dose does not include doses received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, from voluntary participation in medical research programs, or as a member of the public.

(98) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles, in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

(99) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(100) "Person" has the meaning as defined in G.S. 104E-5(11).

(101) "Personnel monitoring equipment" means devices, such as film badges, pocket dosimeters, and thermoluminescent dosimeters, designed to be worn or carried by an individual for the purpose of estimating the dose of radiation received by the individual.

(102) "Pharmacist" means a person licensed to practice pharmacy in North Carolina pursuant to G.S. Chapter 90, Article 4A.

(103) "Physician" means a person licensed to practice medicine in North Carolina pursuant to G.S. Chapter 90, Article 1.

(104) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual dose limits as defined in Rule .1608 of this Chapter.

(105) "Positive pressure respirator" means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(106) "Positron Emission Tomography (PET) radionuclide production facility" means a facility operating an accelerator or a cyclotron for the purpose of producing PET radionuclides.

(107) "Powered air-purifying respirator (PAPR)" means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(108) "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

(a) In a written directive; or

(b) In accordance with the directions of an authorized user.

(109) "Prescribed dose" means:

(a) for teletherapy or accelerator radiation:

(i) the total dose; and

(ii) the dose per fraction as documented in the written directive;

(b) for brachytherapy:

(i) the total source strength and exposure time; or

(ii) the total dose, as documented in the written directive;

(c) for gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

(d) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in a written directive.

(110) "Pressure demand respirator" means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(111) "Public dose" means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee or registrant, or another source of radiation within a licensee's or registrant's control. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with Rule .0358 of this Chapter, or from voluntary participation in medical research programs.

(112) "Pulsed dose rate remote afterloader" means a type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose rate" range, but:

(a) Is approximately one tenth of the activity of typical high dose rate remote afterloader sources; and

(b) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(113) "Qualitative fit test" (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(114) "Quality factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem in this Rule.

(115) "Quantitative fit test" (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(116) "Quarter" means a period of time equal to one fourth of the year observed by the licensee or registrant (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(117) "Quarterly" means either:

(a) at intervals not to exceed 13 weeks; or

(b) once per 13 weeks at about the same time during each 13 week period (completed during the same month of the quarter (first month, second month or third month) each quarter over a time period of several quarters.

(118) "Rad" is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

(119) "Radiation", except as otherwise defined in Section .1400 of this Chapter, has the meaning as defined in G.S. 104E 5(12).

(120) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

(121) "Radiation dose" means dose.

(122) "Radiation machine" has the meaning as defined in G.S. 104E 5(13).

(123) "Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection rules.

(124) "Radioactive material" has the meaning as defined in G.S. 104E 5(14).

(125) "Radioactive waste disposal facility" means any low level radioactive waste disposal facility, as defined in G.S. 104E 5(9c), established for the purpose of receiving low level radioactive waste, as defined in Rule .1202 of this Chapter, generated by another licensee for the purpose of disposal.

(126) "Radioactive waste processing facility" means any low-level radioactive waste facility, as defined in G.S. 104E-5(9b), established for the purpose of receiving waste, as defined in this Rule, generated by another licensee to be stored, compacted, incinerated or treated.

(127) "Radioactivity" means the disintegration of unstable atomic nuclei by emission of radiation.

(128) "Radiobioassay" means bioassay.

(129) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus as published by the International Commission on Radiological Protection. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(130) "Registrant" means any person who is registered with the agency as required by provisions of these Rules or the Act.

(131) "Registration" means registration with the agency in accordance with these Rules.

(132) "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

(133) "Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). As used in this Chapter, the quality factors for converting absorbed dose to dose equivalent are as follows:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalenta
X , gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

a Absorbed dose in rad equal to one rem or the absorbed dose in gray equal to one sievert.

If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, one rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the rules of this Chapter, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body.

If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from the following table to convert a measured tissue dose in rads to dose equivalent in rems:

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

Neutron Energy (MeV)	Quality Factora (Q)	Fluence per Unit Dose Equivalentb (neutrons cm-2 rem-1)
(thermal)	2.5 x 10-8	2	980 x 106
	1 x 10-7	2	980 x 106
	1 x 10-6	2	810 x 106
	1 x 10-5	2	810 x 106
	1 x 10-4	2	840 x 106
	1 x 10-3	2	980 x 106
	1 x 10-2	2.5	1010 x 106
	1 x 10-1	7.5	170 x 106
	5 x 10-1	11	39 x 106
	1	11	27 x 106
	2.5	9	29 x 106
	5	8	23 x 106
	7	7	24 x 106
	10	6.5	24 x 106
	14	7.5	17 x 106
	20	8	16 x 106
	40	7	14 x 106
	60	5.5	16 x 106
	1 x 102	4	20 x 106
	2 x 102	3.5	19 x 106
	3 x 102	3.5	16 x 106
	4 x 102	3.5	14 x 106

a Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.
b Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

(134) "Research and development" means:

(a) theoretical analysis, exploration, or experimentation; or

(b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

(135) "Residual radioactivity" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials of radioactive materials at the site, even if the burials were made in accordance with the provisions of Section .1600 of this Chapter.

(136) "Respiratory protective device" means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

(137) "Restricted area" means an area, access to which is controlled by the licensee or registrant for purposes of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(138) "Roentgen" (R) means the special unit of exposure. One roentgen equals 2.58 x 10 -4 coulombs/kilogram of air.

(139) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

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

(141) "Sealed source and device registry" means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(142) "Self-contained breathing apparatus (SCBA)" means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(143) "Semiannually" means either:

(a) at intervals not to exceed six months; or

(b) once per six months at about the same time during each six month period (completed during the sixth month of each six month period over multiple six month periods).

(144) "Shallow dose equivalent" (Hs), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2).

(145) "SI unit" means a unit of measure from the International System of Units as established by the General Conference of Weights and Measures.

(146) "Sievert" is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

(147) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

(148) "Source material" has the meaning as defined in G.S. 104E-5(15).

(149) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

(150) "Special form radioactive material" means radioactive material which satisfies the following conditions:

(a) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

(b) The piece or capsule has at least one dimension not less than five millimeters (0.197 inch); and

(c) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission, Subpart F of 10 CFR Part 71, and the tests prescribed in Rule .0114 of this Section. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements, Subpart F of 10 CFR Part 71, in effect on June 30, 1984, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

(151) "Special nuclear material" has the meaning as defined in G.S. 104E-5(16).

(152) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope uranium-235 in quantities not exceeding 350 grams of contained uranium-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of uranium-235, uranium enriched in uranium-235 and plutonium in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified in this Rule for the same kind of special nuclear material. The sum of these ratios for all the kinds of special nuclear material in combination shall not exceed one. For example, the following quantities in combination would not exceed the limitations and are within the formula, as follows:

$$\frac{175 \text{ (gram contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} \text{ is } < \text{ or } = 1$$

(153) "State" means the State of North Carolina.

(154) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a therapeutic dose to a tissue volume.

(155) "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

(156) "Supplied-air respirator" (SAR) or "airline respirator" means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

(157) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of sources of radiation and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

(158) "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(159) "These Rules" means Chapter 11 of this Title.

(160) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(161) "To the extent practicable" means to the extent feasible or capable of being done or carried out with reasonable effort, taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

(162) "Total effective dose equivalent" (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(163) "Toxic or hazardous constituent of the waste" means the nonradioactive content of waste which, notwithstanding the radioactive content, would be classified as "hazardous waste" as defined in G.S. 130A-290(8).

(164) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(165) "Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A1 for special form radioactive material or A2 for normal form radioactive material, where A1 and A2 are given in Rule .0113 of this Section or may be determined by procedures described in that Rule. All quantities of radioactive material greater than a Type A quantity are Type B.

(166) "Unit dosage" means a dosage intended for medical use in an individual that has been obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent agreement state requirements.

(167) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

(168) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant.

(169) "User seal check" or "fit check" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

(170) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at one meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

(171) "Waste" means low-level radioactive waste as defined in G.S. 104E-5(9a) and includes those low-level radioactive wastes containing source, special nuclear, or radioactive material that are acceptable for disposal in a land disposal facility. For purposes of this definition, low-level waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in this Rule, and licensed naturally occurring and accelerator produced radioactive material which is not subject to regulation by the U.S. Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, except as defined differently in Rule .1202 of this Chapter.

(172) "Week" means seven consecutive days.

(173) "Weighting factor", wT, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of wT are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	wT
Gonads	0.25
Breast	0.15

Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30a
Whole body	1.00b

a 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.
b For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, wT = 1.0, has been specified.

(174) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(175) "Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

(176) "Working level" (WL) is any combination of short-lived radon daughters (for radon 222: polonium 218, lead 214, bismuth 214, and polonium 214; and for radon 220: polonium 216, lead 212, bismuth 212, and polonium 212) in one liter of air that will result in the ultimate emission of 1.3 x 105 MeV of potential alpha particle energy.

(177) "Working level month" (WLM) means an exposure to one working level for 170 hours.

(178) "Written directive" means an order in writing for a specific patient or human research subject dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation from a licensed source, except as specified in Sub-item (e) of this definition, containing the patient or human research subject's name and the following information:

(a) for the administration of greater than 30 microcuries (1.11 Megabecquerels (MBq)) of sodium iodide I-131, the dosage;

(b) for the therapeutic administration of a radiopharmaceutical other than sodium iodide I-131:

(i) radionuclide;

(ii) dosage; and

(iii) route of administration;

(c) for teletherapy or accelerator radiation therapy:

(i) total dose;

(ii) dose per fraction;

(iii) treatment site; and

(iv) number of fractions;

(d) for high-dose-rate remote afterloading brachytherapy:

(i) radionuclide;

(ii) treatment site;

(iii) dose per fraction

(iv) number of fractions; and

(v) total dose;

~~(e) for all other brachytherapy:~~

~~(i) prior to implantation:~~

~~(A) radionuclide;~~

~~(B) treatment site; and~~

~~(C) dose; and~~

~~(ii) after implantation:~~

~~(A) radionuclide;~~

~~(B) treatment site;~~

~~(C) number of sources;~~

~~(D) total source strength and exposure time; and~~

~~(E) total dose; and~~

~~(f) for gamma stereotactic radiosurgery:~~

~~(i) the total dose;~~

~~(ii) treatment site; and~~

~~(iii) values for the target coordinate settings per treatment for each anatomically distinct treatment site.~~

~~(179) "Year" means the period of time beginning in January used to determine compliance with the provisions of Section .1600 of this Chapter. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.~~

(a) For the purpose of the rules in this Chapter, the following rules, standards, and other requirements are hereby incorporated by reference including any subsequent amendments and editions:

(1) The following parts of 21 CFR Subchapter J:

(A) Part 1000, “General;”

(B) Subpart A 1000.1, “General Provisions - General;”

(C) Subpart A 1000.3(a) through (j),(k),(1), and (n) through (t), “Definitions;”

(D) Subpart A 1000.15, “Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968;”

(E) Part 1002, “Records and Reports;”

(F) Subpart A 1002.1(a) and (c)(4), “Applicability;”

(G) Subpart D 1002.31, “Preservation and inspection of records;”

(H) Part 1003, “Notification of Defects of Failures to Comply;”

(I) Subpart A 1003.1, “Applicability;”

(J) Subpart A 1003.2, “Defect in an electronic product;”

(K) Subpart C 1003.21, “Notification by the manufacturer to affected persons;”

(L) Part 1010, “Performance Standards for Electronic Products - General;”

(M) Subpart A 1010.1, “Scope;”

(N) Subpart A 1010.2(a),(b), and (d), “Certification;”

(O) Subpart A 1010.3, “Identification;”

(P) Subpart A 1010.4(a) and (d), “Variances;”

(Q) Part 1020, “Performance Standards for Ionizing Radiation Emitting Products;”

(R) Section 1020.20, “Cold-cathode gas discharge tubes;”

(S) Section 1020.30, “Diagnostic x-ray systems and their main components;”

(T) Section 1020.31, “Radiographic equipment;”

(U) Section 1020.32, “Fluoroscopic equipment;” and

(V) Section 1020.33, “Computed tomography (CT) equipment.”

(2) "Agreement Between the United States Atomic Energy Commission and the State of North Carolina for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended," signed July 21, 1964.

(b) The rules, standards and other requirements incorporated by reference in Paragraph (a) of this Rule are available free of charge at:

(1) https://www.ecfr.gov/current/title-21/chapter-I/subchapter-J for Subparagraph (a)(1)(A) through (a)(1)(V) of this Rule, and

(2) https://www.nrc.gov/cdn/nmss/pdf/ncagreements.pdf for the agreement between the NRC and the State of North Carolina.

History Note: *Authority G.S. 104E-7(a)(2); ~~10 CFR 20.1003;~~104E-15(a); 104E-25(b); 150B-19(5)(b); 150B-21.6;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989; June 1, 1989; October 1, 1984;
Transferred and Recodified from 10 NCAC 03G .2204 Eff. January 4, 1990;
Amended Eff. January 1, 1994; May 1, 1992;
Temporary Amendment Eff. August 20, 1994, for a Period of 180 Days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 2013; November 1, 2007; May 1, 2006; January 1, 2005; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0104 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0105 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0105 ~~OTHER DEFINITIONS~~DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENECY

~~Definitions of certain other words and phrases as used in these Rules are set forth in Sections .0300, .0500, .0600, .0800, .1200, .1300, .1400, and .1500 of this Chapter. Waste class is defined in Rule .1650 of this Chapter.~~

(a) When an employee of the agency is qualified and is specifically designated by the agency, the employee shall be an authorized representative of the agency to conduct inspections, tests, or surveys.

(b) When a public employee is determined by the agency to be qualified, the agency may designate the employee to conduct tests or surveys with an authorized representative of the agency.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;

Transferred and Recodified from 10 NCAC 03G .2205 Eff. January 4, 1990;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0105 Eff. February 1, ~~2015~~.2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0106 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0106 ~~EXEMPTIONS~~INSPECTIONS AND TESTS

~~(a) The agency may, upon application therefore, grant individual exemptions or exceptions from the requirements of these Rules if it will not result in radiation dose or contamination in excess of the limits prescribed in these Rules for the protection of public health, safety or property.~~

~~(b) Except as otherwise provided in this Rule, common and contract or other carriers, freight forwarders, and warehousemen, who are subject to the regulations of the U.S. Postal Service (39 CFR Parts 14 and 15), are exempt from these Rules to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto. Common, contract, or other carriers who are not exempt pursuant to this Rule are subject to the provisions of Rule .0316 of this Chapter. Notwithstanding these exemptions, common, contract or other carriers are required to comply with the provisions of Rule .0316(c) of this Chapter to the extent that these carriers are transporting spent nuclear fuel, as defined in Rule .0316(c) of this Chapter, upon the highways of North Carolina.~~

~~(c) Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these Rules to the extent that the contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:~~

~~(1) prime contractors performing work for the U.S. Department of Energy at U.S. government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;~~

~~(2) prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;~~

~~(3) prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and~~

~~(4) any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the agency and the U.S. Nuclear Regulatory Commission jointly determine that:~~

~~(A) the exemption of the prime contractor or subcontractor in Subparagraph (c)(4) of this Rule is authorized by law, and~~

~~(B) that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.~~

(a) Inspections. At all reasonable times during hours of operation, each licensee and registrant shall:

(1) allow authorized representatives of the ageny the opportunity to inspect any radiation machine or source of radiation and the facility or premises where any radiation machine or source of radiation is used or stored; and

(2) make available to the agency for inspection, upon reasonable notice, records maintained pursuant to the Rules in this Chapter.

(b) Tests. Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary of any:

(1) radiation machine or source of radiation;

(2) facility wherein any radiation machine or source of radiation is used or stored;

(3) radiation detection and monitoring instruments; and

(4) other equipment and devices used in connection with utilization or storage of any radiation machine or source of radiation.

History Note: *Authority G.S. ~~104E-2;~~ 104E-7; ~~104E-15;~~104E-7(2); 104E-11(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2206 Eff. January 4, 1990;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0106 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0107 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0107 ~~INSPECTIONS~~ IMPOUNDING

~~Each licensee and registrant shall, upon reasonable notice, make available to the agency for inspection records maintained pursuant to provisions of these Rules.~~

Radiation machines and sources of radiation are subject to impounding by authorized representatives of the agency pursuant to the provisions of the Act.

History Note: *Authority G.S. ~~104E-7; 104E-11(a);~~104E-14;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2207 Eff. January 4, 1990;
Amended Eff. May 1, ~~1993'~~1993;
Transferred and Recodified from 15A NCAC 11 .0107 Eff. February 1, ~~2015.~~2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~2019;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0108 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0108 ~~ADDITIONAL REQUIREMENTS~~ ENFORCEMENT

~~(a) The agency may, by license condition, registration condition, or order, when not in conflict with any law, waive any requirement in these Rules or impose additional requirements in accordance with 46 FR 7540 as it deems appropriate or necessary to minimize danger to public health, safety or property. Such additional requirements are subject to appeal procedures contained in Section 15A NCAC 1B .0200.~~

~~(b) The Commission may by rule require radioactive material licensees to procure and file with the department such bond, insurance or other security as the Commission deems necessary to protect the state from costs for emergency response and perpetual maintenance.~~

Any person is subject to administrative penalties pursuant to provisions of the Act for the following:

(1) willful violation or failing to comply with provisions of this Chapter; or

(2) refusal of an inspection in accordance with .0106(a) of this Section or impounding in accordance Rule .0107 of this Section.

History Note: *Authority G.S. 104E-2; 104E-7; ~~104E-18;~~104E-11; 104E-14;~~10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;~~ 104E-(24);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2208 Eff. January 4, 1990;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0108 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0109 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0109 ~~IMPOUNDING~~ RECORDS

~~Sources of radiation are subject to impounding by authorized representatives of the agency pursuant to provisions of the Act.~~

(a) Each registrant shall maintain records:

(1) showing the receipt, transfer, and disposal of all radiation machines and sources of radiation;

(2) documenting operator training; and

(3) additional record requirements specified elsewhere in the Rules of this Chapter.

(b) These records shall be available for agency review during inspection or upon agency request.

History Note: *Authority G.S. 104E-7; ~~104E-14;~~104E-12(a);*
Eff. February 1, 1980;
Transferred and Recodified from 10 NCAC 3G .2210 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0109 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0110 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0110 PROHIBITED USES

~~(a) Hand-held fluoroscopic screens shall not be used.~~

~~(b) Shoe-fitting fluoroscopic devices shall not be used.~~

~~(c) Effective February 1, 1981, plastic pointed position indicating devices on intraoral dental systems shall not be used.~~

~~(d) Effective February 1, 1983, mechanical timers on intraoral dental machines shall not be used.~~

~~(e) Dental fluoroscopy without image intensification shall not be used.~~

~~(f) Non-intensified photofluorographic equipment shall not be used.~~

The agency prohibits the use of the following:

(1) Demonstration or training of radiation machines or sources of radiation without providing shielding to ensure exposure to radiation does not exceed dose limits in Rule .1601(a) of this Section.

(2) Hand-held radiation machines used for diagnostic exams, ordered by a licensed practitioner as defined in Rule .0103(8) of this Section in the diagnosing or treatment of human or animal diseases, except for dental hand-held equipment authorized for use by the agency.

(3) Hand-held fluoroscopic screens;

(4) Shoe-fitting fluoroscopic devices;

(5) Dental fluoroscopy without image intensification; and

(4) Non-intensified photofluorographic equipment.

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. June 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2211 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0110 Eff. February 1, ~~2015.~~2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0112 is proposed for readopption with substantive changes as follows:

10A NCAC 15 .0112 ~~DESIGNATION OF AUTHORIZED REPRESENTATIVE OF THE AGENCY~~ PETITIONING FOR RULEMAKING

~~(a) When an employee of the agency is qualified and is specifically designated by the agency, the employee shall be an authorized representative of the agency to conduct inspections, or tests, or surveys.~~

~~(b) When a public employee of other than the agency is determined by the agency to be qualified, the agency may designate the employee as an authorized representative of the agency to conduct specified inspections, or tests, or surveys.~~

(a) Except for petitions regarding the Rules in Section .1100 of this Chapter, any person wishing to submit a petition for rulemaking requesting the adoption, amendment, or repeal of a Rule in this Chapter shall address the petition to the Radiation Protection Commission care of the Radiation Protection Section and submit the petition to one of the addresses shown in Rule .0111(a) of this Chapter. A petition for adoption, amendment, or repeal of a Rule in Section .1100 of this Chapter shall be addressed to the Department of Health and Human Services care of the Radiation Protection Section and submitted to one of the addresses shown in Rule .0111(a) of this Chapter.

(b) Petitions to adopt a new Rule, or to amend or repeal an existing Rule shall contain the following information:

(1) the proposed text of the new Rule or the proposed text amending a Rule. If the petition is for the repeal of a Rule the petitioner shall not be required to submit proposed Rule text;

(2) statutory authority supporting the new Rule, or amending or repealing a Rule;

(3) reason for the proposed rulemaking action;

(4) effect of the proposed rule change on existing rules;

(5) effect of the proposed rule change on existing practices;

(6) information supporting the proposed rulemaking;

(7) effect of the proposed rule change on the regulated community and the public; and

(8) name and contact information of the petitioner.

(c) The agency shall determine if the petitioned rule change is authorized under G.S. 104E. The agency shall maintain a record of this review.

(d) Petitions failing to contain the information required by Subparagraphs (b)(1) through (b)(7) of this Rule and petitions for rulemaking activities that are not authorized by G.S. 104E as determined by the agency under Paragraph (c) of this Rule shall be denied and the petitioner shall be notified by the agency of this decision and the reason for this decision if the information required by Subparagraph (b)(8) of this Rule is provided in the petition. Denial of a petition for failing to contain the information required by Paragraph (b) of this Rule shall not preclude resubmitting a corrected petition.

(e) Except for petitions denied in accordance with Paragraph (d) of this Rule, the agency shall send the petition to the Department of Health and Human Services (department). The department shall provide copies of the documents required by G.S 150B-20(a) to the Office of Administrative Hearings.

(f) Except for petitions denied in accordance with Paragraph (d) of this Rule and petitions for changes to the Rules in Section .1100 of this Chapter, the agency shall submit the rulemaking petition to the Radiation Protection Commission (commission). The agency may include written recommendations to the commission endorsing or not endorsing the petition for rulemaking when it submits the petition to the commission.

(g) The commission shall grant or deny a rulemaking petition within the time requirements of G.S. 150B20.(b). The commission shall grant or deny a rulemaking petition based on the requirements of G.S. 104E-7(a). The petitioner shall be notified in writing of this decision and the reason for this decision if the information required by Subparagraph (b)(8) of this Rule is provided in the petition. If the commission grants the rulemaking petition the commission shall initiate rulemaking proceedings.

(h) Except for petitions denied in accordance with Paragraph (d) of this Rule, the agency shall submit petitions for changes to the Rules in Section .1100 of this Chapter to the department. The agency may include written recommendations to the department endorsing or not endorsing the petition for rulemaking when it submits the petition to the department.

(i) The department shall grant or deny a rulemaking petition regarding the Rules in Section .1100 of this Chapter within the time requirements of G.S. 150B-20.(b). The department shall grant or deny a rulemaking petition regarding the Rules in Section .1100 of this Chapter based on the requirements of G.S. 104E-19. The petitioner shall be notified in writing of this decision and the reason for this decision if the information required by Subparagraph (b)(8) of this Rule is provided in the petition. If the department grants the rulemaking petition the department shall initiate rulemaking proceedings.

(j) Failure of the commission or the department to grant or deny a rulemaking petition within the time limit set in this Rule is a denial of the petition for rulemaking.

(k) Denial of a rulemaking petition is a final agency action and is subject to judicial review as specified by G.S. 150B-20.(d).

History Note: *Authority G.S. ~~104E-7~~; 104E-15;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2213 Eff. January 4, 1990;
Transferred and Recodified from 15A NCAC 11 .0112 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~2019;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0114 - .0116 are proposed for readoption as a repeal as follows:

10A NCAC 15 .0114 TESTS FOR SPECIAL FORM

10A NCAC 15 .0115 RECORDS

10A NCAC 15 .0116 TESTS

History Note: *Authority G.S. 104E-7; 104E-7(2); 104E-11(a); 104E-12(a); 104E-15;*
Eff. February 1, 1980;
Amended Eff. November 1, 1989;
Transferred and Recodified from 10 NCAC 3G .2215 - 2217 Eff. January 4, 1990;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0114 - .0116 Eff. February 1, ~~2015.~~2015;
Repealed Eff. May 1, 2025.

10A NCAC 15 .0117 is proposed for readoption as a repeal as follows:

10A NCAC 15 .0117 INCORPORATION BY REFERENCE

History Note: *Authority G.S. 104E-7; 104E-15(a); 104E-25(b); 150B-19(5)(b); 150B-21.6;*
Eff. June 1, 1993;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; August 1, 1998; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0117 Eff. February 1, ~~2015~~2015;
Repealed Eff. May 1, 2025.

10A NCAC 15 .0118 is proposed for readoption as a repeal as follows:

10A NCAC 15 .0118 OPTIONAL EARLY COMPLIANCE WITH SECTION .1600

History Note: *Authority G.S. 104E-7(a)(2); 104E-12(a);*
Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0118 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2025.

10A NCAC 15 .0306 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0306 ~~**TYPES OF LICENSES: GENERAL AND SPECIFIC**~~ **SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS**

~~(a) General licenses provided in this Section are effective without the filing of applications with the agency or the issuance of licensing documents to the general licensee, although registration with the agency may be required by the particular general license. The general license is subject to all other applicable rules in this Chapter and any limitations contained in a general license document, if issued.~~

~~(b) Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable rules of this Chapter as well as any limitations and requirements specified in the licensing document.~~

(a) Persons conducting industrial radiography using radioactive materials shall comply with the requirements of 10 CFR 34, which are hereby incorporated by reference including subsequent amendments and editions, except for: 10 CFR 34.5, 34.8, 34.121, and 34.123. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part034/.

(b) Applications required by 10 CFR 34 shall be made on forms provided by the agency. Applications and supporting material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of this Chapter in lieu of the NRC:

(1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive materials licenses, shall submit an Application for Radioactive Materials License. The following information shall appear on the application:

(A) legal business name and mailing address;

(B) physical address(es) where radioactive material shall be used or possessed. The application shall indicate if radioactive materials shall be used at temporary jobsites;

(C) the name, telephone number, and e-mail address of the Radiation Safety Officer;

(D) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, the application may so state;

(E) the application shall indicate if the application is for a new license, or for the renewal of an existing license, by marking the corresponding check box;

(F) if the application is for the renewal of an existing license, the license number shall be provided on the application;

(G) applicants shall indicate the type and category of license as shown on the form by marking the corresponding check box; and

(H) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee, who is authorized by the licensee to sign license applications on behalf of the business or licensee.

(2) Persons applying for an amendment to an existing license shall submit an Application for Amendment of Radioactive Materials and Accelerator Licenses. The following information shall appear on the application:

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

(D) licensee name as it currently appears on the license;

(E) the name, telephone number, and e-mail address of the Radiation Safety Officer;

(F) the name, telephone number, and e-mail address of the individual to be contacted about the application. If this individual is same as the Radiation Safety Officer, item 5b on the application may be left blank;

(G) applicants shall provide a description of the action requested by marking the corresponding checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief description of the action requested in the space provided in item 6b;

(H) explanation of the action requested; and

(I) the printed name, title, and signature of the certifying official. The certifying official shall be an individual employed by the business or licensee who is authorized by the licensee to sign license applications on behalf of the business or licensee.

(3) Applications specified in this Rule are available at: www.ncradiation.net/rms/rmsforms2.htm(Rev01).htm

(c) Reports of leaking sealed sources required by 10 CFR 34.27 shall be made to the agency at the address shown in Rule ~~.0111~~ .0111(a) of this Chapter in lieu of the NRC.

(d) Notifications required by 10 CFR 34.101, including notifications of source disconnects, shall be made to the agency at the address shown in Rule ~~.0111~~ .0111(a) of this Chapter in lieu of the NRC. In addition to the information required by 10 CFR 34.101(b), notifications of devices with failed or worn through S-tubes shall contain the serial number and storage location of the device, whether the device has been disposed of or returned to the manufacturer, and whether personnel contamination occurred.

(e) Requests for exemption under 10 CFR 34.111 shall be made to the agency as specified in Paragraph (b) of this Rule.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 2005;
Transferred and Recodified from 15A NCAC 11 .0306 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0311 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0311 ~~GENERAL LICENSES: LUMINOUS SAFETY DEVICES~~ PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

~~(a) A general license shall be issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:~~

~~(1) each device contains not more than ten curies of tritium or 300 millicuries of promethium-147; and~~

~~(2) each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.~~

~~(b) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in Paragraph (a) of this Rule are exempt from the requirements of Sections .1000 and .1600 of this Chapter except for Rules .1645 and .1646 of this Chapter.~~

~~(c) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.~~

~~(d) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.~~

~~(e) The general license provided in Paragraphs (a) and (b) of this Rule are subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0343, .0344 and .0346 of this Chapter.~~

(a) All persons packaging, preparing for transport, or transporting radioactive materials shall comply with the provisions of 10 CFR 71, which are hereby incorporated by reference including subsequent amendments and editions, as follows;

(1) 10 CFR 71.0, "Purpose and scope;"

(2) 10 CFR 71.1, "Communications and records;" except that communications, notices, and reports required by this Rule shall be sent to the addresses shown in Rule .0111 of this Chapter unless directed otherwise by the agency, in lieu of the NRC;

(4) 10 CFR 71.3, "Requirement for license;"

(5) 10 CFR 71.4, "Definitions;"

(6) 10 CFR 71.5, "Transportation of licensed material;"

(7) 10 CFR 71.7(a), "Completeness and accuracy of information;"

(8) 10 CFR 71.8, "Deliberate misconduct;"

(9) 10 CFR 71.12, "Specific exemptions;"

(10) 10 CFR 71.13, "Exemption of Physicians;"

(11) 10 CFR 71.14(a), "Exemption for low-level materials;"

(12) 10 CFR 71.15, "Exemption from classification as fissile material;"

(13) 10 CFR 71.17, "General license: NRC-approved package;"

(14) 10 CFR 71.21, "General license: Use of foreign approved package;"

(15) 10 CFR 71.22, "General license: Fissile material;"

(16) 10 CFR 71.23, "General license: Plutonium-beryllium special form material;"

(17) 10 CFR 71.47, "External radiation standards for all packages;"

(18) 10 CFR 71.81, "Applicability of operating controls and procedures;"

(19) 10 CFR 71.83, "Assumptions as to unknown properties;"

(20) 10 CFR 71.85(d), "Preliminary determinations;"

(21) 10 CFR 71.87, "Routine determinations;"

(22) 10 CFR 71.88, "Air transport of plutonium;"

(23) 10 CFR 71.89, "Opening instructions;"

(24) 10 CFR 71.91(a), (c) through (d), "Records;"

(25) 10 CFR 71.93, "Inspection and tests;"

(26) 10 CFR 71.95, "Reports;"

(27) 10 CFR 71.97, "Advance notification of shipment of irradiated reactor fuel and nuclear waste." Advanced notifications required by this Subparagraph shall be made to the Governor's designee in lieu of the NRC as follows:

(A) designee: N.C. Highway Patrol Headquarters, Operations Officer;

(B) mailing address: P.O. Box 27687, Raleigh, North Carolina 27611-7687;

(C) telephone: (919) 733-4030 from 8 a.m. to 5 p.m. Monday through Friday except State holidays, and (919) 733-3861 at all other times.

(28) 10 CFR 71.101(a) through (c)(1), (f), (g), "Quality assurance requirements." The quality assurance plan required by 10 CFR 71.101(c)(1) shall be submitted to the agency for review and approval in lieu of the NRC;

(29) 10 CFR 71.103, "Quality assurance organization," except that certificates of compliance shall be issued by the NRC in lieu of the agency;

(30) 10 CFR 71.105, "Quality assurance program;"

(31) 10 CFR 71.106, Changes to quality assurance program;"

(32) 10 CFR 71.127, "Handling, storage, and shipping control;"

(33) 10 CFR 71.129, "Inspection, test, and operating status;"

(34) 10 CFR 71.131, "Nonconforming materials, parts, or components;"

(35) 10 CFR 71.133, "Corrective action;"

(36) 10 CFR 71.135, "Quality assurance records;"

(37) 10 CFR 71.137, "Audits;"

(38) Appendix A to 10 CFR 71, "Determination of A_1 and A_2;"

(39) Table A-1 of Appendix A to 10 CFR 71, "A_1 and A_2 Values for Radionuclides;"

(40) Table A-2 of Appendix A to 10 CFR 71, "Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides," and

(41) Table A-3 of Appendix A to 10 CFR 71, "General Values for A_1 and A_2."

(b) Requests for a specific exemption from this Rule as permitted by 10 CFR 71.12 shall be made on the licensee's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:

(1) licensee name;

(2) license number;

(3) name of the individual requesting the exemption;

(4) contact information for the individual requesting the exemption;

(5) a description of the exemption being requested; and

(6) an explanation describing why the exemption is necessary.

(c) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part071/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0311 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0313 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0313 ~~OWNERSHIP OF RADIOACTIVE MATERIAL~~ EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENTSTATES AND IN OFFSHORE WATERS UNDER SECTION 274

~~A general license shall be issued to own radioactive material without regard to quantity. This general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.~~

(a) All persons using byproduct material, source material, or special nuclear material shall comply with the provisions of 10 CFR 150, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) 10 CFR 150.1, "Purpose;"

(2) 10 CFR 150.2, "Scope;"

(3) 10 CFR 150.3, "Definitions," except that the term "foreign obligations" shall not apply;

(4) 10 CFR 150.4, "Communications," except that questions about this Rule and communications and reports required by this Rule shall be sent to the address shown in Rule .0111(a) of this Chapter unless directed otherwise by the agency, in lieu of the NRC;

(5) 10 CFR 150.11, "Critical Mass;"

(6) 10 CFR 150.20, "Recognition of Agreement State licenses;"

(7) 10 CFR 150.31, "Requirements for Agreement State regulation of byproduct material," and

(8) 10 CFR 150.32, "Funds for reclamation or maintenance of byproduct material;"

(b) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part150/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0313 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1, 2025.

10A NCAC 15 .0316 is proposed for readoption as a repeal as follows:

10A NCAC 15 .0316 GENERAL LICENSES: TRANSPORTATION

History Note: *Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-15(a);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992; October 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0316 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2025.

10A NCAC 15 .0323 is proposed for repeal as follows:

10A NCAC 15 .0323 SPECIFIC LICENSES: SEALED SOURCES IN INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;

Amended Eff. April 1, 1999; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0323 Eff. February 1, 2015;
Readopted Eff. May 1, ~~2023.~~ 2023;
Repealed Eff. May 1, 2025.

10 NCAC 15 .0345 and .0346 are proposed for readoption as a repeal as follows:

10A NCAC 15 .0345 RECIPROCAL RECOGNITION OF LICENSES
10A NCAC 15 .0346 PREPARATION OF RADIOACTIVE MATERIAL FOR TRANSPORT

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-15(a);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1993; November 1, 1989; October 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0345, .0346 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2025.

Rule 10A NCAC 15 .1001 is proposed for amendment as follows

SECTION .1000 - NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS

Codifier's Note: 10A NCAC 03G .3100 was transferred to 15A NCAC 11 .1000 effective January 4, 1990.
Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .1001 NOTICES, INSTRUCTIONS, AND REPORTS TO EMPLOYEES

(a) Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed under the rules in Sections .0300, .0900, .1200, and .1300 of this Chapter shall comply with the provisions of 10 CFR 19 as follows, which are hereby incorporated by reference including subsequent amendments and editions, except that references to and requirements for 10 CFR 2, 50, 52, 54, 60, 63, 72, and 76 shall not apply:

(1) 10 CFR 19.1, "Purpose;"

(2) 10 CFR 19.2, "Scope;"

(3) 10 CFR 19.3, "Definitions," except that the definition of "regulated activities" and "regulated entities" shall not apply. For persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following terms used in 10 CFR 19 shall have the following substitutions:

(A) "license" shall have the same meaning as "registration" as defined in Rule ~~.0104(131)~~ .0103(b) of this Chapter;

(B) "licensed" means “registered” as defined in Rule ~~.0104(131)~~ .0103(b) of this Chapter;

(C) "licensee" shall have the same meaning as "registrant" as defined in Rule ~~.0104(130)~~ .0103(b) of this Chapter;

(D) "materials" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ .0103(b) of this Chapter;

(E) "NRC-licensed" means “registered”; and

(F) "radioactive material" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ .0103(b) of this Chapter.

(4) 10 CFR 19.5, "Communications," except that licensees and registrants shall address communications and reports to the agency as instructed by Rule .0111 of this Chapter in lieu of the NRC;

(5) 10 CFR 19.11, "Posting of notices to workers," except that 19.11(b) and (e) shall not apply;

(A) NRC Form 3 shall not be used in lieu of the Notice to Employees issued by the agency, except as authorized by the agency in writing;

(B) licensees and registrants shall not post other notices, postings, notes, or other materials over the Notice to Employees, nor shall equipment be placed in such a manner that the Notice to Employees is obscured or hidden by that equipment; and

(C) additional copies of the Notice to Employees may be obtained free of charge from the agency by contacting the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC, or online at https://radiation.ncdhhs.gov/;

(6) 10 CFR 19.12, "Instructions to workers;"

(7) 10 CFR 19.13, "Notifications and reports to individuals;"

(8) 10 CFR 19.14, "Presence of representatives of licensees and regulated entities, and workers during inspections," except that 19.14(a) shall not apply;

(9) 10 CFR 19.15, "Consultation with workers during inspections;"

(10) 10 CFR 19.16, "Requests by workers for inspections." Requests for inspections shall be mailed or delivered to the agency as instructed by Rule .0111(a) of this Chapter in lieu of the NRC;

(11) 10 CFR 19.17, "Inspections not warranted; informal review." Communications regarding the agency's decisions with respect to a request for inspection submitted to the agency under Subparagraph (a)(10) shall be mailed or delivered to the agency as instructed by Rule .0111(a) of this Chapter in lieu of the NRC;

(12) 10 CFR 19.18, "Sequestration of witnesses and exclusion of counsel in interviews conducted under subpoena;"

(13) 10 CFR 19.20, "Employee protection;"

(14) 10 CFR 19.31, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:

(A) licensee or registrant name;

(B) license or registration number;

(C) name of the individual requesting the exemption;

(D) contact information for the individual requesting the exemption;

(E) a description of the exemption being requested; and

(F) an explanation describing why the exemption is necessary.

(b) Notwithstanding Subparagraph (a)(5) of this Rule, registrants temporarily working in North Carolina and licensees working in North Carolina under reciprocity may post the Notice to Employees, NRC Form 3, or an equivalent form issued under the authority of the regulatory agency issuing the registration or license.

(c) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part019/.

History Note: *Authority G.S. 104E-7; 104E-12;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .1001 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019;
Amended Eff. October 1, 2023.

10A NCAC 15 .1601 is proposed for amendment as follows:

SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION

10A NCAC 15 .1601 STANDARDS FOR PROTECTION AGAINST RADIATION

(a) Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed pursuant to the rules in Section .0300, .0900, .1200, or .1300 of this Chapter shall comply with the provisions of 10 CFR 20 as follows, which are hereby incorporated by reference including subsequent amendments and editions, except references to and requirements for 10 CFR 50, 52, 60, 63, 72, 73, and 76 shall not apply:

(1) 20.1001, "Purpose," except that non-ionizing radiation from radiation machines registered in accordance with the rules in Section .0200 of this Chapter shall also be regulated by this Rule;

(2) 20.1002, "Scope;"

(3) 20.1003, "Definitions," except that for persons registered with the agency pursuant to the rules in Section .0200 of this Chapter, the following terms used in 10 CFR 20 shall have the following substitutions:

(A) "license" shall have the same meaning as "registration" as defined in Rule ~~.0104(131)~~ .0103(b) of this Chapter;

(B) "licensed" ~~means registered pursuant to the rules in Section .0200~~ shall have the same meaning as “registered” as defined in Rule .0103(b) of this Chapter;

(C) "licensed material" shall have the same meaning as "radiation machine" as defined in Rule ~~.0104(122)~~ .0103(b) of this Chapter, and

(D) "licensee" shall have the same meaning as "registrant" as defined in Rule ~~.0104(130)~~ .0103(b) of this Chapter;

(4) 20.1004, "Units of radiation dose;"

(5) 20.1005, "Units of radioactivity;"

(6) 20.1007, "Communications," except that licensees and registrants shall address communications regarding these rules, notifications, and reports to the agency as instructed by Rule .0111 of this Chapter in lieu of the NRC;

(7) 20.1101, "Radiation protection programs;"

(8) 20.1201, "Occupational dose limits for adults;"

(9) 20.1202, "Compliance with requirements for summation of external and internal doses;"

(10) 20.1203, "Determination of external dose from airborne radioactive material;"

(11) 20.1204, "Determination of internal exposure;"

(12) 20.1206, "Planned special exposures;"

(13) 20.1207, "Occupational dose limits for minors;"

(14) 20.1208, "Dose equivalent to an embryo/fetus;"

(15) 20.1301, "Dose limits for individual members of the public;"

(16) 20.1302, "Compliance with dose limits for individual members of the public;"

(17) 20.1401, "General provisions and scope;"

(18) 20.1402, "Radiological criteria for unrestricted use;"

(19) 20.1403, "Criteria for license termination under restricted conditions;"

(20) 20.1404, "Alternate criteria for license termination;"

(21) 20.1405, "Public notification and public participation," except the agency shall not publish a notice in the Federal Register;

(22) 20.1406, "Minimization of contamination," except that 20.1406(b) shall not apply;

(23) 20.1501, "General;"

(24) 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose;"

(25) 20.1601, "Control of access to high radiation areas;"

(26) 20.1602, "Control of access to very high radiation areas;"

(27) 20.1701, "Use of process or other engineering controls;"

(28) 20.1702, "Use of other controls;"

(29) 20.1703, "Use of individual respiratory protection equipment;"

(30) 20.1704, "Further restrictions on the use of respiratory equipment;"

(31) 20.1705, "Application for use of higher assigned protection factors;"

(32) 20.1801, "Security of stored material;"

(33) 20.1802, "Control of material not in storage;"

(34) 20.1901, "Caution signs;"

(35) 20.1902, "Posting requirements;"

(36) 20.1903, "Exceptions to posting requirements;"

(37) 20.1904, "Labeling containers;"

(38) 20.1905, "Exemptions to labeling requirements," except that 20.1905(g) shall not apply;

(39) 20.1906, "Procedures for receiving and opening packages;"

(40) 20.2001, "General requirements;"

(41) 20.2002, "Method for obtaining approval of proposed disposal procedures;"

(42) 20.2003, "Disposal by release to sanitary sewerage;"

(43) 20.2004, "Treatment or disposal by incineration;"

(44) 20.2005, "Disposal of specific wastes;"

(45) 20.2006, "Transfer for disposal and manifests;"

(46) 20.2007, "Compliance with environmental and health protection regulations;"

(47) 20.2008, "Disposal of certain byproduct material;"

(48) 20.2101, "General provisions;"

(49) 20.2102, "Records of radiation protection programs;"

(50) 20.2103, "Records of surveys;"

(51) 20.2104, "Determination of prior occupational dose;"

(52) 20.2105, "Records of planned special exposures;"

(53) 20.2106, "Records of individual monitoring results;"

(54) 20.2107, "Records of dose to individual members of the public;"

(55) 20.2108, "Records of waste disposal;"

(56) 20.2110, "Form of records;"

(57) 20.2201, "Reports of theft or loss of material." Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter shall make telephone reports of the theft or loss of radiation machines in accordance with 20.2201(a)(1)(i);

(58) 20.2202, "Notifications of incidents;"

(59) 20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits," except that 20.2203(c) shall not apply;

(60) 20.2204, "Reports of planned special exposures;"

(61) 20.2205, "Reports to individuals exceeding dose limits;"

(62) 20.2206, "Reports of individual monitoring," except that 20.2206(a)(1), and 20.2206(a)(3) through (a)(5) shall not apply. The report required by 20.2206(b) shall be submitted upon request by the agency in lieu of the requirements of 20.2206(c);

(63) 20.2207, "Reports of transactions involving nationally tracked sources." Notwithstanding Subparagraph (a)(6) of this Rule, reports required by this Subparagraph shall be made in accordance with 20.2207(f) and (g);

(64) 20.2301, "Application for exemptions," except that the request for exemption shall be made on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this Rule shall be made to the agency at the addresses shown in Rule .0111(a) of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the following information shall be submitted to the agency:

(A) licensee or registrant name;

(B) license or registration number;

(C) name and contact information for the individual requesting the exemption;

(D) a description of the exemption being requested, and

(E) an explanation describing why the exemption is necessary;

(65) 20.2302, "Additional requirements;"

(66) Appendix A to Part 20, "Assigned Protection Factors for Respirators;"

(67) Appendix B to Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage;"

(68) Appendix C to Part 20, "Quantities of Radioactive Material Requiring Labeling;"

(69) Appendix E to Part 20, "Nationally Tracked Source Thresholds," and

(70) Appendix G to Part 20, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests."

(b) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(c) Licensees and registrants shall continue to perform all activities required by the rules of this Chapter, license or registration condition, and shall pay annual fees as instructed on an invoice issued by the agency until the license or registration is terminated. Registrants shall maintain registration of all radiation machines under their control until those units are disposed.

(d) Nothing in the rules of this Chapter shall relieve any person of responsibility for complying with other applicable North Carolina laws and rules.

(e) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/.

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