Fiscal Impact Analysis of
Permanent Rule Readoption and Permanent Rule Amendment
without Substantial Economic Impact

Agency Proposing Rule Change
DHHS/Division of Health Service Regulation

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Impact Summary

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

Rules with Proposed Changes

Rule Readoption with substantive changes:

10A NCAC 15 .0301	General Rules Applicable to the Specific Licensing of Byproduct Material
10A NCAC 15 .0302	General Domestic Licenses for Byproduct Material
10A NCAC 15 .0304	Specific Licenses: Manufacture or Transfer Certain Items Containing Byproduct Material
10A NCAC 15 .0305	Specific Domestic Licenses of Broad Scope for Byproduct Material
10A NCAC 15 .0307	Medical Use of Byproduct Material in Humans
10A NCAC 15 .0308	Panoramic and Underwater Irradiators
10A NCAC 15 .0309	Domestic Licensing of Source Material
10A NCAC 15 .0310	Domestic Licensing of Special Nuclear Material

*See text in Appendix

Rules Proposed for Repeal

Rule Repeals Through Readoption: 10A NCAC 15 .0303, .0312, .0314, .0315, .0317, .0318, .0319, .0320, .0321, .0322, .0324, .0327, .0328, .0329, .0330, .0331, .0332, .0333, .0334, .0335, .0337, .0338, .0339, .0340, .0341, .0342, .0343, .0344, .0348, .0351, .0352, .0353, .0354, .0355, .0356, .0357, .0358, .0359, .0360, .0361, .0362, .0363, .0364, .0365, .0701, .0702

*See text in Appendix

Authorizing Statutes

G.S. 104E-7, 104E-7(a)(2), 104E-7(a)(8), 104E-10, 104E-10(b), 104E-12, 104E-12(a), 104E-13, 104E-18, 104E-20, 10 CFR 30.70, 10 CFR 30.72, 10 CFR 35.2,

Background

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."

Under authority of G.S. 150B-21.3A, Periodic review and expiration of existing rules, DHHS/DHSR and the Radiation Protection Commission submitted a report to the Rules Review Commission and the Joint Legislative Administrative Procedure Oversight Committee. This report was approved and the readoption schedule set at the July 18, 2019, meeting of the Rules Review Commission. All of the rules in this rulemaking action, Rules 10A NCAC 15 .0301 - .0305, .0307 - .0310, .0312, .0314, .0315, .0317 - .0322, .0324, .0327 - .0335, .0337 - .0344, .0348, .0351 - .0365, .0701 and .0702 were determined to be "Necessary With Substantive Public Interest" and will be readopted or readopted as repeals with this rulemaking action.

As mandated by G.S. 150B-19.(4) the agency may not adopt a rule that repeats the content of a law, a rule, or a federal regulation. Prior to this rule making effort, the Rules in Section .0300 of 10A NCAC 15 repeated the federal regulations found in 10 CFR 30 – 33, 35, 36, 40, and 70 in a piecemeal fashion. For example, a single rule such as 10A NCAC 15 .0301 repeats portions of the federal regulations found in 10 CFR 30, 31, 32, 33, 35, 40, and 70. Conversely, all the regulations found in 10 CFR 30 (for example) are scattered throughout Rules 10A NCAC 15 .0301, .0303 - .0304, .0317, .0337 - .0344, .0352 - .0355 and .0357. The other rules in 10A NCAC 15 in Section .0300 follow a similar pattern of repeating the federal regulations in 10 CFR as noted above. To comply with the mandate not to repeat the content of the federal regulations, 10 CFR 30 – 33, 35, 36, 40, and 70 will be adopted by reference individually, including subsequent amendments and editions, across eight separate rules to make compliance easier for the regulated community.

Rules 10A NCAC 15 .0303, .0312, .0317, .0318, , .0319, .0321, .0322, .0327, .0328, .0330, .0333, .0337, .0338, .0339, .0340, .0341, .0342, .0343, .0344, .0351, .0352, .0353, .0354, .0355, .0356, .0357, .0358, .0359, .0360, .0361, .0362, .0363, .0364, .0365, .0701, and .0702 are being repealed during this rulemaking because they have become redundant and are no longer necessary when 10 CFR 30 – 33, 35, 36, 40, and 70 are incorporated by reference, and because they repeat the content of the federal regulations found in 10 CFR.

Rule Changes and Anticipated Fiscal Impact

10A NCAC 15 .0301 General Rules Applicable to the Specific Licensing of Byproduct Material
The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The amended rule removes the scope and applicability statements from the existing rule and is reorganized into Paragraphs with subdivisions where appropriate to improve readability.

- Paragraph (a) incorporates the regulations in 10 CFR 30 by reference, including subsequent amendments and editions.

- Subparagraph (a)(4) incorporates the definitions listed in 10 CFR 30.4, except that references in the definitions to common defense and security are excluded. Common defense and security falls under exclusive NRC jurisdiction.

- Subparagraph (a)(5) provides the agency's address for inquiries regarding the rules and instructs licensees to send notices and reports required by the Rule to the agency instead of the NRC.

- Subparagraph (a)(6) excludes references to common defense and security because those fall under exclusive NRC jurisdiction.

- Subparagraph (a)(16) excludes 10 CFR 30.21(c), which falls under exclusive NRC jurisdiction.

- Subparagraph (a)(19) excludes 10 CFR 30.32(e) because that regulation requires the payment of a fee that is not required by North Carolina.

- Subparagraph (a)(20) is administrative in nature and permits the agency to rely on an environmental assessment made using the requirements of the NC Department of Environmental Quality instead of the US Environmental Protection Agency if the agency wishes to. It also specifies that a NC radioactive materials license will be issued and not a form NRC 374 license. The agency has not licensed facilities requiring any type of environmental assessment and does not foresee the need to do so in the future. There is no anticipated fiscal or opportunity cost impact due to this rule.

- Subparagraph (a)(21) excludes 10 CFR 30.34(d), (e)(1) and (e)(3) which fall under exclusive NRC jurisdiction.

- Subparagraph (a)(22) defines the initialism "DCE" that is not defined in 10 CFR 30 to provide clarity to licensees regarding the requirements of this Rule. The agency does not anticipate a fiscal or opportunity cost impact providing this clarity.

- Subparagraph (a)(25) clarifies the agency requirement for the length of time a licensee may work or store radioactive material at a temporary jobsite before that jobsite must be added to the license as an authorized place of use. This resolves a health and safety issue the agency has encountered with a couple of portable nuclear gauge licensees who set up permanent "temporary" locations of use without informing the agency. The concern that the agency has is that these licensees avoid the regularly scheduled health and safety inspections that are conducted at locations of use listed on the license. Inspection frequencies are risk informed: the higher the chance of exposure to radiation, the more frequent the inspection at the permanent location of use. There are also different inspection requirements for permanent locations of use and temporary locations of use,

with inspections at permanent locations being more rigorous than at temporary locations of use. For example, permanent locations typically require a thorough examination of program records, an inspection of the licensee's facility with extensive interviews with licensee staff and employees and can involve several layers of management. Inspections at temporary locations do not typically go into the same depth as inspections at permanent locations: the records that are required to be at the temporary location are a subset of the records required of the entire radiation safety program, usually only brief interviews with staff at that location are conducted, and observations of licensed activities may or may not be performed depending on whether the licensee is using radioactive material at that location at the time of the inspection. Temporary locations are inspected as opportunity arises, and not all temporary locations are inspected each time the home office is inspected. As a result, a permanent "temporary" location can go through several inspection cycles for that type of license before it is inspected. Inspecting permanent "temporary" locations of use imposes a financial and opportunity cost on the agency that is not compensated through the annual licensing fee the agency charges its licensees. License fees are charged for each location listed on the license, but temporary locations are not listed on the license because they are intended to be used for a short period of time over the course of a year. Opportunity costs include the time and effort it takes to conduct a detailed inspection at the temporary location of use, increased health and safety risk for occupationally exposed workers based at that location due to the decreased inspection frequency and the public. Less frequent inspections at these locations may lead to a feeling of complacency among management and staff at these locations as well. Management and staff will invariably note that the main location is inspected, but not "us," leading to the mistaken conclusion that their regulator "doesn't care." The other opportunity cost impacts licensees who may be at a competitive disadvantage in the marketplace because they are holding, and paying annual fees for, radioactive materials licenses for several permanent locations of use, versus the licensee with one permanent location listed on the license with permanent "temporary" locations that pays only a single license fee. This Rule will level the playing field for licensees with multiple radioactive materials licenses (one for each permanent location of use) by removing this economic disadvantage. The agency does not charge inspection fees, so the effort the agency must expend in resources (agency funds and employee time) to ensure that permanent "temporary" locations are inspected appropriately are unreimbursed. Listing these locations on the license will resolve these issues.

In addition, prior to this rulemaking this requirement was in policy and was unenforceable, although nearly all our licensees have complied with the policy without dissent. To make it enforceable, G.S. 150B-18 requires that this policy be in rule because it is a requirement of the agency (referencing G.S. 150B-2(8a)). The anticipated impact of this addition to the Rule is expected to be minimal because of the small number of licensees whose behavior will be impacted by the change, and who will be required to pay annual license fees for their "permanent" temporary locations of use. Currently, the agency is aware of only one licensee with one "permanent" temporary location of use. This Rule expected to double the annual fee for this licensee.

- Subparagraph (a)(27) excludes 10 CFR 30.41(b)(6) which falls under exclusive NRC jurisdiction.

- 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) provides an address where copies of 10 CFR 30 can be obtained for no cost to our regulated community.

The regulations in 10 CFR 30 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 10A NCAC 15 .0301, .0303, 0304, .0305, .0317, .0337, .0338, .0339, .0340, .0341, .0342, .0343, .0344, .0352, .0353, .0354, .0355, and .0357. Except as noted for Subparagraph (a)(25) discussed in the bulleted items above, there will be no change to the requirements the regulated community must meet because of this proposed rule change.

Another item of note is that the exemption for certain types and quantities of byproduct material removed from Rule .0304, and the exemption for certain devices removed from Rule .0305, are incorporated by reference in this Rule. Nothing changes about the exemptions themselves, only where they appear in 10A NCAC Chapter 15.

None of the proposed changes to Rule 10A NCAC 15 .0301 impose burdens on the regulated community that are not already required by the collection of rules in Section .0300 of Chapter 15, or require any changes to the operations of federal, state or local government. 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 or on enforcement actions. 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 .0302 General Domestic Licenses for Byproduct Material

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes the exemption for certain types and quantities of source material found in 10 CFR 40.13 and is reorganized into Paragraphs with subdivisions where appropriate to improve readability. The exemption for certain types and quantities of source material removed from this Rule is incorporated by reference in Rule .0309.

- Paragraph (a) incorporates 10 CFR 31 by reference, including subsequent amendments and additions.

- Subparagraph (a)(1) provides the agency's address for inquiries regarding the rules and instructs licensees to send notices and reports required by the Rule to the agency unless instructed otherwise.

- Subparagraphs (a)(4) and (a)(10) require the registration of generally licensed devices with the agency and instruct the regulated community how to register these devices and what information is required to be submitted to the agency for registration. There are no changes in the registration requirements from those in the existing rules in Section .0300 of Chapter 15.

- Paragraph (b) is an administrative addition to the Rule to clarify where general license applications for registrations 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) provides an address where copies of 10 CFR 31 can be obtained for no cost to our regulated community.

None of the proposed changes to Rule 10A NCAC 15 .0302 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 .0301, .0309, .0310, .0312, .0314, or .0315 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 .0304 Specific Licenses: Manufacture or Transfer Certain Items Containing Byproduct Material

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes the exemption for certain types and quantities of byproduct material found in 10 CFR 30.18 and is reorganized into Paragraphs with subdivisions where appropriate to improve readability. The exemption removed from this Rule incorporated by reference in Rule .0301.

- Paragraph (a) incorporates 10 CFR 32.1(a), (b), (c)(2), 32.2 and 32.3 by reference and applies to all licensees manufacturing or initially transferring items or devices containing radioactive material. 10 CFR 32.1(c)(1) is not incorporated because it is under exclusive NRC jurisdiction.

- Paragraph (b) incorporates 10 CFR 32.13 and 32.24 and applies to licensees manufacturing or initially transferring devices containing exempt quantities of radioactive material. Paragraph (b) contains only the requirements that are not under exclusive NRC jurisdiction. Since licensing falls under exclusive NRC jurisdiction for these devices, Subparagraph (b)(3) instructs applicants for a license to manufacture or initially transfer devices containing exempt quantities of radioactive material to send these applications to the NRC and not the agency.

- Paragraph (c) incorporates 10 CFR 32.51 – 32.59, 32.61, 32.62, and 32.71 and applies to licensees manufacturing or initially transferring generally licensed devices containing byproduct material.

- Paragraph (d) incorporates 10 CFR 32.71 and 32.74 and applies to licensees manufacturing or initially transferring radiopharmaceuticals or medical devices containing byproduct material for medical use in humans.

- Paragraph (e) incorporates 10 CFR 32.201 and applies to all licenses manufacturing devices containing quantities of byproduct material equal to or greater than the quantities listed in Appendix E of 10 CFR 20.

- Paragraph (f) incorporates 10 CFR 32.210 and 32.211 and directs licensees interested in registering devices with the Sealed Source and Device Registry or amending or inactivating existing registrations issued by the agency to contact the agency.

- Paragraph (g) 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 (g) 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 (h) incorporates 10 CFR 32 by reference, including subsequent amendments, and gives the web address where copies of the regulations in 10 CFR 32 can be obtained free of charge.

None of the proposed changes to Rule 10A NCAC 15 .0304 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 .0301, .0309, .0317, .0318, .0327, .0328, .0330, .0333, or .0337 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 .0305 Specific Domestic Licenses of Broad Scope for Byproduct Material

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes the exemptions for certain devices containing byproduct material in 10 CFR 30.15, 30.19, 30.20, 30.21, and 30.22, and is reorganized into Paragraphs with subdivisions where appropriate to improve readability. The exemptions removed from this Rule are incorporated by reference in Rule .0301.

- Paragraph (a) incorporates 10 CFR 33.1, 33.11(a), 33.12, 33.13, 33.16, and 33.17(a) and (b) by reference and applies to all applicants for specific licenses of broad scope and broad scope licensees. A broad scope license differs from all other specific licenses because the licensees' radiation safety programs are self-regulating. The agency inspects how well broad scope licensees perform the regulatory functions that the agency performs at other types of licensed facilities. Another difference between broad scope licensees and other specific licensees is that broad scope licensees often conduct research using a wide variety of radioactive material, so they are approved to possess and use a wide range of material on their radioactive materials licenses. All other specific licenses are limited in the types and quantities and uses of radioactive materials approved for possession and use. For example, a broad scope licensee may be authorized to possess and use large quantities of any radioactive material for research purposes; while a cardiac clinic may be authorized to possess and use only a single radionuclide (such as technetium-199m) for cardiac imaging purposes.

- Subparagraph (a)(3) requires applicants to meet the requirements of Paragraph (b) of this Rule.

- 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) provides an address where copies of 10 CFR 33 can be obtained for no cost to our regulated community.

None of the proposed changes to Rule 10A NCAC 15 .0305 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 .0301, .0317, or .0324 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 .0307 Medical Use of Byproduct Material in Humans

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes the general licensing requirements for source material found in 10 CFR 40.22 and 40.25, and the reporting requirements required by both regulations. The exemptions removed from this Rule are incorporated by reference in Rule .0309. The proposed rule is reorganized into Paragraphs with subdivisions where appropriate to improve readability.

This Rule has a new requirement for North Carolina medical-use licensees: 10A NCAC 15 .0307(b)(3) adds the requirement that nuclear medicine technicians (NMTs) hold active certification issued by either the American Registry of Radiographic Technologists in nuclear medicine technology (ARRT(N)) or the Nuclear Medicine Technologist Certification Board (CNMT) to collect and obtain data to be used by a physician for medical diagnoses. This requirement does not affect other duties typically associated with NMTs such as receiving doses, drawing up doses, measuring the radioactive content of doses prior to administration, etc., through discharge of the patient afterward.

- Paragraph (a) presents the general information requirements of Subpart A to 10 CFR 35.

- Subparagraph (a)(7) excludes 10 CFR 35.11(c)(1) from incorporation by reference because that regulation is under exclusive NRC jurisdiction.

- Subparagraph (a)(8) instructs applicants for new licenses, renewals of existing licenses or licensees amending their licenses to comply with the provisions of Paragraph (m). Paragraph (m) is administrative and instructs applicants to send applications to the agency and not the NRC, and it lists the contents of the application form.

- Subparagraph (a)(9) excludes 10 CFR 35.13(a)(1) from incorporation by reference because that regulation is under exclusive NRC jurisdiction.

- Subparagraph (a)(10) requires that any notifications required by the Rule be sent to the agency and not the NRC.

- Subparagraph (a)(12) excludes 10 CFR 35.18(a)(2) from incorporation by reference because that regulation is under exclusive NRC jurisdiction.

- Paragraph (b) presents the general administrative requirements of Subpart B to 10 CFR 35.

- Subparagraph (b)(3), requires that NMTs hold active ARRT(N) or CNMT certification to collect data to be used by a physician for medical diagnoses. The intent of this requirement, which is new, is to increase patient safety by limiting exposure to radiation during diagnostic nuclear medical imaging procedures while simultaneously increasing image quality to better serve healthcare providers and patients alike. This differs from the current rule that lists the training requirements that licensees must ensure their NMTs meet, and states that ARRT(N) and CNMT certification provides proof that some of these training requirements have been met. Under the proposed rule, NMTs who do not hold active ARRT(N) or CNMT certification will be required to work under the supervision of NMTs holding these active certifications or authorized users and be in training towards obtaining certification. The proposed Rule has a provision for a three (3) year delayed implementation date to allow NMTs who do not have the required certification to obtain that certification. Certification programs at UNC-CH and local community colleges are full-time one-and-a-half or two-year programs depending on prior education. The rule change does not affect medical licensees who do not perform diagnostic studies on patients or veterinary licensees. The Rule also does not affect other activities that NMTs perform.

  To assess the impact of this Rule change, the agency ran a database query for all hospital-based licensees authorized for diagnostic nuclear imaging and all private practice diagnostic nuclear imaging licensees. Email addresses for licensee contacts and Radiation Safety Officers for those licensees were imported to Excel from the database and sorted for unique email addresses. This resulted in 173 unique email addresses for the 156 licenses impacted by this proposed Rule. All 173 email addressees were sent the same message requesting comments about the impact this Rule might have on their medical practices. Fourteen of these messages were returned as non-deliverable and the agency did not reach out to these licensees because they represent less than ten percent of all impacted licensees. Licensees were given nine days to respond to the request for feedback. Responses received after the due date were also used. The agency received five responses: three asking for clarification of the proposed Rule, an explanation of the current Rule and how it differed from the proposed Rule, and a single inquiry for guidance on how to find online classes for certification. One respondent asked if the proposed Rule impacted therapy licensees, which it does not. One respondent supported the proposed rule and stated that hospitals were already in compliance with the requirement because the Joint Commission requires it, and that most private practice diagnostic medicine practices did not employ NMTs.

  The Joint Commission is an accreditation body for health care facilities, most of which are hospitals. Private practice diagnostic nuclear imaging licensees are seldom accredited. Accreditation may confer a marketing advantage in a competitive health care environment because it demonstrates a commitment to continuing quality improvement. It demonstrates a focus on state-of-the-art performance improvement strategies that may improve access to and reduce the cost of liability insurance coverage and it can attract qualified personnel, who prefer to

serve in an accredited organization. In some markets, accreditation is becoming a prerequisite to eligibility for insurance reimbursement and for participation in managed care plans. These advantages are evidenced by the observed phenomenon in North Carolina of the increasing number of private practice medical clinics with hospital affiliations.

No responses were received opposing the proposed rule.

There are three in-state schools that offer coursework leading up to qualifying to take the certification exams. The cost of textbooks, lodging, transportation, extra fees, malpractice insurance, and personal health insurance required by each school vary, and are not evaluated for this analysis. Tuition at schools outside North Carolina is not evaluated because there are in-state schools that provide this training. These are all full-time programs:

1) UNC-CH, diplomate in nuclear medicine technology. This is a one-year program. Prerequisites are an Associates' Degree (AD) in an applied patient health healthcare related field, or a Bachelors of Science or higher in natural or physical science. In person only. Free tuition.
2) Caldwell Community College and Technical Institute – offers two options:
    - AD in nuclear medicine technology. This is a two-year program and includes coursework over the intervening summer session. Minimum prerequisite is a HS diploma. In person only. Tuition for all the credit hours to complete the entire program is $5320.
    - Nuclear Medicine Technology Diploma. This is a one-year program beginning the summer before the academic year. Minimum prerequisite is an AD in radiological sciences from an accredited program and a High School diploma. In person only. Tuition for all the credit hours to complete the entire program is $4313.
3) Pitt Community College – offers three options, and has both in-person and online courses:
    - AD in nuclear medicine technology. This is a two-year program and includes coursework over the intervening summer. Minimum prerequisite is HS diploma and passing general education coursework prior to applying to the NMT program. Tuition for all the credit hours to complete the entire program after the prerequisites are met is $5320.
    - AD in nuclear medicine technology. This is a two-year program and is offered online. The minimum prerequisite is a HS diploma and a Nurses' Aide class with a minimum of 32 clinical contact hours. Tuition for all the credit hours to complete the entire program after the prerequisites are met is $5320.
    - Nuclear Medicine Technology Diploma. This is a one-and-a-quarter-year program, in person only. The minimum prerequisite is an AD in a patient care specialty other than nuclear medicine and a High School diploma. Tuition for all the credit hours to complete the entire program is $3648.

The agency assumes that individuals holding active certificates issued by ARRT or CNMT in a specialty other than (N), nuclear medicine or nuclear cardiology, and individuals without these certificates employed as NMTs possess the minimum educational requirements to apply for the NMT programs at these schools. For individuals holding active ARRT and CNMT certificates in specialties other than (N), nuclear medicine or nuclear cardiology, it is likely that prior coursework can be credited toward the nuclear medicine curricula from general coursework required of all students in the various health care programs. The agency also assumes that individuals who are working as NMTs who have received the training required by 10A NCAC 15 .0318(h)(1) and (2) but who do not possess the minimum requirements to apply for one of these programs will continue working in a training status under the supervision of an NMT with an appropriate active certificate or under the supervision of an authorized user in lieu of seeking this education. Although this last outcome does skirt the intent of the Rule, it is in compliance with

the letter of the Rule and is anticipated to be a temporary situation because it does put the licensee at risk of being cited a violation of the Rule during an inspection. It is highly unlikely that such a violation will result in a civil penalty absent other severe programmatic insufficiencies. The licensee will be required to come into compliance with the Rule requirements through administrative means, usually by a commitment to comply with the rule and policy and procedure changes.

Undocumented verbal remarks by inspectors indicate that a few private practice diagnostic nuclear imaging licensees in rural areas along the coastal plain employ NMTs who do not hold ARRT(N) or the appropriate CNMT certification. If true, these individuals may need to gain this certification to continue employment. To evaluate this possibility, the agency queried the inspections database to get the number of private practice diagnostic nuclear imaging licensees possibly affected by this Rule. There are 36 private practice diagnostic nuclear imaging licensees in the eastern inspection region (east of Interstate 95). Of these 36 licensees, approximately one third do not have an obvious hospital affiliation. The agency relied on the appearance of a known hospital name as part of the licensee's name to make this determination (e.g. Pitt County Imaging is associated with Pitt County Hospital, etc.). The agency assumes that hospital affiliation drives those licensees to hire only ARRT(N) or CNMT (nuclear medicine or nuclear cardiology) certified individuals because of Joint Commission requirements. To be conservative, the agency is assuming that fifteen of these licensees will need to arrange NMT coverage to provide nuclear medicine imaging services while their NMTs attend school. As noted, the training programs are full time endeavors: students are typically in class, lab, or the clinic during the day for four to five days a week for up to two years. The principal opportunity and financial cost to licensees will be hiring a temporary NMT and training them in the licensee's specific radiation protection program elements to provide coverage during these absences. Based on conversations with NMTs, most licensees do not pay for continuing education credits to maintain certification but do allow paid time off to attend week-long conferences or to take online courses. The agency expects that licensees will not pay for the education of an NMT to obtain the coursework to take the required certification exam, and very few will permit paid time off over a two year period. If we assume one NMT is employed at each of these locations, which is the norm, that's fifteen individuals that will have to seek appropriate certification to continue employment under this proposed Rule. A search on the internet revealed that the average hourly rate for a temporary NMT is $42 per hour and the hourly rate for a permanent NMT is $48 per hour. These average hourly rates are so close together the agency determined that the cost to licensees is about the same, except that permanent employees may be covered under the employer's health care and insurance benefit plans. Therefore, the agency is assuming that there may be a slight cost savings hiring temporary NMTs over permanent NMTs. This cost savings is expected to be minimal given the number of personnel employed at nuclear medicine facilities in general (administrative, clerical, support, physician, nursing, etc.) and the impact of the cost of these benefit plans borne by a licensee for a single individual is not assessed for this analysis.

Based on the anemic response from diagnostic nuclear imaging licensees to the agency's request for comments, the agency concludes that this Rule change is likely to have a minimal impact on the regulated community. It is expected that the cost for this certification will be borne by the NMT and not the licensee, and that the licensee's cost to hire a temp NMT while the permanent NMT is attending school is approximately equal to the cost of employing a permanent NMT.

- Paragraph (c) describes the information that is required to be in a clinical procedures manual (CPM). The requirement for a CPM and its contents are found in the definition of the term in 10A NCAC 15 .0104(25) and not elsewhere in the current rules. This Paragraph is intended to clarify

the requirement for a CPM by moving it from the definitions in the Chapter to this Rule, and to bulletize the items expected to be in it instead of presenting them in paragraph form.

- Paragraph (d) presents the general technical requirements of Subpart C to 10 CFR 35.

- Subparagraph (d)(3) is the same as 10A NCAC 15 .0359 with the addition that the manufacturer's procedures may be followed when direct measurement of the dose to be administered cannot be performed due to the nature of the radiopharmaceutical or the physical configuration of the dose container and the dose calibrator are incompatible.

- Subparagraph (d)(5) clarifies that sealed sources and brachytherapy sources can be placed into decay-in-storage and exempts brachytherapy sources from leak testing requirements once placed into decay-in-storage. This clears up a regulatory ambiguity when licensees place brachytherapy sources in storage that they will not be using again, effectively placing them into decay-in-storage, and the agency cites them for not leak testing and inventorying these sources as required by 10 CFR 35.67. Decay-in-storage is permitted by 10 CFR 35.92 (Subparagraph (d)(10) of this Rule). Since decay-in-storage is already permitted in Rule, there is no financial impact anticipated for this clarification.

- Subparagraph (d)(6) permits licensees to use unlabeled dose carriers under prescribed conditions. This provision was added to this subparagraph to reflect current operating practices at most diagnostic medical clinics. There is no anticipated financial or opportunity cost with this provision.

- Paragraph (e) presents the requirements of Subpart D to 10 CFR 35 for licensees using radiopharmaceuticals for procedures that do not require prior written approval before the administration of material.

- Paragraph (f) presents the requirements of Subpart E to 10 CFR 35 for licensees using radiopharmaceuticals for procedures that do require prior written approval before the administration of material.

- Subparagraph (f)(3) permits the release of contaminated personal items to a patient administered radioactive materials upon discharge from care. The financial and opportunity cost of this provision in the Rule is anticipated to be minimal, although the emotional impact may be high, particularly for pediatric patients given toys to play with while undergoing treatment and those patient's parents. This also codifies in Rule a common practice at nuclear medicine facilities that is not permitted under 10 CFR 35.315 without a specific exemption in the licensee's license.

- Paragraph (g) presents the requirements for performing brachytherapy in Subpart F to 10 CFR 35.315

- Subparagraph (g)(11) clarifies the agency expectation that an Authorized Medical Physicist approve the calibration measurements for brachytherapy sources used for patient treatment.

- Paragraph (h) presents the requirements for using sealed sources for diagnostic uses in Subpart G to 10 CFR 35.

- Paragraph (i) presents the requirements for using sealed sources in select medical devices in Subpart H to 10 CFR 35.

- Paragraph (j) states that any uses of radioactive materials for medical use in humans that are not covered in Rules (e) through (i) are subject to the requirements of Subpart K to 10 CFR 35.

- Paragraph (k) presents the record keeping requirements in Subpart L to 10 CFR.

- Paragraph (l) presents the requirements for incident notification and written reports in Subpart M to 10 CFR.

- Paragraph (m) 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 (n) incorporates 10 CFR 35 by reference, including subsequent amendments and editions, and provides an address where copies of 10 CFR 35 can be obtained for no cost to our regulated community.

As discussed above, the proposed changes to Rule 10A NCAC 15 .0307 will impose a minimal burden on the regulated community and is not expected to impact the operations of federal, state or local government. The opportunity and financial costs for the changes are anticipated to be slight, most of the rule changes are clarifying in nature and permit licensees to conduct business as they are accustomed. Except as noted for Subparagaph (a)(3) of this Rule, the regulatory requirements remain unchanged in the proposed rule from those existing in Rules .0301, .0317, .0318, .0319, .0320, .0321, .0322, .0340, .0341, .0351, .0356, .0358, .0359, .0360, .0361, .0362, .0363, .0364, .0365, .0701 or .0702 from Sections .0300 and .0700, respectively, of Chapter 15. The principal changes of note to this Rule should increase the level of patient care during diagnostic nuclear imaging studies or 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 .0308 Licenses and Radiation Safety Requirements for Irradiators

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes the requirement to comply with the provisions of 10A NCAC 15. 0305(a) for the possession and use of 500 microcuries or less of polonium-210 or 50 millicuries or less of tritium in certain devices. The provisions removed from this Rule are incorporated by reference in Rule .0301. The proposed rule is reorganized into Paragraphs with subdivisions where appropriate to improve readability.

- Paragraph (a) incorporates 10 CFR 36 by reference, including subsequent amendments and editions, except for the regulations in 10 CFR 170. 10 CFR 170 lists the fees that NRC charges its licensees and does not apply to North Carolina licensees.

- Subparagraph (a)(2) excludes references to "common defense and security." Common defense and security is a national concept that falls under exclusive NRC jurisdiction.

- Subparagraph (a)(3) requires applicants to meet the requirements of Paragraph (b) of this Rule.

- Subparagraph (a)(30) instructs licensees to send reports to the agency and not the NRC, and is administrative in nature.

- 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) provides an address where copies of 10 CFR 36 can be obtained for no cost to our regulated community.

None of the proposed changes to Rule 10A NCAC 15 .0308 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 .0317 or .0337 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 .0309 Domestic Licensing of Source Material

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes the requirement to comply with the provisions of 10 CFR 31.5 and the general license for the possession and use of certain devices and the reporting requirements for transferring these devices. The provisions removed from this Rule are incorporated by reference in Rule .0302. The proposed rule is reorganized into Paragraphs with subdivisions where appropriate to improve readability.

- Paragraph (a) incorporates 10 CFR 40 by reference, including subsequent amendments and editions, except for 10 CFR 70.22(b), (c), (f)- (n) and the regulations in 10 CFR 170. The regulations in 10 CFR 70 excluded from incorporation by reference in this Rule are under exclusive NRC jurisdiction. 10 CFR 170 lists the fees that NRC charges its licensees and does not apply to North Carolina licensees.

- Subparagraph (a)(5) excludes those definitions and parts of definitions that are under exclusive NRC jurisdiction.

- Subparagraph (a)(6) instructs licensees to send the notices and reports required by the Rule to the agency unless directed otherwise.

- Subparagraph (a)(11) excludes 10 CFR 40.13(c)(5)(iv) because that regulation falls under exclusive NRC jurisdiction.

- Subparagraph (a)(18) requires applicants to meet the requirements of Paragraph (b) of this Rule, permits the agency to require environmental impact assessments made in accordance with N.C. Department of Environmental Quality requirements in lieu of those in 10 CFR 51, and specifies that reports required by 10 CFR 40.31(g) be sent to the NRC and not the agency.

- Subparagraph (a)(19) permits the agency to base the issuance of a license on an environmental impact assessment made using N.C. Department of Environmental Quality requirements in lieu of those in 10 CFR 51, and excludes 10 CFR 40.32(d), (g) and references and requirements related to uranium enrichment and uranium hexafluoride. The regulations in 10 CFR 40 excluded from incorporation in this Rule fall under exclusive NRC jurisdiction.

- Subparagraph (a)(38) excludes the criteria listed in Appendix A to Part 40 that fall under exclusive NRC jurisdiction.

- 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) provides an address where copies of 10 CFR 40 can be obtained for no cost to our regulated community.

None of the proposed changes to Rule 10A NCAC 15 .0309 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 .0301, .0302, .0306, .0307, .0313, .0317, .0337, .0338, .0339, .0340, .0341, .0343, .0344, .0353, .0354, or .0357 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 .0310 Domestic Licensing of Special Nuclear Material

The Radiation Protection Commission is proposing to readopt this rule with substantive changes. The proposed rule removes the requirement to comply with the provisions of Rule .0309 for the manufacturing, installation, and servicing of certain devices described in Rule .0309. The provisions removed from this Rule are incorporated by reference in Rule .0302. The proposed rule is reorganized into Paragraphs with subdivisions where appropriate to improve readability.

- Paragraph (a) incorporates 10 CFR 70 by reference, including subsequent amendments and editions.

- Subparagraph (a)(4) excludes those parts of definitions referring to common defense and security. Common defense and security falls under exclusive NRC jurisdiction.

- Subparagraph (a)(5) instructs licensees to send notices and reports to the agency in lieu of the NRC unless directed otherwise by the agency.

- Subparagraph (a)(14) requires applicants to meet the requirements of Paragraph (b) of this Rule.

- Subparagraph (a)(17) defines the initialism "DCE" that appears in 10 CFR 70.25(e)(2) that is not defined elsewhere in 10 CFR 70.

- 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) provides an address where copies of 10 CFR 70 can be obtained for no cost to our regulated community.

None of the proposed changes to Rule 10A NCAC 15 .0310 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 .0301, .0306, .0312, .0313, .0316, .0317, .0330, .0337, .0338, .0339, .0340, .0341, .0342, .0343, .0344 or .0353 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.

Summary

The proposed changes to these Rules are largely for the purpose of updating the rules to comply with current federal regulations regarding the licensing and handling of radioactive material. There are two changes to the rules that go beyond the current requirements in 10A NCAC 15 and those in the federal regulations. The first is the new requirement that nuclear medicine technologists hold active ARRT(N) or CNMT certification in nuclear medicine or nuclear cardiology to provide data to a physician for diagnoses of disease in humans. The second is that licensees authorized to use radioactive materials at temporary locations are required to add those locations to their license if they work at those locations

longer than six months. The intent of the first new requirement is to improve patient safety and care during diagnostic procedures using radioactive materials. Better imaging quality by qualified individuals is expected to result in lower patient exposure to radiation. The intent of the second new requirement is two-fold: first, it avoids situations where a licensee has a location of use that is essentially permanent and avoids the regularly scheduled health and safety inspections conducted at permanent locations of use; second, it levels the playing field for those licensees who list temporary locations of use on their licenses as required by agency policy, but not previously codified in Rule, and who pay the additional license fees for those locations. Both of these new requirements are intended to protect the health and safety of the public and occupationally exposed workers. Costs associated with requiring ARRT(N) or CNMT certification in nuclear medicine or nuclear cardiology for nuclear medicine technologists are difficult to assess, and are expected to be minimal for licensees, although individuals working as NMTs that require the schoolwork to sit for the certification exams may bear a higher cost: Tuition at the community colleges that offer certification in nuclear medicine technology is expected to be borne by the individual and not the licensee. The cost to the licensee to hire a temporary nuclear medicine tech to fill in during staff absences for training may result in cost savings, but this cost savings is expected to be minimal. The agency's codification of the agency's policy regarding permanent "temporary" locations of use is expected to have a minimum cost to the regulated community, and may result in a few licensees, all portable nuclear gauge licensees, paying more in license fees than they are paying now. This will effectively level the playing field for licensees already meeting agency expectations about temporary locations of use by complying with agency policies. The agency anticipates that the proposed changes will result in minimal burdens to the regulated community, and that they will not result in changes to operations for local, state, or federal government. The improved clarity of the rules could result in time savings related to the application process for the regulated community and state regulators; however, these time savings are expected to be very minimal.

Appendix

SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL

10A NCAC 15 .0301 is proposed for readoption with substantive changes as follows:

Codifier's Note: 10 NCAC 03G .2400 was transferred to 15A NCAC 11 .0300 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0301 ~~PURPOSE AND SCOPE~~ GENERAL RULES APPLICABLE TO THE SPECIFIC LICENSING OF BYPRODUCT MATERIAL

~~(a) This Section provides for the licensing of radioactive material. No person shall receive, possess, use, transfer, own, transport, manufacture and produce, or acquire radioactive material except as authorized in a specific or general license issued pursuant to, or as otherwise provided in, this Section.~~

~~(b) In addition to the requirements of this Section:~~

~~(1) All licensees are subject to the requirements of Sections .1000, .1100 and .1600 of this Chapter, except as otherwise provided in the rules of this Section;~~

~~(2) Licensees engaged in industrial radiographic operations are subject to the requirements of Section .0500 of this Chapter;~~

~~(3) Licensees using sealed sources in the healing arts are subject to the requirements of Section .0700 of this Chapter;~~

~~(4) Licensees engaged in the operation of radioactive waste disposal facilities are subject to the requirements of Section .1200 of this Chapter; and~~

~~(5) Licensees engaged in well logging operations are subject to the requirements of Section .1300 of this Chapter.~~

~~(c) The rules in this Section do not apply to persons licensed pursuant to the rules in Section .1200 of this Chapter except as specifically provided otherwise in Section .1200.~~

(a) All persons using byproduct material shall comply with the provisions of 10 CFR 30, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) 10 CFR 30.1, "Scope;"

(2) 10 CFR 30.2, "Resolution of conflict;"

(3) 10 CFR 30.3, "Activities requiring license;"

(4) 10 CFR 30.4, "Definitions," except that references in the definitions to common defense and security shall not apply. The term "temporary jobsite" shall mean a location where byproduct materials are used and stored other than those location(s) of use authorized on the license;

(5) 10 CFR 30.6, "Communications," except that notices and reports required by this Rule shall be made to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC;

(6) 10 CFR 30.9, "Completeness and accuracy of information;"

(7) 10 CFR 30.10, "Deliberate misconduct;"

(8) 10 CFR 30.11, "Specific exemptions;"

(9) 10 CFR 30.12, "Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts;"

(10) 10 CFR 30.13, "Carriers;"

(11) 10 CFR 30.14, "Exempt concentration;"

(12) 10 CFR 30.15, "Certain items containing byproduct material;"

(13) 10 CFR 30.18, "Exempt quantities;"

(14) 10 CFR 30.19, "Self-luminous products containing tritium, krypton-85, or promethium-147;"

(15) 10 CFR 30.20, "Gas and aerosol detectors containing byproduct material;"

(16) 10 CFR 30.21(a), (b), and (d), "Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans;"

(17) 10 CFR 30.22, "Certain industrial devices;"

(18) 10 CFR 30.31, "Types of licenses;"

(19) 10 CFR 30.32(a) – (d) and (f) – (j), "Application for specific licenses," except that the requirements of Paragraph (b) of this Rule shall be met.

(20) 10 CFR 30.33, "General requirements for issuance of specific licenses," except the agency may base the issuance of a specific license on information and evaluations made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51, and the agency shall issue a "Radioactive Materials License" in lieu of Form NRC 374;

(21) 10 CFR 30.34(a) – (c), (e)(2), (e)(4), (f) – (k), "Terms and conditions of licenses;"

(22) 10 CFR 30.35, "Financial assurance and recordkeeping for decommissioning," the initials "DCE" shall mean "detailed cost estimate;"

(23) 10 CFR 30.36, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas;"

(24) 10 CFR 30.37, "Application for renewal of licenses;"

(25) 10 CFR 30.38, "Application for amendment of licenses and registration certificates." Licensees shall submit an application for amendment to the agency to add temporary jobsites to the license as authorized places of use if the duration of use or storage at the temporary jobsite exceeds 180 days in any calendar year;

(26) 10 CFR 30.39, "Commission action on applications to renew or amend;"

(27) 10 CFR 30.41(a), (b)(1) – (b)(5), (b)(7), (c), (d), "Transfer of byproduct material;"

(28) 10 CFR 30.50, "Reporting requirements;"

(29) 10 CFR 30.51, "Records;"

(30) 10 CFR 30.52, "Inspections;"

(31) 10 CFR 30.53, "Tests;"

(32) 10 CFR 30.61, "Modification and revocation of licenses and registration certificates;"

(33) 10 CFR 30.62, "Right to cause the withholding or recall of byproduct material;"

(34) 10 CFR 30.70, "Schedule A – Exempt concentrations;"

(35) 10 CFR 30.71, "Schedule B." This schedule shall also be known as the "exempt quantity table;"

(36) 10 CFR 30.72, "Schedule C – Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release;"

(37) Appendix A to Part 30, "Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning;"

(38) Appendix B to Part 30, "Quantities of Licensed Material Requiring Labeling;"

(39) Appendix C to Part 30, "Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning;"

(40) Appendix D to Part 30 "Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds;" and

(41) Appendix E to Part 30, "Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals."

(b) Applications shall be made on forms provided by the agency. One copy of the application 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/.

History Note: *Authority G.S. 104E-7; 104E-9(8); 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0301 Eff. February 1, ~~2015.~~ 2015;
Readopted Eff. May 1. 2024.

10A NCAC 15 .0302 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0302 ~~EXEMPTIONS FOR SOURCE MATERIAL~~ GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

~~(a) Any person possessing source material, or devices containing source material, in quantities not exceeding the limits of 10 CFR 40.13(a) through (c)(8) shall be exempt from the requirement for a radioactive materials license and shall comply with the provisions of 10 CFR 40.13.~~

~~(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.~~

(a) Persons possessing generally licensed items manufactured or initially transferred pursuant to Subpart B of 10 CFR 32 shall comply with the provisions of 10 CFR 31, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) Reports, notifications, and responses to agency requests for information required by this Rule shall be made to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency;

(2) 10 CFR 31.1, "Purpose and scope;"

(3) 10 CFR 31.2, "Terms and conditions;"

(4) 10 CFR 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere," except that the fee required by 10 CFR 170.31 shall not apply. Persons using devices described in 31.5(a) shall be registered with the agency. Device registration shall be made in accordance with Paragraph (b) of this Rule and shall contain the information required by 31.5(c)(13)(iii);

(5) 10 CFR 31.6, "General license to install devices generally licensed in 10 CFR 31.5;"

(6) 10 CFR 31.7, "Luminous safety devices in aircraft;"

(7) 10 CFR 31.8, "Americium-241 and radium-226 in the form of calibration or reference sources;"

(8) 10 CFR 31.9, "General license to own byproduct material;"

(9) 10 CFR 31.10, "General license for strontium 90 in ice detection devices;"

(10) 10 CFR 31.11, "General license for use of byproduct material for certain in vitro clinical or laboratory testing," except that persons required by 31.11(b) to register devices with the agency shall comply with the provisions of Paragraph (b) of this Rule;

(11) 10 CFR 31.12, "General license for certain items and self-luminous products containing radium-226;" and

(12) 10 CFR 31.21, "Maintenance of records;"

(b) Persons registering devices shall use General License Application for Registration forms provided by the agency. These forms are available free of charge at: https://radiation.ncdhhs.gov/rms/rmsgenlicforms.htm. 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. The following information shall appear on the application:

(1) facility name, mailing address, physical address if different from the mailing address, and the name of the county where the facility is located;

(2) type of device;

(3) device manufacturer;

(4) device model numbers and serial numbers;

(5) number of devices being registered, isotopes, and activity;

(6) indicate if the devices have been leak tested by checking the corresponding check box;

(7) if the devices have been leak tested, write down the frequency that leak tests are required;

(8) the name of the person or company performing the leak test;

(9) describe the method of device disposal; and

(10) the signature, printed name, title, date the form is signed and telephone number of the contact person.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part031/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0302 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Adopted Eff. May 1, 2024.

10A NCAC 15 .0303 is proposed for repeal through readoption as follows:

10A NCAC 15 .0303 EXEMPT CONCENTRATIONS: OTHER THAN SOURCE MATERIAL

History Note: *Authority G.S. 104E-7; 104E-10; 104E-20; 10 CFR 30.70;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0303 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0304 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0304 ~~EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL~~ SPECIFIC LICENSES: MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

~~(a) Any person possessing radioactive material in individual quantities specified in 10 CFR 30.18(a) or (b) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.18(c) through (e).~~

~~(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.~~

(a) All persons manufacturing or initially transferring items or devices containing exempt quantities or exempt concentrations of byproduct material, generally licensed and specifically licensed items or devices containing byproduct material, items or devices containing byproduct material for medical use in humans, and persons requesting safety evaluations of sealed sources or devices for registration with the national Sealed Source and Device Registry shall comply with the following requirements of 10 CFR 32:

(1) 10 CFR 32.1(a), (b), and (c)(2), "Purpose and scope;"

(2) 10 CFR 32.2, "Definitions," the term "initially transfer" shall mean the "initial commercial transfer of items and devices to an end user or a commercial or retail reseller;"

(3) 10 CFR 32.3, "Maintenance of records."

(b) All Persons manufacturing or initially transferring items or devices containing exempt quantities of byproduct material shall comply with the following requirements of Subpart A – Exempt Concentrations and Items:

(1) 10 CFR 32.13, "Same: Prohibition of introduction;"

(2) 10 CFR 32.24, "Same: Table of organ doses;" and

(3) applications to manufacture, process, produce, prepare, package, re-package, or initially transfer items or devices for commercial distribution containing exempt concentrations or exempt quantities of byproduct material shall be made to the NRC in lieu of the agency.

(c) All persons manufacturing or initially transferring generally licensed devices containing byproduct material shall comply with Paragraph (g) of this Rule and the following requirements of Subpart B – Generally Licensed Items:

(1) 10 CFR 32.51, "Byproduct material contained in devices for use under 10 CFR 31.5; requirements for license to manufacture, or initially transfer;"

(2) 10 CFR 32.51a, "Same: Conditions of licenses;"

(3) 10 CFR 32.52, "Same: Material transfer reports and records;"

(4) 10 CFR 32.53, "Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer;"

(5) 10 CFR 32.54, "Same: Labeling of devices;"

(6) 10 CFR 32.55, "Same: Quality assurance; prohibition of transfer;"

(7) 10 CFR 32.56, "Same: Material transfer reports;"

(8) 10 CFR 32.57, "Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer;"

(9) 10 CFR 32.58, "Same: Labeling of devices;"

(10) 10 CFR 32.59, "Same: Leak testing of each source;"

(11) 10 CFR 32.61, "Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer;"

(12) 10 CFR 32.62, "Same: Quality assurance; prohibition of transfer;" and

(13) 10 CFR 32.71, "Manufacture and distribution of byproduct material in certain in vitro clinical or laboratory testing under general license."

(d) All persons manufacturing or initially transferring items or devices containing byproduct material for medical use in humans shall comply with Paragraph (g) of this Rule and the following requirements of Subpart C – Specifically Licensed Items:

(1) 10 CFR 32.72, "Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35;" and

(2) 10 CFR 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use."

(e) All persons manufacturing sealed sources containing byproduct material in quantities equal to or greater than the quantities listed in Appendix E of 10 CFR 20 shall comply with Paragraph (g) of this Rule and the requirements of 10 CFR 32.201.

(f) All persons manufacturing or initially transferring sealed sources or devices containing byproduct material under this Rule for commercial distribution and persons requesting safety evaluations of sealed sources or devices for registration with the national Sealed Source and Device Registry shall comply with the following requirements of Subpart D – Sealed Source and Device Registration:

(1) 10 CFR 32.210, "Registration of product information;"

(2) 10 CFR 32.211, "Inactivation of certificates of registration of sealed sources and devices;" and

(3) requests for safety evaluations and registration of product information under this Paragraph and inactivation of certificates of registration of sealed sources and devices issued by the agency 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.

(g) Applications shall be made on forms provided by the agency. One copy of the application 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(h) The regulations cited in this Rule from 10 CFR Part 32 are hereby incorporated by reference, including subsequent amendments and editions. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part032/.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.71;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0304 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017,
Readopted Eff. May 1, 2024.

10A NCAC 15 .0305 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0305 ~~EXEMPT ITEM CONTAINING OTHER THAN SOURCE MATERIAL~~ SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

~~(a) Any person possessing items containing radioactive material listed in 10 CFR 30.15(a)(1) through (9) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.15.~~

~~(b) Any person possessing self-luminous products listed in 10 CFR 30.19(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.19.~~

~~(c) Any person possessing gas and aerosol detectors listed in 10 CFR 30.20(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.20.~~

~~(d) Any person possessing radioactive drugs containing carbon-14 urea for diagnostic use in humans listed in 10 CFR 30.21(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.21.~~

~~(e) Any person possessing industrial devices listed in 10 CFR 30.22(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR 30.22.~~

~~(f) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.~~

(a) Persons engaging in activities involving the use of more than one type of radioactive material and who have established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations in compliance with the Rules of this Chapter shall comply with the provisions of 10 CFR 33, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) 10 CFR 33.1, "Purpose and scope;"

(2) 10 CFR 33.11(a), "Types of specific licenses of broad scope;"

(3) 10 CFR 33.12, "Applications for specific licenses of broad scope," except that the requirements of Paragraph (b) of this Rule shall be met;

(4) 10 CFR 33.13, "Requirements for the issuance of a Type A specific license of broad scope;"

(5) 10 CFR 33.16, "Application for other specific licenses;" and

(6) 10 CFR 33.17(a), (b), "Conditions of specific licenses of broad scope."

(b) Applications shall be made on forms provided by the agency. One copy of the application 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 instructions

for completing the application printed on the application form shall be followed. 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 instructions for completing the application printed on the application form shall be followed. 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part033/.

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; April 1, 1999; June 1, 1993; October 1, 1982; September 1, 1981;
Transferred and Recodified from 15A NCAC 11 .0305 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024

10A NCAC 15 .0307 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0307 ~~GENERAL LICENSES: SOURCE MATERIAL~~ MEDICAL USE OF BYPRODUCT MATERIAL IN HUMANS

~~(a) Any person possessing source material in quantities equal to or less than the quantities shown in 10 CFR 40.22(a) shall be issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10 CFR 40.22(b) through (e).~~

~~(b) Any person possessing depleted uranium for the purpose authorized in 10 CFR 40.25(a) shall be issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10 CFR 40.25(b) through (e).~~

~~(c) Reports required by 10 CFR 40.22(b)(4) or 40.25(c) shall be sent to the agency at the address shown in Rule .0111 of this Chapter.~~

~~(d) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl~~.

(a) All persons using radioactive materials for medical use in humans shall comply with the general information requirements of Subpart A to 10 CFR 35, as follows:

(1) 10 CFR 35.1, "Purpose and scope;"

(2) 10 CFR 35.2, "Definitions;"

(3) 10 CFR 35.5, "Maintenance of records;"

(4) 10 CFR 35.6, "Provisions for the protection of human research subjects;"

(5) 10 CFR 35.7, "FDA, other Federal, and State requirements;"

(6) 10 CFR 35.10, "Implementation;"

(7) 10 CFR 35.11, "License required," except that 35.11(c)(1) shall not apply;

(8) 10 CFR 35.12, "Application for license, amendment, or renewal," except that the requirements in Paragraph (m) of this Rule shall be met;

(9) 10 CFR 35.13, "License amendments," except that 35.13(a)(1) shall not apply;

(10) 10 CFR 35.14, "Notifications," except that notifications required by this rule shall be submitted to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency;

(11) 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope;"

(12) 10 CFR 35.18, "License issuance," except 35.18(a)(2) shall not apply; and

(13) 10 CFR 35.19, "Specific exemptions."

(b) All persons using radioactive materials for medical use in humans shall comply with the general administrative requirements of Subpart B to 10 CFR 35, as follows:

(1) 10 CFR 35.24, "Authority and responsibilities for the radiation safety program;"

(2) 10 CFR 35.26, "Radiation protection program changes;"

(3) 10 CFR 35.27, "Supervision." Persons using instrumentation for the collection of data to be used by a physician shall hold active nuclear medicine technology (N) certification issued by the American Registry of Radiographic Technologists (ARRT) or hold active certification issued by the Nuclear Medicine Technologist Certification Board (NMTCB) within three (3) years of the effective date of this readopted Rule, or shall be in training and under the supervision of an individual holding active ARRT(N) or NMTCB certification or an authorized user;

(4) 10 CFR 35.40, "Written Directives;"

(5) 10 CFR 35.41, "Procedures for administrations requiring a written directive;"

(6) 10 CFR 35.49, "Suppliers for sealed source and devices for medical use;"

(7) 10 CFR 35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer;"

(8) 10 CFR 35.51, "Training for an authorized medical physicist;"

(9) 10 CFR 35.55, "Training for an authorized nuclear pharmacist;"

(10) 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist;"

(11) 10 CFR 35.59, "Recentness of training;" and

(12) licensees administering radioactive materials to patients shall have a physician, a nurse practitioner, or a physicians' assistant available to provide emergency life-saving assistance in the event of a medical emergency. These individuals are not required to be users of radioactive materials.

(c) All persons administering radioactive materials to humans not requiring a written directive shall develop, document, maintain, and require the use of, a clinical procedures manual. This manual shall be approved in writing by an authorized user, and shall include, for each nuclear medicine procedure not requiring a written directive performed at the facility:

(1) the range of radiopharmaceutical dosages;

(2) the method used to determine the dosage;

(3) the route of administration;

(4) provision of job-specific training and assistance to medical personnel in the administration of radioactive material for purposes including, but not limited to, the evaluation of cardiac ischemia in the emergent setting and localization of seizure foci as an adjunct to epilepsy monitoring; and

(5) any other information the licensee determines to be useful for patient care, and to prevent the occurrence of medical events.

(d) All persons using radioactive materials for medical use in humans shall comply with the general technical requirements of Subpart C to 10 CFR 35, as follows:

(1) 10 CFR 35.60, "Possession, use, and calibration of instruments used to measure the activity of byproduct material;"

(2) 10 CFR 35.61, "Calibration of survey instruments;"

(3) 10 CFR 35.63, "Determination of dosages of unsealed byproduct material for medical use," except that the determination of dosages of unsealed photon emitting byproduct material shall be made only by direct measurement of radioactivity. If direct measurement of the dosage is not feasible because of the nature of the radiopharmaceutical, the manufacturer's recommendations for determining the dosage shall be used;

(4) 10 CFR 35.65, "Authorization for calibration, transmission, and reference sources;"

(5) 10 CFR 35.67, "Requirements for possession of sealed sources and brachytherapy sources," except that sealed sources and brachytherapy sources placed in storage may be decayed-in-storage as permitted by Subparagraph (d)(10) of this Paragraph. Brachytherapy sources placed into decay-in-storage shall be exempt from leak testing and the semi-annual inventory requirements of this Subparagraph;

(6) 10 CFR 35.69, "Labeling of vials and syringes," except that syringe shields and dose carriers used to shield or transport syringes labeled in accordance with this Rule shall not be required to be labeled when under the continuous direct control of the individual measuring the dose in accordance with Subparagraph (d)(3) of this Rule and administering the dose to the patient;

(7) 10 CFR 35.70, "Surveys of ambient radiation exposure rate;"

(8) 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material;"

(9) 10 CFR 35.80, "Provision of mobile medical service;" and

(10) 10 CFR 35.92, "Decay-in-storage," except that licensees may hold byproduct material with a half-life of less than or equal to 275 days for decay-in-storage.

(e) Persons using unsealed radioactive material for medical use not requiring a written directive shall comply with the requirements of Subpart D to 10 CFR 35, as follows:

(1) 10 CFR 35.100, "Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required;"

(2) 10 CFR 35.190, "Training for uptake, dilution, and excretion studies;"

(3) 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required;"

(4) 10 CFR 35.204, "Permissible molybdenum-99, strontium-82, and strontium-85 concentrations;" and

(5) 10 CFR 35.290, "Training for imaging and localization studies."

(f) Persons using unsealed radioactive material for medical use requiring a written directive shall comply with the requirements of Subpart E to 10 CFR 35, as follows:

(1) 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required;"

(2) 10 CFR 35.310, "Safety instruction;"

(3) 10 CFR 35.315, "Safety precautions;" except that patient's or human research subject's personal items that cannot be effectively decontaminated to a level indistinguishable from the natural

background may be released to them upon discharge, provided that the patient or human research subject is instructed not to share such items with others;

(4) 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required;"

(5) 10 CFR 35.392, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries);"

(6) 10 CFR 35.394, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries);" and

(7) 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive."

(g) Persons using sealed source radioactive material for medical use in manual brachytherapy shall comply with the requirements of Subpart F to 10 CFR 35, as follows:

(1) 10 CFR 35.400, "Use of sources for manual brachytherapy;"

(2) 10 CFR 35.404, "Surveys after source implant and removal;"

(3) 10 CFR 35.406, "Brachytherapy sources accountability;"

(4) 10 CFR 35.410, "Safety instructions;"

(5) 10 CFR 35.415, "Safety precautions;"

(6) 10 CFR 35.432, "Calibration measurements of brachytherapy sources;"

(7) 10 CFR 35.433, "Strontium-90 sources for ophthalmic treatments;"

(8) 10 CFR 35.457, "Therapy-related computer systems;"

(9) 10 CFR 35.490, "Training for use of manual brachytherapy sources;"

(10) 10 CFR 35.491, "Training for ophthalmic use of strontium-90;" and

(11) activities listed in Subparagraphs (g)(6) and (g)(7) of this Rule shall be approved by an Authorized Medical Physicist.

(h) Persons using sealed source radioactive material for medical diagnosis shall comply with the requirements of Subpart G to 10 CFR 35, as follows:

(1) 10 CFR 35.500, "Use of sealed sources and medical devices for diagnosis;" and

(2) 10 CFR 35.590, "Training for use of sealed sources and medical devices for diagnosis."

(i) Persons using sealed source radioactive material for medical use in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall comply with the requirements of Subpart H to 10 CFR 35, as follows:

(1) 10 CFR 35.600, "Use of a sealed source in a remote afterloading unit, teletherapy unit, or gamma stereotactic radiosurgery unit;"

(2) 10 CFR 35.604, "Surveys of patients and human research subjects treated with a remote afterloader unit;"

(3) 10 CFR 35. 605, "Installation, maintenance, and repair;"

(4) 10 CFR 35.610, "Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"

(5) 10 CFR 35.615, "Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"

(6) 10 CFR 35.630, "Dosimetry equipment;"

(7) 10 CFR 35.632, "Full calibration measurements on teletherapy units;"

(8) 10 CFR 35.633, "Full calibration measurements on remote afterloader units;"

(9) 10 CFR 35.635, "Full calibration measurements on stereotactic radiosurgery units;"

(10) 10 CFR 35.642, "Periodic spot-checks for teletherapy units;"

(11) 10 CFR 35.643, "Periodic spot-checks for remote afterloader units;"

(12) 10 CFR 35.645, "Periodic spot-checks for on stereotactic radiosurgery units;"

(13) 10 CFR 35.647, "Additional technical requirements for mobile remote afterloader units;"

(14) 10 CFR 35.652, "Radiation surveys;"

(15) 10 CFR 35.655, "Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units;"

(16) 10 CFR 35.657, "Therapy-related computer systems;" and

(17) 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units."

(j) Persons using radioactive material for medical use, or radiation from radioactive material for medical use, that are not specifically addressed in Paragraphs (e) through (i) of this Rule shall comply with requirements of Subpart K to 10 CFR 35.

(k) All persons licensed by the agency for the medical use of radioactive material shall maintain records required by Subpart L to 10 CFR 35, as follows:

(1) 10 CFR 35.2024, "Records of authority and responsibilities for radiation protection programs;"

(2) 10 CFR 35.2026, "Records of radiation protection program changes;"

(3) 10 CFR 35.2040, "Records of written directives;"

(4) 10 CFR 35.2041, "Records of procedures for administrations requiring a written directive;"

(5) 10 CFR 35.2060, "Records of calibrations of instruments used to measure the activity of unsealed byproduct materials;"

(6) 10 CFR 35.2061, "Records of radiation survey instrument calibrations;"

(7) 10 CFR 35.2063, "Records of dosages of unsealed byproduct material for medical use;"

(8) 10 CFR 35.2067, "Records of leak tests of sealed sources and brachytherapy sources;"

(9) 10 CFR 35.2070, "Records of surveys for ambient radiation exposure rate;"

(10) 10 CFR 35.2075, "Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material;"

(11) 10 CFR 35.2080, "Records of mobile medical services;"

(12) 10 CFR 35.2092, "Records of decay-in-storage;"

(13) 10 CFR 35.2203, "Records of molybdemum-99, strontium-82, and strontium-85 concentrations;"

(14) 10 CFR 35.2310, "Records of safety instruction;"

(15) 10 CFR 35.2404, "Records of surveys after source implant and removal;"

(16) 10 CFR 35.2406, "Records of brachytherapy source accountability;"

(17) 10 CFR 35.2432, "Records of calibration measurements of brachytherapy sources;"

(18) 10 CFR 35.2433, "Records of decay of strontium-90 sources for ophthalmic treatments;"

(19) 10 CFR 35.2605, "Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"

(20) 10 CFR 35.2610, "Records of safety procedures;"

(21) 10 CFR 35.2630, "Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"

(22) 10 CFR 35.2632, "Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations;"

(23) 10 CFR 35.2642, "Records of periodic spot-checks for teletherapy units;"

(24) 10 CFR 35.2643, "Records of periodic spot-checks for remote afterloader units;"

(25) 10 CFR 35.2645, "Records of periodic spot-checks for gamma stereotactic radiosurgery units;"

(26) 10 CFR 35.2647, "Records of additional technical requirements for mobile remote afterloader units;"

(27) 10 CFR 35.2652, "Records of surveys of therapeutic treatment units;" and

(28) 10 CFR 35.2655, "Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units."

(l) All persons licensed by the agency for the medical use of radioactive material shall make, or cause to be made, the reports required by Subpart M to 10 CFR Part 35. Notifications made by telephone shall be made to the agency in lieu of the NRC Operations Center. Written reports and correspondence required by this Rule shall be submitted to the agency at the address shown in Rule .0111 of this Chapter unless otherwise directed by the agency, in lieu of the NRC Regional Office:

(1) 10 CFR 35.3045, "Report and notification of a medical event;"

(2) 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child;"

(3) 10 CFR 35.3067, "Report of a leaking source;" and

(4) 10 CFR 35.3204, "Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations."

(m) Applications shall be made on forms provided by the agency. One copy of the application 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 free of charge at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm

(n) The regulations cited in this Rule from 10 CFR 35 are hereby incorporated by reference, including subsequent amendments and editions. Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0307 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0308 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0308 ~~GENERAL LICENSES: OTHER THAN SOURCE MATERIAL~~ LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

~~Any person possessing static elimination devices, or ion generating tubes containing 500 microcuries or less of Polonium 210, or ion generating tubes containing 50 millicuries or less of tritium, shall comply with Rule .0305(a) of this Section.~~

(a) Persons irradiating objects or materials using sealed sources containing radioactive materials shall comply with the provisions of 10 CFR 36, which are hereby incorporated by reference including subsequent amendments and editions, except that the requirements of 10 CFR 170 shall not apply, as follows:

(1) 10 CFR 36.1, "Purpose and scope;"

(2) 10 CFR 36.2, "Definitions," except that references to common defense and security shall not apply;

(3) 10 CFR 36.11, "Application for a specific license," except that the requirements of Paragraph (b) of this Rule shall be met;

(4) 10 CFR 36.13, "Specific licenses for irradiators;"

(5) 10 CFR 36.15, "Commencement of construction;"

(6) 10 CFR 36.17, "Applications for exemptions;"

(7) 10 CFR 36.19, "Requests for written statements;"

(8) 10 CFR 36.21, "Performance criteria for sealed sources;"

(9) 10 CFR 36.23, "Access control;"

(10) 10 CFR 36.25, "Shielding;"

(11) 10 CFR 36.27, "Fire protection;"

(12) 10 CFR 36.29, "Radiation monitors;"

(13) 10 CGR 36.31, "Control of source movement;"

(14) 10 CFR 36.33, "Irradiator pools;"

(15) 10 CFR 36.35, "Source rack protection;"

(16) 10 CFR 36.37, "Power failures;"

(17) 10 CFR 36.39, "Design requirements;"

(18) 10 CFR 36.41, "Construction monitoring and acceptance testing;"

(19) 10 CFR 36.51, "Training;"

(20) 10 CFR 36.53, "Operating and emergency procedures;"

(21) 10 CFR 36.55, "Personnel monitoring;"

(22) 10 CFR 36.57, "Radiation surveys;"

(23) 10 CFR 36.59, "Detection of leaking sources;"

(24) 10 CFR 36.61, "Inspection and maintenance;"

(25) 10 CFR 36.63, "Pool water quality;"

(26) 10 CFR 36.65, "Attendance during operations;"

(27) 10 CFR 36.67, "Entering and leaving the radiation room;"

(28) 10 CFR 36.69, "Irradiation of explosive or flammable materials;"

(29) 10 CFR 36.81, "Records and retention periods;" and

(30) 10 CFR 36.83, "Reports," except that reports required by this Rule shall be made to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency, in lieu of the NRC.

(b) Applications shall be made on forms provided by the agency. One copy of the application 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part036/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 2005; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0308 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0309 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0309 ~~GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES~~ DOMESTIC LICENSING OF SOURCE MATERIAL

~~(a) Any person possessing devices listed in 10 CFR 31.5(a) meeting the requirements of 10 CFR 31.5(b) shall be issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10 CFR 31.5(c) and (d), except that the fees specified in 10 CFR 31.5(c)(13)(ii) shall not apply to persons issued a general license under this Rule.~~

~~(b) Reports, requests for prior approval to transfer devices authorized under this Rule, and any other correspondence required by 10 CFR 31.5 shall be sent to the agency at the address listed in Rule .0111 of this Chapter.~~

~~(c) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.~~

(a) Persons using source material and byproduct material as defined in this Rule shall comply with the provisions of 10 CFR 40, which are hereby incorporated by reference including subsequent amendments and editions, except that references to importation and exportation of radioactive material and references to and requirements of 10 CFR 70.22(b), (c), (f) – (n), and 10 CFR 110 shall not apply, as follows:

(1) 10 CFR 40.1, "Purpose;"

(2) 10 CFR 40.2, "Scope;"

(3) 10 CFR 40.2a, "Coverage of inactive tailings sites;"

(4) 10 CFR 40.3, "Licensing requirements;"

(5) 10 CFR 40.4, "Definitions," except that the definition of "foreign obligations," "reconciliation," and references in the definitions to common defense and security shall not apply;

(6) 10 CFR 40.5, "Communications," except that notices and reports shall be made to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency or specified otherwise in this Rule, in lieu of the NRC;

(7) 10 CFR 40.9, "Completeness and accuracy of information;"

(8) 10 CFR 40.10, "Deliberate misconduct;"

(9) 10 CFR 40.11, "Persons using source material under certain Department of Energy and Nuclear Regulatory Commission contracts;"

(10) 10 CFR 40.12(a), "Carriers;"

(11) 10 CFR 40.13, "Unimportant quantities of source material," except 10 CFR 40.13(c)(5)(iv);

(12) 10 CFR 40.14, "Specific Exemptions;"

(13) 10 CFR 40.20, "Types of licenses;"

(14) 10 CFR 40.21, "General license to receive title to source or byproduct material;"

(15) 10 CFR 40.22, "Small quantities of source material;"

(16) 10 CFR 40.25, "General license for use of certain industrial products or devices;"

(17) 10 CFR 40.26, "General license for possession and storage of byproduct material as defined in this part;"

(18) 10 CFR 40.31(a), (b), (d), (f) – (i), "Application for specific licenses," except that the requirements of Paragraph (b) of this Rule shall be met, the agency may require information and evaluations made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51, and reports required by 10 CFR 40.31(g) shall be submitted to the NRC in lieu of the agency;

(19) 10 CFR 40.32, "General requirements for issuance of specific licenses," except that the agency may base the issuance of a specific license on information and evaluations made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51, and 10 CFR 40.32(d), (g), and references to and requirements for uranium enrichment and uranium hexafluoride facilities shall not apply;

(20) 10 CFR 40.34, "Special requirements for issuance of specific licenses;"

(21) 10 CFR 40.35, "Conditions of specific licenses issued pursuant to 10 CFR 40.34;"

(22) 10 CFR 40.36, "Financial assurance and recordkeeping for decommissioning," the initials "DCE" shall mean "detailed cost estimate;"

(23) 10 CFR 40.41(a) – (c), (e)(2), (e)(4), (f), "Terms and conditions of licenses;"

(24) 10 CFR 40.42, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas;"

(25) 10 CFR 40.43, "Renewal of licenses;"

(26) 10 CFR 40.44, "Amendment of licenses at request of licensee;"

(27) 10 CFR 40.45, "Commission action on application to renew or amend;"

(28) 10 CFR 40.46, "Inalienability of licenses;"

(29) 10 CFR 40.51(a), (b)(1) – (b)(5), (b)(7), (c), (d), "Transfer of source or byproduct material;"

(30) 10 CFR 40.54, "Requirements for license to initially transfer source material for use under the 'small quantities of source material' general license;"

(31) 10 CFR 40.55, "Conditions of licenses to initially transfer source material for use under the 'small quantities of source material' general license: Quality control, labeling, safety instructions, and records and reports;"

(32) 10 CFR 40.60, "Reporting requirements;"

(33) 10 CFR 40.61, "Records;"

(34) 10 CFR 40.62, "Inspections;"

(35) 10 CFR 40.63, "Tests;"

(36) 10 CFR 40.65, "Effluent monitoring reporting requirements;"

(37) 10 CFR 40.71, "Modification and revocation of licenses," and

(38) Appendix A to Part 40, "Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content," except Criterion 11A - F and 12 shall not apply.

(b) Applications shall be made on forms provided by the agency. One copy of the application 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part040/.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 2005; January 1, 1994; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0309 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0310 is proposed for readoption with substantive changes as follows:

10A NCAC 15 .0310 ~~GENERAL LICENSES: MANUFACTURE, TRANSFER, INSTALL GENERALLY LICENSED DEVICES~~ DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

~~(a) Any person possessing a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or another Agreement State authorizing the manufacture, installation, or servicing of a device described in Rule .0309 of this Section shall be authorized to install, service, and uninstall these devices in accordance with the provisions of 10 CFR 31.6.~~

~~(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.~~

(a) Persons using special nuclear material as defined in this Rule shall comply with the provisions of 10 CFR 70, which are hereby incorporated by reference including subsequent amendments and editions, as follows:

(1) 10 CFR 70.1(a) and (b), "Purpose;"

(2) 10 CFR 70.2, "Scope;"

(3) 10 CFR 70.3, "License requirements;"

(4) 10 CFR 70.4, "Definitions," except that references in the definitions to common defense and security shall not apply;

(5) 10 CFR 70.5, "Communications," except that notices and reports shall be made to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC unless otherwise specified by the agency;

(6) 10 CFR 70.9, "Completeness and accuracy of information;"

(7) 10 CFR 70.10, "Deliberate misconduct;"

(8) 10 CFR 70.11, "Persons using special nuclear material under certain DOE and NRC contracts;"

(9) 10 CFR 70.12, "Carriers;"

(10) 10 CFR 70.17, "Specific exemption;"

(11) 10 CFR 70.18, "Types of licenses;"

(12) 10 CFR 70.19, "General license for calibration and reference sources;"

(13) 10 CFR 70.20, "General license to own special nuclear material;"

(14) 10 CFR 70.21(a)(2), (a)(3), (b), "Filing," except that the requirements of Paragraph (b) of this Rule shall be met;

(15) 10 CFR 70.22(a), (d), and (e), "Contents of application;"

(16) 10 CFR 70.23(a)(1) – (5), "Requirements for the approval of applications;"

(17) 10 CFR 70.25(a)(2), (b) – (h), "Financial assurance and recordkeeping for decommissioning," the initials "DCE" shall mean "detailed cost estimate;"

(18) 10 CFR 70.31(a) and (b), "Issuance of license;"

(19) 10 CFR 70.32(a)(2), (a)(3), (a)(8), (a)(9), (b)(2), and (b)(5), "Conditions of licenses;"

(20) 10 CFR 70.33, "Applications for renewal of licenses;"

(21) 10 CFR 70.34, "Amendment of licenses;"

(22) 10 CFR 70.35, "Commission action on applications to renew or amend;"

(23) 10 CFR 70.36, "Inalienability of licenses;"

(24) 10 CFR 70.38, "Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor structures;"

(25) 10 CFR 70.39, "Specific licenses for the manufacture or initial transfer of calibration sources;"

(26) 10 CFR 70.41, "Authorized use of special nuclear material;"

(27) 10 CFR 70.42(a), (b)(1) – (b)(5), (b)(7), (c), (d), "Transfer of special nuclear material;"

(28) 10 CFR 70.50, "Reporting requirements;"

(29) 10 CFR 70.51, "Records requirements;"

(30) 10 CFR 70.55(a) and (b), "Inspections;"

(31) 10 CFR 70.56, "Tests;" and

(32) 10 CFR 70.81, "Modification and revocation of licenses."

(b) Applications shall be made on forms provided by the agency. One copy of the application 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: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

(c) Copies of the regulations incorporated by this Rule are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part070/.

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 .0310 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024.

10A NCAC 15 .0312 is proposed for repeal through readoption as follows:

10A NCAC 15 .0312 GENERAL LICENSES: CALIBRATION AND REFERENCE

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 .0312 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0314 - .0315 are proposed for repeal through readoption as follows:

10A NCAC 15 .0314 GENERAL LICENSES: IN VITRO CLINICAL OR LABORATORY TESTING

10A NCAC 15 .0315 GENERAL LICENSES: ICE DETECTION DEVICES

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 .0314 - .0315 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0317 - .0322 are proposed for repeal through readoption as follows:

10A NCAC 15 .0317	**SPECIFIC LICENSES: FILING APPLICATION AND GENERAL REQUIREMENT**
10A NCAC 15 .0318	**SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE**
10A NCAC 15 .0319	**SPECIFIC LICENSES: HUMAN USE IN HOSPITALS**
10A NCAC 15 .0320	**SPECIFIC LICENSES: HUMAN USE BY INDIVIDUAL PHYSICIANS**
10A NCAC 15 .0321	**SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE OF UNSEALED RADIOACTIVE MATERIALS**
10A NCAC 15 .0322	**SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES**

History Note: *Authority G.S. 104E-7; ~~104E-7(2);~~ 104E-7(a)(2); 104E-10(b); 10 CFR 35.2;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007; August 1, 2002; April 1, 1999; May 1, 1993; May 1, 1992; November 1, 1989; October 1, 1984;
Transferred and Recodified from 15A NCAC 11 .0317 - .0322 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0324 is proposed for readoption as a repeal as follows:

10A NCAC 15 .0324 SPECIFIC LICENSES: BROAD SCOPE

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0324 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff May 1, 2024.

10A NCAC 15 .0327 – .0335 are proposed for readoption as a repeal as follows:

10A NCAC 15 .0327 SPECIFIC LICENSES: EXEMPT GAS AND AEROSOL DETECTORS
10A NCAC 15 .0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED
10A NCAC 15 .0329 SPECIFIC LICENSES: LUMINOUS SAFETY DEVICES IN AIRCRAFT
10A NCAC 15 .0330 SPECIFIC LICENSES: MANUFACTURE OF CALIBRATION SOURCES
10A NCAC 15 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS
10A NCAC 15 .0332 SPECIFIC LICENSES: MANUFACTURE OF ICE DETECTION DEVICES
10A NCAC 15 .0333 SPECIFIC LICENSES: MANUFACTURE OF RADIOPHARMACEUTICALS
10A NCAC 15 .0334 SPECIFIC LICENSES: GENERATORS AND REAGENT KITS
10A NCAC 15 .0335 SPECIFIC LICENSES: PRODUCTS CONTAINING DEPLETED URANIUM

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; November 1, 2007; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0327 - .0335 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0337 – .0344 are proposed for readoption as a repeal as follows:

10A NCAC 15 .0337	**ISSUANCE OF SPECIFIC LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES**
10A NCAC 15 .0338	**SPECIFIC TERMS AND CONDITIONS OF LICENSES**
10A NCAC 15 .0339	**EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING**
10A NCAC 15 .0340	**RENEWAL OF LICENSES**
10A NCAC 15 .0341	**AMENDMENT OF LICENSES AT REQUEST OF LICENSEE**
10A NCAC 15 .0342	**AGENCY ACTION ON APPLICATIONS TO RENEW OR AMEND**
10A NCAC 15 .0343	**TRANSFER OF MATERIAL**
10A NCAC 15 .0344	**MODIFICATION: REVOCATION: AND TERMINATION OF LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES**

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-13; 104E-18;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1993; May 1, 1992; June 1, 1989;
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; April 1, 1999; August 1, 1998; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0337 - .0344 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0348 is proposed for readoption as a repeal as follows:

10A NCAC 15 .0348 SPECIFIC LICENSES: CERTAIN INCINERATOR FACILITIES

History Note: *Authority G.S. ~~104E-7(2);~~ 104E-7(a)(2); 104E-7(a)(8); 104E-10(b);*
Eff. October 1, 1984;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0348 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0351 is proposed for readoption as a repeal as follows:

10A NCAC 15 .0351 SPECIFIC LICENSES: MOBILE NUCLEAR MEDICINE SERVICES

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b);*
Eff. June 1, 1989;
Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0351 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0352 - .0355 are proposed for readoption as a repeal as follows:

10A NCAC 15 .0352 EMERGENCY PLANS

10A NCAC 15 .0353 FINANCIAL ASSURANCE AND RECORD-KEEPING FOR DECOMMISSIONING

10A NCAC 15 .0354 METHODS OF FINANCIAL ASSURANCE FOR DECOMMISSIONING

10A NCAC 15 .0355 FINANCIAL TESTS: SELF- AND PARENT CO. GUARANTEES: DECOMMISSIONING FUNDING

History Note: *Authority G.S. 104E-7; 104E-18; 10 CFR 30.72;*
Eff. May 1, 1992;
Amended Eff. October 1, 2013; May 1, 2006; April 1, 1999; August 1, 1998; January 1, 1994; May 1, 1993; October 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0352 - .0355 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0356 - .0357 are proposed for readoption as a repeal as follows:

10A NCAC 15 .0356 PROCEDURES FOR ADMINISTRATIONS REQUIRING A WRITTEN DIRECTIVE

10A NCAC 15 .0357 REPORTING REQUIREMENTS

History Note: *Authority G.S. 104E-7; 104E-7(a)(2); 104E-10(b);*
Temporary Adoption Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0356 - .0357 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0358 is proposed for readoption as a repeal as follows:

10A NCAC 15 .0358 RELEASE OF PATIENTS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS

History Note: *Authority G.S. 104E-7(a)(8); 104E-12;*
Eff. August 1, 1998;
Amended Eff. October 1, 2013;
Transferred and Recodified from 15A NCAC 11 .0358 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024,

10A NCAC 15 .0359 - .0362 are proposed for readoption as a repeal as follows:

10A NCAC 15 .0359 MEASUREMENTS/DOSAGES OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE

10A NCAC 15 .0360 SURVEYS OF RADIOPHARMACEUTICAL AREAS FOR RADIATION EXPOSURE RATE

10A NCAC 15 .0361 MEDICAL USE OF UNSEALED RADIOACTIVE MATERIAL

10A NCAC 15 .0362 DECAY-IN-STORAGE

History Note: *Authority G.S. 104E-7; 104E-7(a)(2); 104E-10(b); 104E-12;*
Eff. April 1, 1999;
Amended Eff. October 1, 2013; November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0359 - .0362 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0363 - .0365 are proposed for readoption as a repeal as follows:

10A NCAC 15 .0363 PROVISIONS FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS

10A NCAC 15 .0364 MEDICAL EVENTS

10A NCAC 15 .0365 REPORT AND NOTIFICATION OF A DOSE TO AN EMBRYO/FETUS OR A NURSING CHILD

History Note: *Authority G.S. 104E-7; 104E-7(a)(2); 104E-10(b); 104E-12;*
Eff. November 1, 2007;
Transferred and Recodified from 15A NCAC 11 .0363 - .0365 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0701 - .0702 are proposed for readoption as a repeal as follows:

SECTION .0700 - USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

Codifier's Note: 10 NCAC 03G .2800 was transferred to 15A NCAC 11 .0700 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0701 SCOPE

10A NCAC 15 .0702 MANUAL BRACHYTHERAPY

History Note: *Authority G.S. 104E-7; 104E-12(a);*
Eff. February 1, 1980;
Amended Eff. November 1, 2007; January 1, 2005; April 1, 1999; January 1, 1994; May 1, 1993; October 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0701 - .0702 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.