Fiscal Note Analysis for Proposed Rule Change
DHSR Radiation Protection Section

Agency Proposing Rule Change

North Carolina Radiation Protection Commission

Contact Persons

Nadine Pfeiffer, DHSR Rule-making Coordinator – 919-855-3 811
James Albright, Radiation Protection Environment Program Consultant – 919-814-2251
Lee Cox, Section Chief, Radiation Protection Section – 919-814-2252
David Crowley, Manager, Radioactive Materials Branch, RPS – 919-814-2303

Statutory Authority

G.S. 104E-7, G.S. 104E-10, G.S. 104E-12, G.S. 104E-15, G.S. 104E-18, G.S. 104E-19, G.S. 104E-20; G.S. 150B-21.6

Impact Summary

State government:	Yes
Local government:	No
Substantial impact:	No
Private entities:	Yes

Background & Rules Requirements:

North Carolina's Governor entered into an Agreement with the United States Atomic Energy Commission (Now United States Nuclear Regulatory Commission (NRC)) effective August 1, 1964.[1] This Agreement provided for the discontinuance of United States Atomic Energy Commission regulatory authority and responsibility within the State. For the Agreement to be approved, the United States Atomic Energy Commission had to determine that the North Carolina program for radiation protection was compatible with federal regulations, and that the program was adequate to protect public health and safety.

The North Carolina Radiation Protection Section (RPS) within the Department of Health and Human Services, Division of Health Service Regulation, is the organization charged with maintaining the Agreement with the NRC on behalf of the State. Part of the Agreement requires North Carolina to continue to maintain rules that are compatible with NRC's radiation protection rules. In most cases, the North Carolina radiation protection program rules must be identical with the matching federal rule. To enforce this, RPS is audited by the NRC every four years to verify that the State's radiation protection program remains compatible with that of the NRC, and that it is adequate to protect public health and safety. This audit is conducted under the NRC's Integrated Materials Performance Evaluation Program, and are called IMPEP reviews. The next anticipated IMPEP review has not been scheduled, but should occur in March, 2018.

Compatibility with the NRC requirements is also beneficial to licensees because many licensees may start businesses in North Carolina, but market their products nationwide, or plan to expand nationwide. By maintaining compliance with and transparency to NRC requirements the Radiation Protection Section is aiding businesses in North Carolina in creating a culture of uniform practices that can be easily transported across the U.S. and that would be compliant in all other States. This also helps encourage licensees when choosing to move a business to North Carolina, because radiation protection programs

[1] The North Carolina Agreement with the US Atomic Energy Commission can be found at the following link: https://scp.nrc.gov/special/regs/ncAgreements.pdf

will not have to be rewritten to requirements that are specific to North Carolina that are not congruent with the rest of the country.

Potential impacts of the loss of Agreement State status is discussed in the following section.

Impact from Failure to Remain Compatible with NRC Regulations:
The NRC may elect to terminate the Agreement and resume regulatory authority over radioactive materials use in North Carolina should the State's radiation safety program be found incompatible and inadequate to protect public health and safety. Reverting back to federal control would result in substantial fee increases for North Carolina business entities that require use of radioactive materials. In most cases, the NRC radioactive materials license fees are at least double the current North Carolina licensing fees. Also, the NRC charges its licensees inspection fees, while the State doesn't. The agency estimates that failure to maintain Agreement State status could result in fee increases and additional costs to radioactive materials licensees across the state of up to $6.7 million annually (see Table 1 below).

In this discussion, it is important to note that although losing State Agreement status is a possibility, it is an extreme outcome and is very unlikely to occur. The evaluation of an Agreement State's program with regard to protecting health and safety that occurs during an IMPEP review has eleven different topic areas that are called 'performance indicators'. Rule compatibility is but one of these performance indicators, and although it partially drives some of the other performance indicators, incompatible rules by themselves are not sufficient to cause an Agreement State to lose Agreement State status. The State's entire radiation protection program, or a very large part of it, would need to be found not sufficient to protect public health and safety from the adverse effects of exposure to radiation during an IMPEP review to start the path toward termination of the Agreement. In addition, the NRC has a process in place to prevent this from occurring through a program called 'heightened oversight' of an Agreement State's radiation protection program. Heightened oversight is a process where the NRC conducts more frequent audits of a State's radiation safety program and gets those State officials involved that need to be involved to make the changes necessary to bring the State back around to being compliant and compatible with the NRC's health and safety program.

While the exact probability of incurring higher federal fees as a result of failing to adopt rules similar to federal requirements is unknown, this analysis provides an estimate of the potential fee increase for the purposes of establishing a baseline (counterfactual situation) for the proposed rule. Given that the probability that licensees would be subjected to higher license fees is most likely lower than 15%, the impact of this is not substantial. The failure to adopt this set of rules does not create a significant enough effect on the overall compatibility of our statewide radiation safety program to trigger immediate action from the NRC. However, as rulemaking continues on the federal level, the failure of the State to adopt this set of rules, and federal rules promulgated in the future, could lead to a situation where the Agreement was at risk.

The agency computed estimated savings from potentially avoiding higher federal fees using current NRC license fees and inspection fees, as published in 10 CFR 170.21 and 170.32, and current North Carolina license fees, as published in 10A NCAC 15 .1106. Note, North Carolina does not charge licensees an inspection fee, but instead accounts for inspection resources within the annual licensing fees, so NRC inspection fees had to be annualized for the purpose of computing the cost differential. Therefore, the total annual savings was calculated by adding the NRC license fee and the adjusted annualized NRC inspection fee (inspection fee divided by frequency) and subtracting the North Carolina license fee, multiplied by the number of licenses in each category. The calculations for savings per type of licensee

used the number of licensees in the State listed in the North Carolina Radiation Protection license databases. There are currently approximately 630 specific licensees licensed in the State. The number of licensees has remained stable over the past decade, so it is unlikely that it would change significantly in the future and therefore this analysis assumes very little growth in the number of licensees.

The NRC has not proposed any fee changes and therefore it is reasonable to assume that fees will not increase within the next 5 years. Projecting ahead, the agency does not anticipate raising license fees before 2019. The current fee structure is adequate to fund the agency's expected costs and expansion budget requirements plus reserves until that time. The agency assumes that the number of licensees will grow about 1% per year through 2019 based upon historical data presented in IMPEP reports published on the NMSS Agreement State website.

An additional impact from failure to maintain the Agreement State status would be that the State would lose the ability to regulate licensed activities. This would result in the loss of roughly 1.2M annual dollars (based on Table 1) in revenue to the Radiation Protection Section; however, the loss would be negated by the laying off of nearly fifteen Radioactive Materials Branch staff. Revenue loss to the State was calculated by multiplying the number of licenses for each licensing type by the amount of each license fee. The biggest impact would not be financial but to public health and safety; there would no longer be local radiation safety professionals who could respond quickly to incidents, allegations and nuclear emergencies. The Radioactive Materials Branch provides subject matter experts and health physics support and guidance during incidents and emergencies involving radioactive materials and exposure to radioactive sources.

Table 1. Potential Annual License Cost Savings from Maintaining the NC Agreement State Status with the NRC

Type	Current Licensees	Estimated Licensees in 2019*	NRC License Fee	NRC Inspection Fee	NC License Fee	Inspection Frequency	Annual Cost Savings in 2019
Medical Broad	5	5	$46,100	$5,500	$5,250	2	$218,000
Academic Broad	5	5	$46,100	$5,500	$3,500	2	$226,750
R&D Broad	5	5	$14,700	$5,400	$3,000	3	$67,500
Industrial Radiology (booth & field)	18	19	$25,900	$4,000	$3,500	1	$501,600
Industrial Radiology (booth only)	3	3	$25,900	$4,000	$2,600	1	$81,900
Hospital Nuclear Medicine (diagnostic)	57	59	$8,600	$2,700	$2,900	3	$389,400
Hospital Nuclear Medicine (therapeutic and new technologies)	58	60	$8,600	$2,700	$2,900	2	$423,000
Hospital Nuclear Medicine (brachytherapy)	8	8	$17,900	$8,800	$2,900	3	$143,467
Private Practice Nuclear Medicine (diagnostic)	158	163	$8,600	$2,700	$950	3	$1,393,650
Private Practice (therapeutic and new technologies)	5	5	$8,600	$2,700	$950	2	$45,000
Private Practice Nuclear Med. (brachytherapy)	0	0	$17,900	$8,800	$950	3	$0

Type	Current Licensees	Estimated Licensees in 2019*	NRC License Fee	NRC Inspection Fee	NC License Fee	Inspection Frequency	Annual Cost Savings in 2019
Mobile Nuclear Medicine (diagnostic)	8	8	$8,600	$2,700	$1,600	3	$63,200
Teletherapy	0	0	$17,900	$8,800	$2,100		$0
Fixed Nuclear Gauges	52	54	$4,900	$1,500	$550	5	$251,100
Portable Nuclear Gauges	134	138	$4,900	$1,500	$425	4	$669,300
Gas Chromatography (laboratory)	4	4	$4,900	$1,500	$375	5	$19,300
Distribution (Radiopharmacy and other commercial activities)	23	24	$16,900	$6,500	$2,250	2	$429,600
>100kCi irradiator (panoramic)	4	4	$140,900	$61,200	$8,500	2	$652,000
<100kCi irradiator (self-shielded)	4	4	$9,100	$3,200	$4,500	5	$20,960
Educational R&D Laboratory	13	13	$8,700	$3,500	$1,900	5	$97,500
Water Remediation	3	3	$4,900	$1,500	$1,350	5	$11,550
Service and or Repair	30	31	$14,900	$6,400	$400	5	$489,180
Industrial/Lab "Other"	96	99	$4,900	$1,500	$500	5	$465,300
General License Gauge (annual registration required)	96	99	$400	n/a	$350	5	$4,950
General License Gauge (annual registration not required)	147	151	$400	n/a	$200	5	$30,200
Hospital Accelerator – first unit or for one unit	92	95	n/a	n/a	$2,000	5	n/a
Hospital Accelerator for each additional unit	42	43	n/a	n/a	$200	5	n/a
Industrial Accelerator – first unit or for one unit	10	10	n/a	n/a	$2,000	5	n/a
Industrial Accelerator each additional unit	3	3	n/a	n/a	$200	5	n/a
Accelerator - Sales, refurbishment and distribution	2	2	n/a	n/a	$2,000	5	n/a
New and Renewal Application (Z) - processing fee	141	145					$0
SS&D Review (per SS&D application) New Applications	0	0	$16,200	$7,700	$10,000		$0
SS&D Review (per SS&D application) Revisions or Amendments	0	0	$16,200	$7,700	$10,000		$0
Total	**1,226**	**1,262**					**$6,694,407**

***** Based on the current number of licensees and the assumption that these numbers would all grow by 1% per year until 2019.

Summary and Purpose of adopting compatible regulations with NRC Regulations and proposed other changes:

The proposed rules are necessary to maintain compliance with changes made to the federal regulations by the NRC over the last five years. When the NRC amends the federal regulations, the amended regulations are published in the *Federal Register*, and summarized in documents known as Regulatory Action Technical Summaries as they are adopted by NRC. The technical summaries may be published several times a year, each summary encompassing different revisions of the NRC rules. In addition, in a letter dated May 13th, 2014, the NRC made comments on the regulations adopted by North Carolina in October of 2013; and in a letter dated August 18th, 2014, the NRC made comments on proposed rule language under consideration by the Radiation Protection Commission. The comments made by NRC in these two letters are also addressed by the proposed rules submitted with this fiscal note. Addressing these comments is required to maintain compatibility with the federal regulations.

In addition to maintaining compatibility with the NRC, the intent of these proposed rule changes is to increase the protection of public health and safety from hazardous exposure to radiation and to reduce the burden of complying with these rules. Two brief examples of this intent are as follows:

- 10A NCAC 15 .0307 is being amended because the NRC realized that certain chemical and physical forms of source material were more easily ingested, inhaled, or absorbed into the body (higher risk) than other forms of this same material. The NRC amended the federal rule to lower the quantities of the higher risk forms of source material that can be possessed under this rule to better protect health and safety of the public, and the agency proposes to follow suit.
- 10A NCAC 15. 0305 is being amended because the NRC has determined that certain devices do not pose the danger to public health and safety as previously believed. Accordingly, the regulation of these devices was relaxed and the possession and use of these devices is no longer regulated; which in turn, relieves the public of an unnecessary regulatory burden.

These proposed rules are also to being amended to bring them into compliance with the provisions of the Administrative Procedures Act, NCGS 150B, and to consolidate similar rules under a single rule. Prior to this rulemaking the Radiation Protection Commission adopted the language from NRC word-for-word and copied them into the North Carolina rules. As this is no longer an approved approach, the rules now incorporate the federal rule by reference as required by NCGS 150B.

Overall:

This fiscal note summarizes the cost of implementation for each of the new requirements being adopted by reference. The Radiation Protection Section identified two rules out of the thirty rules proposed for amendment with impacts to Federal Government, State Government, and the private sector.

Table 2: Summary of the impact as reported by this document

	First Year Impact			Annual Impact for Subsequent Years		
Entity	**Rule .0302***	**Rule .0357‡**	**Rule .1004†**	**Rule .0302***	**Rule .0357‡**	**Rule .1004†**
Federal Government	$1,494	$0	$0	$3,062	$0	$0
State Government	($406)	$312	$1,840	$72	$312	$1,840
Local Government	$0	$0	$0	$0	$0	$0
Non-government (privately owned)	$7,644	$424	$60,400	$4,929	$424	$60,400
Total Cost by Rule	**$8,732**	**$736**	**$62,240**	**$8,063**	**$736**	**$62,240**
TOTAL COST	**$71,708**			**$71,039**		
5-Year Net Present Value (7% discount rate)	~$312,300					

*Impact to Federal and State Government are based on fees less costs to the agency. Parentheses indicate a negative number.

‡Reflects the additional cost of providing the incident reports required by this rule change that are not currently required by a rule.

†Reflects the additional cost of providing exposure reports to individuals requesting them prior to termination under the amended rule.

Summary of Proposed Rule Changes and Impact

The proposed changes are discussed below. Changes described in this document include incorporating several federal regulations by reference required for adoption. Other rule changes were made to provide guidance to find the referenced federal rule and to remove language from the State rule that repeated the content of the federal rule. The changes do not require expenditures by or provide any savings to State or local government entities, or create impacts that exceed $500,000 per year.

10A NCAC 15 .0302 – Exemptions for Source Material: This rule is being revised to maintain compatibility with 10 CFR 40.13. This rule provides for exemption from licensing based upon the quantity of radioactive material possessed and used as source material, and source material used in certain objects and devices. Changes to this rule include:

- The addition of the word ‘transfers’ to the rule. The initial federal rule erroneously omitted the word ‘transfers’ although it requires a transfer of material for a person to ‘receive’ or ‘possess’ radioactive material.
- A date after which glazed ceramic tableware containing source material is no longer exempted from regulation. North Carolina has one general licensee producing glazed ceramic art who will be affected by this regulatory change. This licensee will be required to obtain a specific license from the State of North Carolina to possess and use source material for this purpose, and a specific license issued by NRC to distribute these art pieces once they are manufactured.
- A reduction in the quantity of source material that can be used in glass products that are exempt from licensing from ten percent by weight to two percent by weight. North Carolina has no licensees producing glass products containing more than two percent by weight of source material.

Impact

The estimated cost to the licensee producing glazed ceramic art to obtain the specific licenses required to continue this activity under this rule change is based upon cost estimates provided by a current specific licensee authorized to possess and use source material for producing borosilicate glass rods containing very small quantities of source material (uranium) to be sold to, and distributed to, glass artisans creating glass sculptures and decorative non-food-use glassware. For the purpose of this analysis, the agency assumes these changes would only affect the current licensee and there would not be new licensees in the near future in this category.

This licensee estimated that labor and costs involved in applying for both the North Carolina specific license and the NRC distribution license was approximately $1,000. The licensee was not able to break down the costs incurred while applying for both licenses because they did not keep records of the effort and costs for preparing the applications and supporting material. This cost estimate was applied equally ($500 each) to both the North Carolina and NRC license application efforts. License fees come from 10A NCAC 15 .1106(a) for North Carolina, and 10 CFR 170.31 (license type 11240) for the NRC. In addition, the NRC charges an hourly rate of $268/hour for inspections (10 CFR 170.20). North Carolina does not charge inspection fees; the cost of inspections is covered by the annual license fee.

Based on previous experience and interviews with Radioactive Materials Branch inspections staff, an average of eight hours per inspection is devoted to preparing for, conducting, and writing up inspections of specific licensees. The same level of effort is credited for inspections conducted by the NRC to determine the cost to the NRC. Inspections are conducted on a five-year frequency for this license type. Licensing staff interviews indicate that approximately 12 hours of staff time, on average, is spent on licensing per new license action. Approximately 6 hours of licensing staff time is spent, on average, for amendments that do not involve new or renewing licenses. It is conservatively assumed that one licensing action per year will be performed by the State for this licensee, and that the NRC will conduct no licensing actions once the initial distribution license is issued. This estimate is based upon the observation that the general licensee has required no assistance from the State since the general license registration was issued in 2004. Interview of the general license coordinator indicates that approximately 8 hours is spent on each general license action; this action includes reviewing the application for general license registration, issuing the general license, and conducting inspection activities.

Costs to North Carolina for the various activities requiring an hourly breakdown were calculated using the average annual Radioactive Materials Branch staff salary by activity multiplied by a factor of 1.4 to cover the cost of benefits provided by the State. For licensing staff this is approximately $38/hour, and for inspections staff this is approximately $39/hour. The general licensing coordinator handles both licensing and inspections of general licensees. The hourly cost associated with this activity is approximately $52/hour. Administrative costs to the State associated with both inspections and licensing activities is based upon the hourly cost of an administrative assistant and IT staff (database management, end user support, etc.), and costs approximately $58 per hour spent on an activity. It is assumed that approximately one-quarter of an hour is spent supporting the Radioactive Materials Branch for licensing and inspections per license. Recurring costs are spread out as average annual cost over the inspection frequency, which is once every five years. This is shown in the table as an annual cost with a 5 year annualized basis. The impact for this licensee, and State and federal government is as follows:

Table 3: Estimated Cost Differential of the Proposed Specific License

A. Cost to Licensee

Description of cost	**General license cost (current)**	**Specific license (proposed)**	**Cost difference**
First Year			
Labor cost to apply for NC license	N/A, already possesses GL	$500	$500
Labor cost to apply for NRC license	N/A, not regulated by NRC	$500	$500
NC annual license fee (lic type: Other)	$200	$500	$300
NRC annual license fee (lic type: 11240)	N/A	$2,700	$2,700
NC inspection fee (for initial inspection)	$0	$0	$0
NRC inspection fee (for initial inspection)	N/A	$2,144	$2,144
Cost of program management (0.5 x lic fees)	$100	$1,600	$1,500
First year cost*	**$300**	**$7,944**	**$7,644**
Second and subsequent years			
NC annual license fee	$200	$500	$300
NRC annual license fee	N/A, not regulated by NRC	$2,700	$2,700
NC inspection fee (annualized over 5 yr)	$0	$0	$0
NRC inspection fee (annualized over 5 yr)	N/A	$429	$429
Cost of program management (0.5 x lic fees)	$100	$1,600	$1,500
Annual cost in the 2nd and subsequent years*	**$300**	**$5,229**	**$4,929**

B. Cost to State Government

Description of cost to State Government	**General license cost (current)**	**Specific license**	**Cost difference**
First Year			
NC annual license fee (this is revenue)	$200	$500	$300
Licensing: receipt, review, issuance (new)	$0 (no amendments in 12 years)	$456	$456
Inspections (initial inspection)	$62	$312	$250
Administrative support	$15	$15	$0
First year cost*	**$123**	**($283)**	**($406)**
Second and subsequent years			
NC annual license fee (this is revenue)	$200	$500	$300
Licensing: receipt, review, issuance (amend)	$0 (no amendments in 12 years)	$228	$228
Inspections (annualized over 5 yr)	$62	$62	$0
Administrative support	$15	$15	$0
Annual cost in the 2nd and subsequent years*	**$123**	**$195**	**$72**

C. Cost to Federal Government

Description of cost to Federal Government	General license cost (current)	Specific license (proposed)
First Year		
NRC annual license fee (this is revenue)	N/A, not regulated by NRC	$2,700
NRC inspection fee (this is revenue)		$2,144
Licensing: receipt, review, issuance (new)		$3,216
Administrative: admin support, IT support		$134
First year cost*		**$1,494**
Second and subsequent years		
NRC Annual license fee (this is revenue)		$2,700
NRC Insp. fee (revenue, annualized over 5 yr)		$429
Administrative: admin support, IT support		$67
Annual cost in the 2nd and subsequent years*		**$3,062**

*Licensing fee (revenue) less costs in tables 3., A., B., and C., above. In table 3.C., the column titled 'Specific license (proposed)' also represents the change in costs due to the rule change because the baseline is zero (there is no cost to the Federal Government under the current rule).

10A NCAC 15 .0304 – Exempt Quantities: Other Than Source Material: Minor revision of this rule was made to maintain compatibility with NRC 10 CFR 30.18. The specific requirement was to add the word 'transfer' to this rule as required by the NRC letter dated May 13, 2014. Note that under the terms of the Agreement, a license issued by the NRC is required for the commercial transfer of exempt quantities of radioactive materials or devices containing exempt quantities of radioactive material. No new requirements were added for these licensees.

Impact
No impact is anticipated from this rule change.

10A NCAC 15 .0305 – Exempt Item Containing Other Than Source Material: Revisions to this existing rule were made to maintain compatibility with NRC 10 CFR 30.15, 30.19, 30.20, 30.21, 30.22, and as suggested by the NRC in their letters dated May 13th and August 19th, 2014. The principle change to this rule that was of concern for this fiscal note is in the change in designation of certain devices from generally licensed to being exempt from regulation. In North Carolina this means that the devices regulated under 10A NCAC 15 .0308 as generally licensed devices would become exempt from regulation under this rule. No additional requirements were added or removed for general licensees by this rule change. Note: A generally licensed device is a device containing radioactive material that has been designed and manufactured in such a way that it is very unlikely that the device would fail in such a manner that the public would be exposed to dangerous levels of radiation, or would receive a significant dose from exposure to these devices while in use. General licenses are issued under 10A NCAC 15 .0306(a) and do not require the submission of an application to the agency or the issuance of licensing documents by the agency.

Impact
This federal rule change was thought to result in fewer general licensees since these devices would be exempt from regulation (10 CFR 30.22) with the corresponding savings to these general licensees balanced by the loss of revenue to the agency and an across the board reduction in administrative costs.

The agency performed several searches of its records and databases and no specific or general licensees were identified possessing these devices. Since there are no affected licensees, there is no anticipated impact.

10A NCAC 15 .0307 – General Licenses: Source Material: Revision of this rule is necessary to maintain compatibility with 10 CFR 40.22. The changes to this rule include:

- The addition of dispersible forms of source material to the rule to discern them from non-dispersible forms of source material. The increased risk associated with readily dispersible forms of source material (easily aerosolized and inhaled, or easily soluble and absorbed through the skin or ingested) is taken into account by lowering the quantity of this material that can be possessed under this rule.
- The addition of uranium removed from drinking water treatment processes and a corresponding possession limit for uranium that is unchanged from the previous rule. This provides for a general licensing route for corporations and firms for the removal of source material from drinking well water that were previously generally licensed for the simple possession of uranium under this rule.
- The addition of laboratories analyzing environmental samples with a corresponding possession limit for uranium that is unchanged from the previous rule. This provides for a general licensing route for corporations and forms to possess readily dispersible forms of source material found in environmental samples under this rule that were previously generally licensed for the simple possession of uranium.
- A prohibition against using source material for medical use on humans without a license issued by the NRC authorizing this use.
- An exemption from licensing for the permanent disposal of small quantities of source material.
- A prohibition against exporting source material possessed under this rule except under the authorization of a specific license issued by the NRC.
- A requirement for general licensees to conduct activities to minimize contamination of their facility and the environment and to notify the agency if contamination is found in excess of the limits in 10A NCAC 15 .1653(b).
- A requirement that a specific license is required for the initial transfer of source material to someone possessing it under a general license.

Impact

The changes made to the federal rules incorporated into this rule are complex and cover several different areas. The remarks below are compiled from extensive searches of the agency's licensing database and from reviews of inspection records where appropriate:

- The recognition by NRC that more readily dispersible forms of source material (uranium) posed a greater health hazard than less dispersible forms, and subsequent rule-making, had the potential for an economic impact affecting water remediation licensees that remove source material from well water: the source material is pumped out of the ground already dissolved in drinking water. It would also have a potential for a negative impact for laboratories handling environmental samples containing source material. The lowered possession limits in 10 CFR 40.22(a)(1) for dispersible forms of source material could have made both of these activities difficult to perform under this rule; or in the case of water remediation, more expensive because the filter media used to remove source material from water would need to be replaced more frequently to maintain possession below the limits imposed by virtue of this rule change. However, the addition of 10

CFR 40.22(a)(3), specifically addressing the removal of uranium from water wells, and 40.22(a)(4) specifically addressing environmental samples handled by laboratories, preserves the higher possession limit of this rule that was in place prior to adoption of the changes made to this rule. Since there is no change in the possession limits for either of these two activities, there is no anticipated impact.

- There are no North Carolina licensees using source material in the practice of medicine. No licensees are impacted by the prohibition against the medical use of source material
- The collection of source material for disposal is considered acting as a low level radioactive waste facility (see NCGS 104E-5(9b)). Low level radioactive waste facilities are prohibited by NCGS 104E-7(b), unless the General Assembly authorizes a facility for this purpose. This is significant because North Carolina has no licensees authorized to accept low level radioactive waste from the public or another person for a fee. No impact.
- The exportation of source material possessed under this rule requires a specific license issued by the NRC because the exportation of radioactive material falls under NRC jurisdiction as a part of the Agreement (10 CFR 150.15(2)). No fiscal impact is expected due to this rule change.
- Based upon a search of general license licensee files, no North Carolina general licensees are likely to be impacted by the requirement to conduct activities to prevent contamination of their facilities. Most general licensees in North Carolina possess sealed sources, the few that don't possess only very small quantities of unsealed radioactive material in testing kits that are used indoors in controlled areas. Thus, contamination of the environment is highly unlikely.
- Based upon a search of the agency's general licensee license files, North Carolina has no general licensees distributing generally licensable quantities of source material as was permitted by the previous edition of this rule.

Based upon this analysis, no impact is anticipated by these rule changes.

10A NCAC 15 .0308 – General Licenses: Other than Source Material: The devices formerly regulated by this rule are reclassified as exempt devices under 10A NCAC 15 .0305. The NRC determined that these devices, which are static eliminators and ion generating tubes containing tritium and polonium, are safe to possess and use without a license. Thus, the requirement for a license was rescinded. This rule now references 10A NCAC .0305.

Impact

The impact is discussed under rule 10A NCAC 15 .0305. No impact is expected from this rule change because no North Carolina general licensees were identified as possessing these devices. Although this rule could have been repealed since its subject matter moved to another rule, the Radiation Protection Commission preferred to keep it in place to assist licensees who may need this guidance, and to maintain the current structure of 10A NCAC Chapter 15.

10A NCAC 15 .0309 – General Licenses: Measuring Gauging: Controlling Devices: Revisions to this existing rule were made to maintain required compatibility with NRC 10 CFR 31.5, and as recommended by the NRC in their letters dated May 13, 2014 and August 19, 2014. The changes made by the amended federal rule (10 CFR 31.5) carried through into this proposed rule removed language in the rule permitting general licensees to dispose of radioactive material by exporting it. Note that the export and import of radioactive material falls under the NRC's exclusive jurisdiction (10 CFR 150.15(2)) as part of the Agreement. The rule changes suggested in the NRC letters were to correct a reference to another North Carolina rule cited in .0309, and to bring the State's leak testing requirements into compatibility with those of the NRC. In this proposed rule change the incorrect rule reference is removed entirely,

replaced by the language incorporating the NRC rules by reference. Regarding the leak testing requirements, it appears that the comments submitted by the NRC regarding leak testing under this rule in their letters dated in May and August, 2014, were made about language in the rule prior to the final rule adopted in 2013. The leak test requirements currently in .0309 are nearly identical to the requirements in 10 CFR 31.5(c)(2).

Impact:
No impact is anticipated from these rule changes. The prohibition against exporting radioactive material placed into 10 CFR 31.5 by the NRC echoes the preexisting prohibition against this activity in the Agreement (10 CFR 150.15(2)). Thus, North Carolina does not have the authority to issue licenses for the exportation of radioactive material under the Agreement, and consequently there are no North Carolina licensees affected by this rule change. Likewise, the leak test provisions of .0309 mirror those in 31.5, and were adopted by the State in 2013. No impact is anticipated from this rule change

10A NCAC 15 .0310 – General Licenses: Manufacture, Transfer, Install Generally Licenses Devices: This rule is being amended to maintain compatibility with 10 CFR 31.6, and to comply with the provisions against repeating a federal rule in N.C.G.S 150B-19(4). The change to this rule is a change in the rule's compatibility category, with no change in the regulatory requirements of 10 CFR 31.6. This rule is also being amended to address comments made by the NRC in their letter dated May 13th, 2014, regarding the transfer of these devices. To reduce the regulatory burden of 10A NCAC Chapter 15, these comments are addressed in 10A NCAC 15 .0317, where the rules regarding the manufacture and transfer of devices containing radioactive material are being consolidated.

Impact:
All NRC regulations are classified by how important they are with regard to protecting public health and safety and the affects the rule has on interstate trade. The greater the risk of harm to public health and safety or effects causing an imbalance in interstate trade, the higher the compatibility category for that rule. The higher the compatibility category, the greater the requirement that that rule be adopted almost verbatim by the Agreement States. Changes to a federal rule's compatibility class does not necessarily mean a change in the regulations promulgated by an Agreement State, unless that State fails to have rules equivalent to the federal rule. North Carolina's rule, 10A NCAC 15 .0310, is equivalent to 10 CFR 31.6 and much of the language in .0310 prior to this rule change simply repeated that found in 31.6. Therefore, there is no anticipated impact from this rule change.

10A NCAC 15 .0316 – General Licenses: Transportation: This rule is being revised to maintain compatibility with 10 CFR 30.13, 40.12, 40.23, 70.12, 70.20a, 70.20b, the notification requirements of 10 CFR 71.97 and 73.37(b)(2) for the transportation of radioactive waste or nuclear fuel, respectively, and the prohibition against shipping more than 20 curies or 20 grams of special nuclear material by passenger aircraft in 10 CFR 150.21. Changes made to this rule to comply with the provisions of 10 CFR 30.13, 40.12, and 70.12 include the reclassification of transportation related activities as exempt from regulation that were formerly carried out under a general license issued under this rule. Changes made to 10 CFR 40.23, 70.20a and 70.21b, maintain the requirement for the issuance of general licenses for the transportation of natural uranium other than uranium ore, certain classifications of special material and irradiated nuclear fuel in light of the exemption afforded for other transportation related activities. Changes made to this rule to maintain compatibility with the rule changes made in 10 CFR Parts 40 and 70 also involve changes to compatibility categories of the rules. Changes made to this rule to comply with 10 CFR Part 71.97 and 73.37(b)(2) are for the addition of a requirement for the notification of federally

recognized Indian Tribes when large quantities of radioactive waste, nuclear fuel or spent nuclear fuel are transported across Tribal lands.

Impact:
License fees are not required for the activities that were carried out under the general license formerly issued under this rule and these activities are not inspected by the agency. Consequently, there is no cost to the State or to local government and private entities for the reclassification of this activity from generally licensed to exempt from regulation. The general licenses that will continue to be issued under this rule for the transportation of certain types of radioactive material will likewise have no impact since these activities are not charged license fees and they are not inspected by the agency. As noted earlier in this fiscal note, general licenses are issued in accordance with 10A NCAC 15 .0306. North Carolina has three licensees that are potentially impacted by the addition of federally recognized Indian Tribes to the list of entities requiring notification for the shipment of large quantities of radioactive material, nuclear fuel, etc., through their Tribal lands. A review of the last ten years of inspection records for these licensees revealed that shipments from these facilities never exceeded a little over half the quantity of radioactive material requiring notification under this rule. No impact is anticipated for this rule change.

10A NCAC 15 .0317 – Specific Licenses: Filing Application and General Requirements: This rule is being revised to incorporate provisions from 10 CFR Part 30 and Part 32 specifying how to apply for certification through the Sealed Source and Device Registration Program maintained by the State. Manufacturers of devices containing radioactive material are required to test these devices to ensure that consumer protections are in place and to apply to the State for evaluation of the design and safety testing results of these devices before they can be marketed. These evaluations are then published for all regulatory agencies to review prior to issuing a license to possess or use these devices. The evaluations also require that prototype devices are tested and that the manufacturer has manufacturing quality assurance processes in place to ensure product quality. North Carolina currently performs these evaluations and issues Sealed Source and Device Registration certificates as part of our Agreement State program, but the State does not have rules equivalent to 10 CFR 32.210 that are necessary to be compatible with the NRC. This rule is required so that there are regulations in place for this activity versus continuing to perform it based upon a policy of following federal guidance and rules for it, which is prohibited by NCGS 150B-18. This rule is also revised to consolidate guidance for applying for radioactive materials licenses for a variety of activities into a single rule, and to implement suggestions made in the NRC letters dated May 13th and August 19th, 2014, to bring North Carolina's regulations into compatibility with the federal regulations.

Impact: Sealed Source Device and Registration reviews are not common activities. The most recent one was done several years ago and cost the State approximately $10,000 in Consulting fees, and approximately eighty hours of staff time for the two Health Physicists tasked with performing the review. Based upon the rate-per-hour used for Rule .0302, above, of $38/hour for licensing staff time, the cost to the State is approximately $3,040 for managing and completing the review. Administrative and miscellaneous costs are an additional $500. This yields a total cost for these reviews of around $14,000 per review. The cost to the State is not anticipated to increase as a result of this rule change. Costs to the applicant are highly variable, and depend upon the complexities of the device to be manufactured as reflected in the application for registration. Discussion with one of our two manufacturing licensees yielded an estimate of $5,000 for prototype testing and compiling information for submission to the agency. Note that there is no application fee for these activities, nor is there a registration fee once the review is completed. The alternative to this rule, which is to not implement this change is twofold: one, is to cease performing these reviews and the second is to continue the reviews but to continue relying upon

policy, not regulation, to perform them. Since these reviews are part of North Carolina's Agreement with NRC, it is not practical, nor desirable, to cease performing them. NCGS 150B-18 prohibits the use of policy in place of a rule, so neither alternate option is viable. No net impact is anticipated with this rule adoption.

10A NCAC 15 .0327 – Specific Licenses: Exempt Gas and Aerosol Detectors: This rule is being revised to add the requirement that a specific license issued by the NRC is required for the distribution of devices containing exempt quantities of radioactive materials to be compatible with 10 CFR 32.26. This requirement is not a new one: the Agreement with NRC embodied in 10 CFR 150.15(a)(6) requires a NRC distribution license for all devices containing exempt quantities of radioactive material.

Impact: There is no change to the regulated activity. No impact.

10A NCAC 15 .0328 – Specific Licenses: Manufacture Devices to Persons Licensed: This rule is being amended to avoid repeating a federal regulation; which is prohibited by NCGS 150B-19(4) and to address comments made by NRC in their letters dated May 13th and August 19th, 2014. It is also being amended to consolidate the regulations controlling applying for a radioactive materials license into a single rule, 10A NCAC 15 .0317, to reduce the regulatory burden associated with having two related rules dealing with the same subject matter.

Impact: No change in regulatory requirements are created with this rule change. No impact.

10A NCAC 15 .0329 – Specific Licenses: Luminous Safety Devices in Aircraft: This rule is being amended to avoid repeating a federal regulation; which is prohibited by NCGS 150B-19(4). It is also being amended to consolidate the regulations controlling applying for a radioactive materials license into a single rule, 10A NCAC 15 .0317, to reduce the regulatory burden associated with having two related rules dealing with the same subject matter.

Impact: No change in regulatory requirements are created with this rule change. No impact.

10A NCAC 15 .0330 – Specific Licenses: Manufacture of Calibration Sources: This rule is being amended to avoid repeating a federal regulation; which is prohibited by NCGS 150B-19(4). It is also being amended to consolidate the regulations controlling applying for a radioactive materials license into a single rule, 10A NCAC 15 .0317, to reduce the regulatory burden associated with having two related rules dealing with the same subject matter.

Impact: No change in regulatory requirements are created with this rule change. No impact.

10A NCAC 15 .0331 – Specific Licenses-Manufacture of in Vitro Test Kits: This rule is being amended to avoid repeating a federal regulation; which is prohibited by NCGS 150B-19(4). It is also being amended to consolidate the regulations controlling applying for a radioactive materials license into a single rule, 10A NCAC 15 .0317, to reduce the regulatory burden associated with having two related rules dealing with the same subject matter.

Impact: No change in regulatory requirements are created with this rule change. No impact.

10A NCAC 15 .0332 – Specific Licenses: Manufacture of ice Detector Devices: This rule is being amended to avoid repeating a federal regulation; which is prohibited by NCGS 150B-19(4). It is also

being amended to consolidate the regulations controlling applying for a radioactive materials license into a single rule, 10A NCAC 15 .0317, to reduce the regulatory burden associated with having two related rules dealing with the same subject matter.

Impact: No change in regulatory requirements are created with this rule change. No impact.

10A NCAC 15 .0335 – Specific Licenses: Products Containing Depleted Uranium: This rule is being amended to avoid repeating a federal regulation; which is prohibited by NCGS 150B-19(4). It is also being amended to consolidate the regulations controlling applying for a radioactive materials license into a single rule, 10A NCAC 15 .0317, to reduce the regulatory burden associated with having two related rules dealing with the same subject matter.

Impact: No change in regulatory requirements are created with this rule change. No impact.

10A NCAC 15 .0337 – Issuance of Specific Licenses and Sealed Source and Device Registration Certificates: This rule is being revised to maintain compatibility with 10 CFR 30.39, 36.13, and 39.13, to provide guidance to our licensees for the requirements that the agency uses for the issuance of a specific license for the use of radioactive materials, and to incorporate that same guidance for the issuance of Sealed Source and Device registration certificates to be compatible with 10 CFR 32.210.

Impact: This rule makes no new regulatory requirements except for those related to 10 CFR 32.210. The impact of incorporating 10 CFR 32.210 for the regulation of the review and issuance of Sealed Source and Device Registration certificates is discussed in this fiscal note under 10A NCAC 15 .0317, above. No impact is anticipated from this rule change.

10A NCAC 15 .0338 – Specific Terms and Conditions of Licenses: This rule is being amended to provide guidance to our licensees for what to expect as conditions of issuance of their specific licenses to possess and use radioactive material. This amendment also replaces language inadvertently removed from the rule when it was amended in 2013, requiring regulatory approval before licensed activities are transferred to another party. This language is required to maintain compatibility with 10 CFR 30.34, 40.46, and 70.36.

Impact: The rule makes no new regulatory requirements. No impact is anticipated.

10A NCAC 15 .0343 – Transfer of Material: This rule is being amended to maintain compatibility with 10 CFR 30.41, 40.51, and 70.42, and to provide guidance on the requirements for transferring radioactive material as well as to incorporate the requirement that a license issued by the NRC is required for the exportation of radioactive material from the United States.

Impact: The rule changes to maintain compatibility with 10 CFR Part 30, 40, and 70, imposes no new regulatory requirements on North Carolina licensees because the exportation of radioactive material falls under NRC jurisdiction as a part of the Agreement (10 CFR 150.15(2)). No impact is anticipated from this rule change.

10A NCAC 15 .0344 – Modification: Revocation: And Termination of Licenses and Sealed Source and Device Registration Certificates: This rule is being amended to maintain compatibility with 10 CFR 30.61, to provide guidance for agency actions to modify, revoke, or terminate specific licenses for

the use and possession of radioactive materials, and to provide rules for the modification, revocation, or termination of Sealed Source and Device Registration certificates issued by the agency.

Impact: The change in this rule concerns the modification, revocation, or termination of Sealed Source and Device Registration certificates. This rule makes no other new regulatory requirements. The impact depends upon the nature of the actions that the licensee and the agency must take to conduct registration certification changes requested by the licensee (registration certification holder). For Sealed Source and Device Registration certificate revocation or termination the costs are expected to be relatively low, and primarily administrative in nature. However, modifications to these registration certificates could be as high as those for newly issued Sealed Source and Device Registration certificates if the proposed modifications are extensive relative to the existing certificate. Therefore, the highest estimated impact assumes that the level of effort for the modification of these certificates is the same as for the issuance of new ones as described in 10A NCAC 15 .0317.

10A NCAC 15 .0353 – Financial Assurance for Record-Keeping for Decommissioning: This rule is being amended to remain compatible with 10 CFR 30.35, 40.36, and 70.25 and to address comments made by the NRC in the letter dated August 2014 correcting a reference in 10A NAC 15 .0353 to Appendix B of 10 CFR Part 30. One of the main changes is the inclusion of the requirement for monitoring subsurface areas for contamination and accounting for decommissioning below ground level if required. This rule is also being amended to provide regulatory guidance: (1) to licensees who may possess several different types of radioactive material, and (2) specifying that the need for financial assurance is based upon the quantity of radioactive material authorized by a specific license or requested by an applicant for a specific license, not the quantity of radioactive material in actual possession.

Impact: Historical data from the last twenty years indicates that North Carolina has no licensees that are authorized to use radioactive material in such a manner that contamination of the subsurface is expected. For example, North Carolina has no licensees authorized to apply unsealed radioactive materials in the environment for research purposes. Unsealed radioactive materials are those that are in a readily dispersible powder, liquid, or gaseous form, rather than an impermeable solid or encapsulated in a non-permeable jacket or source shield. The agency's historical interpretation of 10A NCAC 15 .1613(a) is that licensees are required to perform surveys that are necessary to comply with 10A NCAC 15, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of radioactive material present, or radiological hazards that could be present. Surveys of the subsurface are a reasonable requirement if a licensee applies radioactive material in an uncontained area where it is reasonable to assume that contamination of the surface soil is likely. Since this is a requirement preceding this rule change and the change clarifies the meaning of monitoring in the current rule, no impact is anticipated from this rule change.

10A NCAC 15 .0354 – Methods of Financial Assurance for Decommissioning: This rule is being amended to remain compatible with 10 CFR 30.35(f), 40.36(e), and 70.25(f) to permit the self-guarantee of funds sufficient for decommissioning authorized by 10A NCAC 15 .0355. Prior to this rule change, licensees were permitted to guarantee the availability of funds for decommissioning based upon the agency policy of applying the requirements for a parent company guarantee of funds to those licensees desiring to fund themselves. Enforcing a rule through policy is prohibited by NCGS 150B-18, and this regulatory change addressed this situation.

Impact: The requirements for providing financial assurance for decommissioning have not changed except in regard that the self-guarantee of funds is placed into the regulation. No impact.

10A NCAC 15 .0355 – Financial Tests: Self- and Parent Company Guarantees: Decommissioning Funding: This rule is being amended to provide guidance for the self-guarantee, and parent company guarantee, of funds sufficient for decommissioning for a wide variety of licensees currently without regulatory guidance. This rule codifies current agency practice and maintains compatibility with 10 CFR 30.35(f), 40.36(e), and 70.25(f).

Impact: This rule change holds the asset and funding requirements required to 'pass' the financial test stipulated in this rule constant across the board for all licensees at the level (currently) prior to this rule amendment. This will result in no increased or decreased costs for licensees in North Carolina. No impact is anticipated from this rule change.

10A NCAC 15 .0357 – Reporting Requirements: This rule is being amended to maintain compatibility with 10 CFR 70.50(c)(2) to require a follow-up report within 30 days of the initial report of any incident requiring reporting to the agency by 10 CFR 70.50(a) or (b).

Impact: The submission of the follow-up incident report is a new regulatory requirement. The cost for creating and providing this report to the agency is anticipated to be the same as the current cost of providing a written report in response to inspection activities conducted by the agency to investigate the cause and impact of reportable incidents involving radioactive materials. Assuming that it takes the licensee's radiation safety officer approximately eight hours to collect information, interface with agency inspectors, create and submit the report, at a cost of $53 per hour; the licensee's cost of producing this report and submitting it to the agency is estimated to be $424. For conservatism it is assumed that the Radiation Safety Officer handles all investigative and administrative tasks associated with generating and submitting this report on behalf of the licensee. The cost to the state is estimated to be comparable to that of the licensee but at a lower hourly rate. Assuming that agency actions are conducted entirely by a radioactive materials inspector, and that approximately eight hours are spent receiving, reviewing, interfacing with the licensee, and responding to the licensee's incident report at a cost of $39/hour; the cost to the State is approximately $312 per incident.

The estimate for the licensees' hourly rate is taken from www.payscale.com, which reports an average annual salary for Radiation Safety Officers in the United States of $76,000/year (the site was updated in January 2016). The hourly rate was determined by taking the average annual salary, multiplying it by 1.4 to account for benefits provided to employees that are paid for by the licensee (in addition to salary), dividing that number by the number of work-hours in a year (2,000), and multiplying the result by eight.

10A NCAC 15 .0359 – Measurement/Dosages of Unsealed Radioactive Material For Medical Use: This rule is being amended to maintain compatibility with 10 CFR 35.63(d) and to address comments made in the NRC letter dated May 13th, 2014. During licensing and inspections, the agency relies upon federal guidance and the manufacturer's guidance for the QA/QC of equipment used to measure radioactivity. Licensees also rely upon this guidance while preparing their materials use programs. Because radioactive materials decay at a known rate, medical use licensees order radiopharmaceuticals around patient schedules. Changes to this rule include a prohibition against using any dose that falls outside twenty percent of the prescribed dose range unless authorized by an authorized user (a physician) prior to administration.

Impact: One broad scope medical licensee, five private practice nuclear medicine licensees, five hospital-based nuclear medicine licensees, and four radiopharmacy licensees were contacted about the impact of

this rule upon their businesses. There are five broad scope medical licensees, 130 hospital –based medical licensees, 140 private practice medical licenses, and four radiopharmacy licensees in the State. After contacting ten medical use licensees and inquiring about the impact of this rule change on their licensed activities, it was determined that there was no variation in the respondents' responses. The same was found to be true among the radiopharmacy licensees contacted for this fiscal note. One of the radiopharmacy licensees contacted is responsible for seven of twelve licensed sites, two are responsible for four licensed sites and one for one licensed site in North Carolina. All of the radiopharmaceutical license respondents indicated that NC Board of Pharmacy rules require that all doses sent out for human use had to be within ten percent of the prescribed dose. Interviews with all 11 of the medical use licensees indicate that they have never received a dose falling outside twenty percent of the prescribed dose range, and all had policies and procedures requiring a revision to the prior written directive for a patient if the measured dose fell outside of ten percent of the prescribed dose after receipt. Based upon this information, no impact is anticipated for this rule change.

10A NCAC 15 .0521 – Performance Requirements for Radiography Equipment: This rule is being amended to maintain compatibility with 10 CFR 30.20(a)(1) which corrects the address for the American National Standards Institute where copies of the standards can be obtained; as well as 10 CFR 34.20(d) and (e) that are addressed in the NRC letter commenting on proposed rule language dated August 19th, 2014. 34.20(d) requires that all radiography equipment in use after January 10, 1996 comply with the performance requirements of 34.20, while the current North Carolina rule only requires a label on the device stating that the device meets this performance requirement. 34.20(e) permits manufacturers to use an alternate test to test the torque on industrial radiography drive mechanisms. The current North Carolina rule also permits the use of alternate tests to test the torque, but does not state the standard that this torque test must meet or exceed in order to be acceptable. Because of these shortcomings, the NRC determined that this rule (10A NCAC 15 .0521) does not meet the compatibility requirements for 10 CFR 30.20(d) or (e), and the rule must be revised to maintain compatibility by the State.

Impact: Changes to the contact information where to obtain copies of the performance requirement standards for industrial radiography equipment does not impact the cost of performing the activities conducted under this rule. North Carolina has no industrial radiographer device manufacturers, so 34.20(e) does not apply. All industrial radiography equipment sold in the United States since the federal rule went into effect over two decades ago meets the requirements of 34.20(d), however, equipment manufactured abroad and equipment brought into the United States from abroad may not meet this requirement. This rule is intended to prevent the use of substandard equipment in the United States. No North Carolina licensees are impacted by this rule change. No impact is anticipated.

10A NCAC 15 .1004 – Notifications and reports to Individuals: This rule is being amended to be compatible with 10 CFR 19.13(e) and to address comments in the NRC letter dated May 13th, 2014. 10 CFR 19.13(e) requires licensees to provide exposure reports to employees who are terminating employment, or their designee, at termination upon request by the employee. Prior to this rule change, 19.13(c) required licensees to provide exposure results upon request to former employees, and licensees had thirty days to provide the exposure report to the former employee or their designee. The change in 10 CFR 19.13 is that 19.13(e) requires licensees to provide exposure reports to current employees who are terminating employment at termination. Whereas before, licensees had a 30-day period to provide these reports to the former employee after termination.

Impact: Information obtained from five national dosimetry vendors (Landauer, Global Dosimetry Services, Mirion, CHPDosimetry, and MP Dosimetry), indicate that exposure reports are provided online

at no extra charge for all individuals monitored through those companies' dosimetry services. None of these providers are located in North Carolina. The agency anticipates that the cost of providing exposure reports to employees terminating employment at termination under 19.13(e) to be approximately twenty percent of the cost of providing this same information to former employees requesting this information after termination under 19.13(c). The justification for this assumption is that most employees terminating employment are not seeking employment by another licensee so they don't request these reports, or if they are, they don't request these reports until after termination. This assumption is based upon anecdotal evidence during discussions with licensees who frequently hire individuals with previous work experience using radioactive materials, and find that they have to follow up with the new hire's previous employer to obtain the worker's previous exposure history. Many employees appear to be hesitant to approach their employer to obtain their exposure history prior to terminating employment. This means that most of the cost associated with providing these exposure reports actually falls after termination, which is covered under 19.13(c), and not 19.13(e). Searching the agency's licensing and registration databases indicates that the agency currently has approximately 1,255 licensees and 8,133 registrants. In the table that follows, the number of licensees and x-ray registrants comes from database information, and is broken down by license type. The estimated number of monitored employees per licensee by license type or registration was obtained through inspection data, registration records, and discussions with affected licensees. For conservatism, it is assumed 10% of this workforce leaves employment each year. For more discussion on this topic, refer to the sensitivity analysis done in Table 8 below.

Table 4: Annual estimated number of employees leaving employment by license type

Licensee (by type) and x-ray registrants (incl. the agency)	Licensees/ registrants	Total estimated monitored employees	Estimated turnover
Broad scope (medical – Private)	4	2,400	240
Broad scope (medical – State institution)	1	600	60
Broad scope (academic – Private)	2	300	30
Broad scope (academic – State institution)	3	450	45
Broad scope (industrial)	5	150	15
Hospital-based medical	130	3,900	390
Private practice medical	140	1,680	168
Portable nuclear gauge (private)	200	2,000	200
Portable nuclear gauge (NCDOT)	1	32	3
Industrial radiography	25	175	18
Other licensed activities	240	1,200	120
Accelerator (medical and industrial)	500	1,500	150
Radiation Protection Section (agency)	1	32	3
X-ray registrants	8,133	24,399	2,440
Total			**3,882**

The estimated annual cost of compliance is determined from inspections data that indicates that roughly 10% of this workforce quits employment, retires, changes jobs to ones not requiring the use of radioactive material, or otherwise become unemployed over the course of an average year. Twenty percent of these employees quitting employment are assumed to request exposure reports prior to termination under 19.13(e). Although these reports are provided free of charge by the companies providing the exposure records, it requires the licensee or registrant approximately two work hours to produce each report and to provide it to the employee requesting one. If we assume the individuals creating these reports cost their employer $40/hour (wage plus benefits) then the cost-per-licensee-per report is $80.

Table 5: Annual cost of providing exposure reports to employees prior to termination under this rule change

Licensee (by type) and x-ray registrants (incl. the agency)	Estimated turnover	Estimated to be affected by 19.13(e)	Estimated annual cost per lic type
Broad scope (medical – Private)	240	48	$3,840
Broad scope (medical – State institution)	60	12	$960
Broad scope (academic – Private)	30	6	$480
Broad scope (academic – State institution)	45	9	$720
Broad scope (industrial)	15	3	$240
Hospital-based medical	390	78	$6,240
Private practice medical	168	34	$2,720
Portable nuclear gauge (private except as below)	200	40	$3,200
Portable nuclear gauge (NCDOT) †	3	1	$80
Industrial radiography	18	4	$320
Other licensed activities	120	24	$1,920
Accelerator (medical and industrial)	150	30	$2,400
Radiation Protection Section (agency) †	3	1	$80
X-ray registrants	2,440	488	$39,040
TOTAL	**3,882**	**778**	**~$62,240**

In the table above, licenses that are part of State government are identified as being State institutions, NCDOT, and the 'agency'. This list includes one broad scope medical licensee, three broad scope academic licensees, one portable nuclear gauge licensee, and the Radiation Protection Section. All other licensees and registrants are private sector entities. The annual fixed cost to the State due to this rule change is estimated to be approximately $1,840 year, account for about 3 percent of turnover. The rest of the projected cost, approximately $60,400, is borne by private entities. There is no cost to the Federal government from this rule change because North Carolina is an Agreement State, and changes to 10A NCAC Chapter 15 do not affect licensees under Federal jurisdiction.

†Based upon the assumptions made for the number of employed individuals requesting exposure histories prior to leaving employment, these entities calculated to less than one. A value of one was assigned to each of these entities for the cost associated with this rule change for conservatism.

10A NCAC 15 .1613 – Surveys: This rule is being amended so that it is compatible with 10 CFR 20.1501. Specifically, the rule adds the requirement that licensees address subsurface contamination during surveys performed by the licensee if it is necessary and reasonable to evaluate subsurface contamination based upon licensed activities. Additionally, if surveys of the subsurface are necessary, records of those surveys have to be kept with the licensee's decommissioning records.

Impact: An analysis of the agency's licensing and inspections records reveal that North Carolina has no active licensees that are authorized to conduct activities where it is necessary or reasonable to evaluate the potential for subsurface contamination. Outdoor use, uses that discharge to the subsurface, or uncontained applications of radioactive material are not authorized under any active license issued by the agency. Historically, the agency has required licenses to conduct surveys that are necessary to detect and assess the types, quantities, and activities of radioactive material in all areas of use. Licenses would be expected to conduct surveys of the subsurface if it was likely that contamination of the surface could occur during normal conditions of use. No impact is anticipated from this rule change. North Carolina has only had one

licensee who went inactive more than 25 years ago who would have been affected by this change, therefore this analysis assumes there would not be any licensees impacted in the near future.

10A NCAC 15 .1645 – Reports of Theft or Loss of Licensed Radioactive Material: This rule is being amended to maintain compatibility with the reporting requirements of 10 CFR 20.2201 if radioactive material is stolen or lost. Specifically, licensees do not have to submit a report under this rule if the theft or loss of radioactive material has already been reported to the agency under a different regulatory requirement, and then lists those regulatory citations.

Impact: This rule was put into place to avoid reporting duplication and to clarify what reporting requirements apply under which circumstances. Since this rule is for clarification only, it imposes no new regulatory requirements and is not anticipated to have an impact on the State or any licensees.

10A NCAC 15 .1653 – Radiological Requirements for License Termination: This rule is being revised to maintain compatibility with 10 CFR 20.1403, 20.1404, and 20.1406, which are all found in Subpart E to 10 CFR Part 20. The changes made to 20.1403 includes instructions to assume a one percent annual real rate of return on investment for monies placed into a trust fund, and the deletion of part of this rule and the renumbering of the subsequent rules in 20.1403. The change made to 20.1604 is to 20.1406(a) and is already incorporated into 10A NCAC 15 .1653(c)(3). The change made to 20.1406 is to 20.1406(c), and requires licensees to conduct operations to minimize contamination of the subsurface.

Impact: The changes made to 10 CFR 20.1403 are for clarification purposes and to standardize around a standard assumption for fund growth instead of relying upon assumptions made by the licensee regarding the rate-of-return on investment for financial assurance for decommissioning. Regarding changes to 10 CFR 30.1406, a review of agency license and inspections records determined that no North Carolina licensees conduct activities that might reasonably be expected to contaminate the subsurface. No impact is anticipated from this rule change.

Uncertainties Regarding Proposed Rule Changes

- *Growth in number of total licensees:*
  Determining future trends in the growth or loss of the number of licensees in the State is difficult. Historical data indicates that the State experienced a growth rate of about 40% in the number of specific licensees over the nine-year period between 1995 and 2004, averaging about a 4.5% increase per year. In 1995, the earliest date that this data is available online from IMPEP reporting, North Carolina had 538 specific licensees. The State experienced growth in this sector of the economy and by 2004, data from IMPEP reporting indicates that this number grew to 751 specific licensees. Contrasted with that positive growth rate, a decade later, in 2014, (the latest data from IMPEP reporting) indicates that the number of specific licenses dropped by 18% to 618, an average annual decrease of 1.8%. The cause for the loss of approximately 130 specific licenses over the decade between 2004 and 2014 has not been investigated, but it assumed to be due to technological and economic changes occurring during that period. As can be determined from Table 1 above, the State currently has 630 specific licensees. This represents an increase in the number of specific licensees of about 12 in the two-year period between 2014 and 2016. This calculates to an average growth rate of two percent over the two-year period, or one percent a year.

It is assumed that the number of general licensees and registrants are affected by the same market forces and have experienced the same percentage growth over time as specific licensees experienced for the purposes of the analyses that follow. The agency anticipates that the actual growth rate experienced over the next five years to follow the current experienced growth rate of one percent a year. As previously discussed, license fees are not anticipated to be changed until after 2019.

Table 6. Sensitivity analysis for licensee growth assumption on potential cost savings

Change in the Number of Licensees	Annual Cost Savings
-5%	$5,497,908
-2%	$6,236,217
-1%	$6,346,647
0%	$6,520,527
1%	**$6,694,407**
2%	$6,820,437
5%	$7,627,075

- *Growth in number of licensees affected by change to 10A NCAC 15 .0302:*
  As the number of licensees affected by the regulatory change to 15A NCAC .0302 is increased, the first year cost to the state increases. This is offset by revenue generated by licensees not impacted by the changes made to .0302, and by income received during the second and subsequent years as shown below. Because the NRC fee structure allows for cost recovery through charging fees to offset labor costs, the Federal Government does not experience the loss in revenue faced by the State during the first year. Currently, only one licensee is impacted by this rule change. The table below shows how the impact would change if in the future more licensees were to be affected.

Table 7. Sensitivity analysis for licensee growth assumption on impact of changes to exemptions for source materials

	First Year Impact				Annual Impact for Subsequent Years			
Number of Licensees	State Gov't	Federal Gov't	Licensees	**Total**	State Gov't	Federal Gov't	Licensees	**Total**
1	($406)	$1,494	$7,644	**$8,732**	$72	$3,062	$4,929	**$8,063**
2	($812)	$2,988	$15,288	**$17,464**	$144	$6,124	$9,858	**$16,126**
5	($2,030)	$7,470	$38,220	**$43,660**	$360	$15,310	$24,645	**$40,315**
7	($2,842)	$10,458	$53,508	**$61,124**	$504	$21,434	$34,503	**$56,441**
10	($4,060)	$14,940	$76,440	**$87,320**	$720	$30,620	$49,290	**$80,630**

- *Percent of turnover employees affected by 10A NCAC 15 .1004:*
  Discussions with several Radiation Safety Officers responsible for a variety of licensed activities indicated that the number of employees leaving employment varied by the type of activity and the nature of employment. The highest annual turnaround rate occurred among the undergraduate

student-worker populations at medical and academic broad licenses. It must be noted that the number of undergraduate student-workers comprises a small proportion of the population of occupationally exposed employees at these licensee facilities. Thus, the higher turnaround rate among the undergraduate student-worker population is offset by the rest of the occupational worker population. The lowest turn around rate was found among technical and professional staff, with many licensees experiencing near zero annual employee turn around rates.

For purposes of this cost analysis, it was assumed that a baseline of 10% of the occupationally exposed worker population left employment (termination) each year and that 20% of these employees leaving employment would request their exposure history report from their employer prior to their termination date. This assumption is based upon data from inspection records and conversations with Radiation Safety Officers while preparing this fiscal note.

The sensitivity analysis of the cost to State Government and private entities thus has two variables. The first being the number of employees leaving employment, the second being the percentage of those employees requesting exposure history reports prior to termination. Assuming that the labor cost to produce each exposure history report remains constant at $80 per report, the table below shows the effect the assumptions about turnover and employees requesting history reports have on the estimated impact to state government and private sector.

Table 8. Sensitivity analysis for turnover assumptions on impact of changes to history reports upon separation

A. *State Gov't Cost*		Assumption on percent separating who request a history report						
		5%	10%	15%	**20%**	25%	35%	50%
Turnover Assumption	2%	$80	$160	$240	$320	$400	$560	$1,040
	5%	$240	$400	$640	$880	$1,280	$1,680	$2,320
	10%	$400	$880	$1,280	**$1,840**	$2,240	$3,120	$4,560
	15%	$640	$1,440	$2,080	$2,720	$3,360	$4,800	$6,800

B. *Private Cost*		Assumption on percent separating who request a history report						
		5%	10%	15%	**20%**	25%	35%	50%
Turnover Assumption	2%	$2,960	$6,000	$9,120	$12,240	$15,280	$21,120	$30,240
	5%	$7,520	$15,200	$22,560	$30,240	$37,760	$52,720	$75,600
	10%	$15,200	$30,240	$45,360	**$60,400**	$75,600	$105,680	$150,880
	15%	$22,560	$45,360	$67,920	$90,480	$113,120	$158,400	$226,400

As expected, the actual cost is highly dependent upon the starting population, the percentage of employees leaving employment and the percentage of the employees leaving employment requesting exposure history reports. At the lowest percentages, for example, 2% of the employees terminating employment with 5% requesting of those employees requesting the reports resulted in the lowest costs (the minimum cost to produce a single report, $80). At the other extreme, where 15% of employees separated and half of those employees requested these reports, the total cost to licensees and state government could be close to four times the impact estimated in this analysis.

10A NCAC 15 .0302 is proposed for amendment as follows:

10A NCAC 15 .0302 EXEMPTIONS FOR SOURCE 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) Any person is exempt from licensure to the extent that any person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 0.05 percent of the mixture, compound, solution, or alloy.~~

~~(b) Any person is exempt from licensure to the extent that any person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, no person shall refine or process ore containing source material.~~

~~(c) Any person is exempt from licensure to the extent that any person receives, possesses, uses, or transfers:~~

~~(1) any quantities of thorium contained in:~~

~~(A) incandescent gas mantles;~~

~~(B) vacuum tubes;~~

~~(C) welding rods;~~

~~(D) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;~~

~~(E) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;~~

~~(F) rare earth metals and compounds, mixtures, and products containing not more than 0.04 percent by weight thorium, uranium or any combination of these;~~

~~(G) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;~~

~~(2) source material contained in the following products:~~

~~(A) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;~~

~~(B) glassware containing not more than ten percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass, or ceramic used in construction;~~

~~(C) piezoelectric ceramic containing not more than two percent by weight source material;~~

(D) glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States before July 25, 1983;

(3) photographic film, negatives, and prints containing uranium or thorium;

(4) any finished product or part fabricated of, or containing, tungsten or magnesium-thorium alloys; provided that the thorium content of the alloy does not exceed four percent by weight and that the exemption contained in this Rule shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of the product or part;

(5) uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of the counterweights when:

(A) the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR 40;

(B) each counterweight has been impressed with the following legend clearly legible through any plating or other covering, which states, "DEPLETED URANIUM";

(C) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";

(D) the exemption contained in this Subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any counterweights other than repair or restoration of any plating or other covering;

(E) the requirements specified in Subparagraphs (c)(5)(B) and (C) of this Rule need not be met by counterweights manufactured prior to December 31, 1969; provided, that the counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM";

(6) natural or depleted uranium metal used as shielding constituting part of any shipping container; provided that:

(A) The shipping container is conspicuously and legibly impressed with the legend, "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and

(B) The uranium metal is encased in mild steel or equally fire-resistant metal with a minimum wall thickness of one-eighth inch or 3.2 mm;

(7) thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium; and that the exemption contained in this Subparagraph shall not be deemed to authorize either:

(A) the shaping, grinding, or polishing of the lens or manufacturing processes other than the assembly of the lens into optical systems and devices without any alteration of the lens; or

(B) the receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eye pieces in binoculars or other optical instruments;

~~(8) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium;~~

~~(9) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:~~

~~(A) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide);~~

~~(B) The thorium content in the nickel-thoria alloy does not exceed four percent by weight.~~

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.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0304 is proposed for amendment as follows:

10A NCAC 15 .0304 EXEMPT QUANTITIES: OTHER THAN SOURCE 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) Any person who possesses radioactive material received or acquired under the general license formerly provided in Rule .0303(b) of this Section is exempt from the requirements for a license set forth in this Section to the extent that such person possesses, uses, transfers or owns such radioactive material.~~

~~(b) This Rule does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.~~

~~(c) No person shall, for the purposes of commercial distribution, transfer individual quantities of radioactive materials to persons exempt from regulation in Paragraph (a) of this Rule except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 for source and byproduct material.~~

~~(d) Licensees for commercial distribution shall not transfer the quantities of radioactive material to persons exempt under Paragraph (f) of this Rule if the licensee knows or has reason to believe that the recipient will redistribute the quantities to persons exempt under Paragraph (f) of this Rule.~~

~~(e) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits in Paragraph (f) of this Rule, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this Section.~~

~~(f) Except as provided in Paragraphs (b) and (c) of this Rule, any person is exempt from the rules of this Chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in the following table:~~

~~EXEMPT QUANTITIES~~

~~Radioactive Material~~	~~Microcuries~~
~~Antimony-122 (Sb-122)~~	~~100~~
~~Antimony-124 (Sb-124)~~	~~10~~
~~Antimony-125 (Sb-125)~~	~~10~~
~~Arsenic-73 (As-73)~~	~~100~~
~~Arsenic-74 (As-74)~~	~~10~~
~~Arsenic-76 (As-76)~~	~~10~~
~~Arsenic-77 (As-77)~~	~~100~~
~~Barium-131 (Ba-131)~~	~~10~~
~~Barium-133 (Ba-133)~~	~~10~~
~~Barium-140 (Ba-140)~~	~~10~~
~~Bismuth-210 (Bi-210)~~	~~1~~
~~Bromine-82 (Br-82)~~	~~10~~
~~Cadmium-109 (Cd-109)~~	~~10~~
~~Cadmium-115m (Cd-115m)~~	~~10~~
~~Cadmium-115 (Cd-115)~~	~~100~~
~~Calcium-45 (Ca-45)~~	~~10~~
~~Calcium-47 (Ca-47)~~	~~10~~
~~Carbon-14 (C-14)~~	~~100~~
~~Cerium-141 (Ce-141)~~	~~100~~
~~Cerium-143 (Ce-143)~~	~~100~~
~~Cerium-144 (Ce-144)~~	~~1~~
~~Cesium-129 (Cs-129)~~	~~100~~
~~Cesium-131 (Cs-131)~~	~~1,000~~
~~Cesium-134m (Cs-134m)~~	~~100~~
~~Cesium-134 (Cs-134)~~	~~1~~

~~Cesium-135 (Cs 135)~~	~~10~~
~~Cesium-136 (Cs 136)~~	~~10~~
~~Cesium-137 (Cs 137)~~	~~10~~
~~Chlorine-36 (Cl 36)~~	~~10~~
~~Chlorine-38 (Cl 38)~~	~~10~~
~~Chromium-51 (Cr 51)~~	~~1,000~~
~~Cobalt-57 (Co 57)~~	~~100~~
~~Cobalt-58m (Co-58m)~~	~~10~~
~~Cobalt-58 (Co 58)~~	~~10~~
~~Cobalt-60 (Co 60)~~	~~1~~
~~Copper-64 (Cu 64)~~	~~100~~
~~Dysprosium-165 (Dy 165)~~	~~10~~
~~Dysprosium-166 (Dy-166)~~	~~100~~
~~Erbium-169 (Er 169)~~	~~100~~
~~Erbium-171 (Er 171)~~	~~100~~
~~Europium-152 (Eu 152) 9.2h~~	~~100~~
~~Europium-152 (Eu 152) 13 yr~~	~~1~~
~~Europium-154 (Eu 154)~~	~~1~~
~~Europium-155 (Eu 155)~~	~~10~~
~~Fluorine-18 (F 18)~~	~~1,000~~
~~Gadolinium-153 (Gd 153)~~	~~10~~
~~Gadolinium-159 (Gd 159)~~	~~100~~
~~Gallium-67 (Ga 67)~~	~~100~~
~~Gallium-72 (Ga 72)~~	~~10~~
~~Germanium-68 (Ge 68)~~	~~10~~
~~Germanium-71 (Ge 71)~~	~~100~~
~~Gold-195 (Au 195)~~	~~10~~
~~Gold-198 (Au 198)~~	~~100~~
~~Gold-199 (Au 199)~~	~~100~~
~~Hafnium-181 (Hf 181)~~	~~10~~
~~Holmium-166 (Ho 166)~~	~~100~~
~~Hydrogen-3 (H 3)~~	~~1,000~~
~~Indium-111 (In 111)~~	~~100~~
~~Indium-113m (In 113m)~~	~~100~~
~~Indium-114m (In 114m)~~	~~10~~
~~Indium-115m (In 115m)~~	~~100~~
~~Indium-115 (In 115)~~	~~10~~

~~Iodine-123 (I 123)~~	~~100~~
~~Iodine-125 (I 125)~~	~~1~~
~~Iodine-126 (I 126)~~	~~1~~
~~Iodine-129 (I 129)~~	~~0.1~~
~~Iodine-131 (I 131)~~	~~1~~
~~Iodine-132 (I 132)~~	~~10~~
~~Iodine-133 (I 133)~~	~~1~~
~~Iodine-134 (I 134)~~	~~10~~
~~Iodine-135 (I 135)~~	~~10~~
~~Iridium-192 (Ir 192)~~	~~10~~
~~Iridium-194 (Ir 194)~~	~~100~~
~~Iron-52 (Fe 52)~~	~~10~~
~~Iron-55 (Fe 55)~~	~~100~~
~~Iron-59 (Fe 59)~~	~~10~~
~~Krypton-85 (Kr 85)~~	~~100~~
~~Krypton-87 (Kr 87)~~	~~10~~
~~Lanthanum-140 (La 140)~~	~~10~~
~~Lutetium-177 (Lu 177)~~	~~100~~
~~Manganese-52 (Mn 52)~~	~~10~~
~~Manganese-54 (Mn 54)~~	~~10~~
~~Manganese-56 (Mn 56)~~	~~10~~
~~Mercury-197m (Hg 197m)~~	~~100~~
~~Mercury-197 (Hg 197)~~	~~100~~
~~Mercury-203 (Hg 203)~~	~~10~~
~~Molybdenum-99 (Mo 99)~~	~~100~~
~~Neodymium-147 (Nd 147)~~	~~100~~
~~Neodymium-149 (Nd 149)~~	~~100~~
~~Nickel-59 (Ni 59)~~	~~100~~
~~Nickel-63(Ni 63)~~	~~10~~
~~Nickel-65 (Ni 65)~~	~~100~~
~~Niobium-93m (Nb 93m)~~	~~10~~
~~Niobium-95 (Nb 95)~~	~~10~~
~~Niobium-97 (Nb 97)~~	~~10~~
~~Osmium-185 (Os 185)~~	~~10~~
~~Osmium-191m (Os 191m)~~	~~100~~
~~Osmium-191 (Os 191)~~	~~100~~
~~Osmium-193 (Os 193)~~	~~100~~

~~Palladium-103 (Pd 103)~~	~~100~~
~~Palladium-109 (Pd 109)~~	~~100~~
~~Phosphorus-32 (P 32)~~	~~10~~
~~Platinum-191 (Pt 191)~~	~~100~~
~~Platinum-193m (Pt 193m)~~	~~100~~
~~Platinum-193 (Pt 193)~~	~~100~~
~~Platinum-197m (Pt 197m)~~	~~100~~
~~Platinum-197 (Pt 197)~~	~~100~~
~~Polonium-210 (Po 210)~~	~~0.1~~
~~Potassium-42 (K 42)~~	~~10~~
~~Potassium-43 (K 43)~~	~~10~~
~~Praseodymium-142 (Pr 142)~~	~~100~~
~~Praseodymium-143 (Pr 143)~~	~~100~~
~~Promethium-147 (Pm 147)~~	~~10~~
~~Promethium-149 (Pm 149)~~	~~10~~
~~Rhenium-186 (Re 186)~~	~~100~~
~~Rhenium-188 (Re 188)~~	~~100~~
~~Rhodium-103m (Rh 103m)~~	~~100~~
~~Rhodium-105 (Rh 105)~~	~~100~~
~~Rubidium-81 (Rb 81)~~	~~10~~
~~Rubidium-86 (Rb 86)~~	~~10~~
~~Rubidium-87 (Rb 87)~~	~~10~~
~~Ruthenium-97 (Ru 97)~~	~~100~~
~~Ruthenium-103 (Ru 103)~~	~~10~~
~~Ruthenium-105 (Ru 105)~~	~~10~~
~~Ruthenium-106 (Ru 106)~~	~~1~~
~~Samarium-151 (Sm 151)~~	~~10~~
~~Samarium-153 (Sm 153)~~	~~100~~
~~Scandium-46 (Sc 46)~~	~~10~~
~~Scandium-47 (Sc 47)~~	~~100~~
~~Scandium-48 (Sc 48)~~	~~10~~
~~Selenium-75 (Se 75)~~	~~10~~
~~Silicon-31 (Si 31)~~	~~100~~
~~Silver-105 (Ag 105)~~	~~10~~
~~Silver-110m (Ag 110m)~~	~~1~~
~~Silver-111 (Ag 111)~~	~~100~~
~~Sodium-22 (Na 22)~~	~~10~~

~~Sodium-24 (Na 24)~~	~~10~~
~~Strontium-85 (Sr 85)~~	~~10~~
~~Strontium-89 (Sr 89)~~	~~1~~
~~Strontium-90 (Sr 90)~~	~~0.1~~
~~Strontium-91 (Sr 91)~~	~~10~~
~~Strontium-92 (Sr 92)~~	~~10~~
~~Sulfur-35 (S 35)~~	~~100~~
~~Tantalum-182 (Ta 182)~~	~~10~~
~~Technetium-96 (Tc 96)~~	~~10~~
~~Technetium-97m (Tc 97m)~~	~~100~~
~~Technetium-97 (Tc 97)~~	~~100~~
~~Technetium-99m (Tc 99m)~~	~~100~~
~~Technetium-99 (Tc 99)~~	~~10~~
~~Tellurium-125m (Te 125m)~~	~~10~~
~~Tellurium-127m (Te 127m)~~	~~10~~
~~Tellurium-127 (Te 127)~~	~~100~~
~~Tellurium-129m (Te 129m)~~	~~10~~
~~Tellurium-129 (Te 129)~~	~~100~~
~~Tellurium-131m (Te 131m)~~	~~10~~
~~Tellurium-132 (Te 132)~~	~~10~~
~~Terbium-160 (Tb 160)~~	~~10~~
~~Thallium-200 (Tl 200)~~	~~100~~
~~Thallium-201 (Tl 201)~~	~~100~~
~~Thallium-202 (Tl 202)~~	~~100~~
~~Thallium-204 (Tl 204)~~	~~10~~
~~Thulium-170 (Tm 170)~~	~~10~~
~~Thulium-171 (Tm 171)~~	~~10~~
~~Tin-113 (Sn 113)~~	~~10~~
~~Tin-125 (Sn 125)~~	~~10~~
~~Tungsten-181 (W 181)~~	~~10~~
~~Tungsten-185 (W 185)~~	~~10~~
~~Tungsten-187 (W 187)~~	~~100~~
~~Vanadium-48 (V 48)~~	~~10~~
~~Xenon-131m (Xe 131m)~~	~~1,000~~
~~Xenon-133 (Xe 133)~~	~~100~~
~~Xenon-135 (Xe 135)~~	~~100~~
~~Ytterbium-175 (Yb 175)~~	~~100~~

~~Yttrium-87 (Y 87)~~	~~10~~
~~Yttrium-88 (Y 88)~~	~~10~~
~~Yttrium-90 (Y 90)~~	~~10~~
~~Yttrium-91 (Y 91)~~	~~10~~
~~Yttrium-92 (Y 92)~~	~~100~~
~~Yttrium-93 (Y 93)~~	~~100~~
~~Zinc-65 (Zn 65)~~	~~10~~
~~Zinc-69m (Zn 69m)~~	~~100~~
~~Zinc-69 (Zn 69)~~	~~1,000~~
~~Zirconium-93 (Zr 93)~~	~~10~~
~~Zirconium-95 (Zr 95)~~	~~10~~
~~Zirconium-97 (Zr 97)~~	~~10~~
~~Any radioactive material not listed above other than alpha-emitting radioactive material~~	~~0.1~~

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.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0305 is proposed for amendment as follows:

10A NCAC 15 .0305 EXEMPT ITEM CONTAINING OTHER THAN SOURCE 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) Authority must be obtained from the U.S. Nuclear Regulatory Commission to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material whose subsequent possession, use, transfer, and disposal are exempted from the rules of this Chapter.~~

~~(b) Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products, any person is exempt from the rules of this Chapter to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:~~

~~(1) Timepieces or hands or dials containing not more than the following quantities of radioactive material and not exceeding the following levels of radiation:~~

~~(A) 25 millicuries of tritium per timepiece;~~

~~(B) five millicuries of tritium per hand;~~

~~(C) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);~~

~~(D) 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per any other timepiece;~~

~~(E) 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;~~

~~(F) 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);~~

~~(G) the levels of radiation from hands and dials containing promethium-147, when measured through 50 milligrams per square centimeter of absorber:~~

~~(i) for wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;~~

~~(ii) for pocket watches, 0.1 millirad per hour at one centimeter from any surface;~~

~~(iii) for any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface; or~~

~~(iv) one microcurie of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.~~

~~(2) Balances of precision containing not more than one millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007;~~

(3) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007;

(4) Ionization chamber smoke detectors containing not more than one microcurie of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(5) Electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material and provided further, that the levels of radiation from each electron tube containing radioactive material does not exceed one millirad per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber. For purposes of this Subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents:

(A) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(B) one microcurie of cobalt-60;

(C) five microcuries of nickel-63;

(D) 30 microcuries of krypton-85;

(E) five microcuries of cesium-137; and

(F) 30 microcuries of promethium-147; and

(6) Ionizing radiation measuring instruments containing for purposes of internal calibration or standardization, sources of radioactive material each not exceeding the applicable quantity set forth in Rule .0304(f) of this Section, and each instrument contains no more than 10 exempt quantities.

(c) For purposes of Subparagraph (b)(5) of this Rule, where there is involved a combination of radionuclides, the limit for the combination shall be derived as follows:

(1) Determine for each radionuclide in an ionizing radiation measuring instrument the ratio between the quantity present in the instrument and the exempt quantity established in Rule .0304 (f) of this Section for the specific radionuclide when not in combination;

(2) No ratio shall exceed one and the sum of such ratios shall not exceed 10; and

(3) For the purpose of Part (b)(8), 0.05 microcurie of americium-241 is considered an exempt quantity under Rule .0304 of this Section.

(d) Self-luminous products are exempt as provided in this Paragraph.

(1) Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from the rules of this Chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission

~~pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.~~

~~(2) The exemption in Subparagraph (d)(1) of this Rule does not apply to tritium, krypton 85, or promethium 147 used in products for frivolous purposes or in toys or adornments.~~

~~(e) Gas and aerosol detectors are exempt as provided in this Paragraph.~~

~~(1) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the rules of this Chapter to the extent that the person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall be manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR 32, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.~~

~~(2) Gas and aerosol detectors previously manufactured and distributed to general licensees before November 30, 2007 in accordance with a specific license issued by an agreement state are exempt from the rules in this Chapter, provided that the devices are labeled in accordance with the specific license authorizing distribution of the general licensed device, and providing further that the devices meet the requirements of Rule .0327 of this Section.~~

~~(f) Except as follows, any person is exempt from the requirements for a license set forth in this Section provided that such person receives, possesses, uses, transfers, owns or acquires capsules containing approximately one microcurie (37kBq) Carbon-14 urea each for "in-vivo" diagnostic use for humans:~~

~~(1) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license from the agency; and~~

~~(2) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license from the U.S. Nuclear Regulatory Commission.~~

~~(g) Nothing in this Rule relieves persons from complying with applicable FDA and other federal regulations, and North Carolina requirements governing the receipt, administration, and use of drugs.~~

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.15; 10 CFR 30.19; 10 CFR 30.20;*
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.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0307 is proposed for amendment as follows:

10A NCAC 15 .0307 GENERAL LICENSES: SOURCE MATERIAL

(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) A general license shall be issued authorizing use and transfer of not more than 15 pounds of source material at any one time by persons in the following categories:~~

~~(1) pharmacists using the source material solely for the compounding of medicinals;~~

~~(2) physicians using the source material for medicinal purposes;~~

~~(3) persons receiving possession of source material from pharmacists and physicians in the form of medicinals or drugs;~~

~~(4) commercial and industrial firms, and research, educational, and medical institutions, and state and local governmental agencies for research, development, educational, commercial or operational purposes.~~

~~(b) Pursuant to this general license no person shall receive more than a total of 150 pounds of source material in any one calendar year.~~

~~(c) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in Paragraph (a) of this Rule are exempt from the provisions of Sections .1000 and .1600 of this Chapter to the extent that the receipt, possession, use, or transfer is within the terms of the general license, provided that this exemption shall not be deemed to apply to any person who is also in possession of source material under a specific license issued pursuant to the rules in this Section.~~

~~(d) A general license shall be issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.~~

~~(e) A general license shall be issued to receive, acquire, possess, use, or transfer in accordance with the provisions of Subparagraphs (e)(2), (3), (4) and (5) of this Rule, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.~~

~~(1) The general license in Paragraph (e) of this Rule applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of~~

the products or devices pursuant to Rule .0336 of this Section or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(2) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by Paragraph (e) of this Rule shall file with the agency appropriate form(s) provided by the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on appropriate form(s) provided by the agency the following information and such other information as may be required by that form:

(A) name and address of the registrant;

(B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in Paragraph (e) of this Rule and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) name, title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in Part (e)(2)(B) of this Rule.

(3) The registrant possessing or using depleted uranium under the general license established by Paragraph (e) of this Rule shall report in writing to the agency any changes in information furnished by him on the appropriate form(s) provided by the agency. The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by Paragraph (e) of this Rule shall:

(A) not introduce such depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(B) not abandon such depleted uranium;

(C) transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of Rule .0343 of this Section;

(i) In the case where the transferee receives the depleted uranium pursuant to the general license established by Paragraph (e) of this Rule, the transferor shall furnish the transferee a copy of this Rule and a copy of the appropriate agency form described in Subparagraph (e)(2) of this Rule;

(ii) In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or agreement state regulations equivalent to Paragraph (e) of this Rule, the transferor shall furnish the transferee a copy of this Rule and a copy of the appropriate

~~agency form accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in this Rule;~~

~~(D) within 30 days of any transfer, report in writing to the agency the name and address of the person receiving the depleted uranium pursuant to such transfer;~~

~~(E) not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.~~

~~(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by Paragraph (e) of this Rule is exempt from the requirements of Sections .1000 and .1600 of this Chapter with respect to the depleted uranium covered by that general license.~~

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.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0308 is proposed for amendment as follows:

10A NCAC 15 .0308 GENERAL LICENSES: OTHER THAN SOURCE MATERIAL

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) A general license shall be issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31:~~

~~(1) static elimination devices designed for use as static eliminators which contain as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device;~~

~~(2) ion generating tube designed for ionization of air and containing, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device.~~

~~(b) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.~~

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.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0309 is proposed for amendment as follows:

10A NCAC 15 .0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES

(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) A general license shall be issued to acquire, receive, possess, use, or transfer in accordance with Paragraphs (b), (c), and (d) of this Rule, radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere to:~~

~~(1) commercial and industrial firms;~~

~~(2) research, educational and medical institutions;~~

~~(3) individuals in the conduct of their business; and~~

~~(4) federal, state, or local government agencies.~~

~~(b) The general license in Paragraph (a) of this Rule applies only to radioactive material contained in devices which have been:~~

~~(1) manufactured or initially transferred and labeled in accordance with the specifications contained in a specific license issued pursuant to Rule .0328 of this Section or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes distribution of the devices to persons generally licensed pursuant to equivalent regulations; and~~

~~(2) received from one of the specific licensees referenced in Subparagraph (b)(1) of this Rule or through a transfer completed in accordance with Subparagraph (c)(8) or (c)(9) of this Rule.~~

~~(c) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license issued under Paragraph (a) of this Rule shall:~~

~~(1) assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by the labels;~~

~~(2) assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at six-month intervals or at alternative intervals as are specified in the label, except as follows:~~

~~(A) Devices containing only krypton need not be tested for leakage of radioactive material; and~~

~~(B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma, or beta and gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;~~

~~(3) assure that the tests required by Subparagraph (c)(2) of this Rule and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment are performed:~~

~~(A) in accordance with the instructions provided on labels affixed to the device, except that tests for leakage or contamination may be performed by the general licensee using leak test kits provided and analyzed by a specific licensee who is authorized to provide leak test kit services; or~~

~~(B) by a person holding a specific license or registration which authorizes the providing of services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state;~~

~~(4) maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3) of this Rule, including:~~

~~(A) the name of the person(s) performing the test(s) and the date(s) of the test(s);~~

~~(B) the name of the person(s) performing installation, servicing and removal of any radioactive material, shielding or containment;~~

~~(C) the retention of leakage or contamination, on-off mechanism and on-off indicator test records shall be retained for three years after the required test is performed or until the sealed source is disposed of or transferred; and~~

~~(D) the retention of other records of tests required in Subparagraph (c)(3) of this Rule shall be retained for three years from the date of the recorded test or until the device is disposed of or transferred.~~

~~(5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the~~

detection of 0.005 microcurie or more removable radioactive material, immediately suspend operation of the device until it has been:

(A) repaired by the manufacturer or other person authorized to repair the device(s) by a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state; or

(B) disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device; and within 30 days, the transferor will furnish to the agency at the address in Rule .0111 of this Chapter a report containing a description of the event and the remedial action taken. If 0.005 microcurie or more of removable radioactive contamination is detected, or if the failure of or damage to a source of radiation is likely to result in the contamination of the facility or the environment, a plan for ensuring that the facility and the environment are acceptable for unrestricted use shall be submitted to the agency at the address in Rule .0111 of this Chapter.

(6) not abandon the device containing radioactive material;

(7) except as provided in Subparagraph (c)(8) or (c)(9) of this Rule, transfer or dispose of the device containing radioactive material only by export in accordance with 10 CFR Part 110 or by transfer to a person holding a specific license authorizing receipt of the device; and, within 30 days after transfer of a device to a specific licensee or export of a device, shall furnish to the agency at the address in Rule .0111 of this Chapter, a report that contains:

(A) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(B) the name, address and specific license number of the person receiving the device (the license number not applicable if exported); and

(C) the date of the transfer; and

(8) obtain written approval by the Agency before transferring the device to any other specific licensee not identified in this Rule. However, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(A) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) removes, alters, covers, or clearly and unambiguously augments as defined in 10 CFR 31.5 the existing label otherwise required by Paragraph (c)(1) of this Rule so that the device is labeled in compliance with Rule .0328(a)(3) of this Chapter; however, the manufacturer, model number, and serial number must be retained;

(C) obtains the manufacturer's or initial transferor's information concerning maintenance that are applicable under the specific license (such as leak testing procedures); and

(D) reports the transfer under Subparagraph (c)(7) of this Rule.

(9) transfer or dispose of the device by export as provided by Subparagraph (c)(7) of this Rule, or by transfer to another general licensee only where the device:

(A) remains in use at a particular location. The transferor shall give the transferee a copy of this Rule and any safety documents identified in the label of the device. The transferor shall, within 30 days of the transfer, report to the agency at the address in Rule .0111 of this Chapter the manufacturer's or initial transferor's name, serial number, and model number of device transferred; the name and mailing address of the transferee; and the name, title, and telephone number of the individual identified by the transferee pursuant to Subparagraph (c)(11) of this Rule; or

(B) is held in storage by the licensee or an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee;

(10) comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting radiation incidents, theft or loss of licensed material, but is exempt from the other requirements of Section .1600 of this Chapter;

(11) appoint an individual responsible for having knowledge of the requirements contained in these Rules and the authority for taking the actions required to comply with these Rules. The general licensee, through this individual, shall ensure the day-to-day compliance with these Rules. The appointment of such an individual does not relieve the general licensee of any of its responsibility in this regard;

(12) register, when required by the agency, any source of radiation subject to a general license in accordance with the rules in this Section. Each address for a location of use represents a separate general license and requires a separate registration action;

(13) register, on an annual basis, all devices containing, based on the activity indicated on the label, at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi (37MBq) of cobalt-60, 1 mCi (37 MBq) of americium-241, 0.1 mCi (3.7 MBq) of radium-226, or any other transuranic isotope. Each address for a location of use represents a separate general license and requires a separate registration action. Annual registration consists of verifying, correcting, or adding to the information provided in a request for annual registration within 30 days of a request from the agency. The general licensee shall furnish the following information for annual registration:

(A) the name and mailing address of the general licensee;

(B) information about each device to include the manufacturer or initial transferor, model number, serial number, the radioisotope, and the activity indicated on the label;

(C) the name, title, and telephone number of the responsible person designated as a representative of the general licensee in accordance with Subparagraph (c)(11) of this Rule;

(D) the address or location at which the device(s) are to be used or stored. For portable devices that are granted a general license by the agency, the address of the primary place of storage;

~~(E) certification by the responsible person designated by the general licensee that the information concerning the device(s) has been verified through a physical inventory and a check of label information; and~~

~~(F) certification by the responsible person designated by the general licensee that they are aware of the requirements of the general license;~~

~~(14) report changes to the mailing address to the agency within 30 days of the effective date of the change;~~

~~(15) report changes to the name of the general licensee to the agency within 30 days of the effective date of the change;~~

~~(16) respond to written requests from the agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the agency a written justification for the request;~~

~~(17) not hold devices that are not in use for longer than two years. If devices that have shutters are not in use, the shutter shall be locked in the closed position. Leak testing is not required during the period of storage; however, when devices are returned to service or transferred to another person, the devices must be tested for leakage and shutter operation. Devices kept in standby for future use shall be excluded from the two year time limit if quarterly physical inventories of these devices are performed while in standby.~~

~~(d) The general license in Paragraph (a) of this Rule does not authorize the manufacture or import of devices containing radioactive material.~~

~~(e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a), .0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.~~

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.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0310 is proposed for amendment as follows:

10A NCAC 15 .0310 GENERAL LICENSES: MANUFACTURE, TRANSFER, INSTALL GENERALLY LICENSED DEVICES

(a) Any person who is authorized to manufacture, install, or service a device described in Rule .0309 of this Section, pursuant to a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or another Agreement State 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.

~~Any person who is authorized to manufacture, install or service a device described in Rule .0309 of this Section pursuant to a specific license issued by the agency, the U.S. Nuclear Regulatory Commission or an agreement state is hereby granted a general license to install and service the device described in Rule .0309, provided the following requirements are met:~~

~~(1) The person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each report shall identify each general licensee, to whom the device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~

~~(2) The device is manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the U.S. Nuclear Regulatory Commission or an agreement state;~~

~~(3) The person shall assure that any labels satisfy the requirements in Rule .0309 of this Section and shall furnish to each general licensee, to whom he transfers a device or on whose premises he installs a device, a copy of the general license contained in Rule .0309 of this Section;~~

~~(4) The person shall ensure that each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model and serial number, the isotope and quantity, the words "Caution: Radioactive Material," the radiation symbol described in Rule .1623 of this Chapter, and the name of the manufacturer or initial transferor;~~

~~(5) The person shall ensure that each device meeting the criteria of Rule .0309 of this Chapter bears a permanently embossed, etched, stamped or engraved label affixed to the source housing, if separable, or the device if the source housing is not separable. The label shall include the words, "Caution: Radioactive Materials," and, if space and accessibility permit, the radiation symbol described in Rule .1623 of this Chapter;~~

~~(6) If a device is to be transferred for use under the general license granted in Rule .0309(c)(12) of this Chapter, each person that is licensed under this Rule shall provide the following information to each person to whom the device is being transferred prior to the device being transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to the initial transfer to the intermediate person. The required information includes:~~

(a) a copy of the general license document referenced in Rule .0306 of this Chapter or if no license document is issued, a copy of the letter issued by the agency indicating a license exists in accordance with Rule .0309 of this Chapter. If the prospective general licensee is in the jurisdiction of the Nuclear Regulatory Commission or another Agreement State, the notification shall include a statement advising the person receiving the device of the agency that has jurisdiction over the device;

(b) a copy of Rule .0309 of this Section. If the prospective general licensee is in the jurisdiction of the Nuclear Regulatory Commission or another Agreement State, the notification of transfer shall include the name or title, address, and telephone number of the contact at the proper regulatory agency that has jurisdiction over the person receiving the device;

(c) a list of services, as provided by the manufacturer, that can be performed only by a specific licensee;

(d) information on acceptable disposal options, including estimated cost of disposal; and

(e) a statement that loss or improper disposal of the device may result in formal enforcement actions.

(7) Each device transferred after January 1, 2005 shall meet the labeling requirements;

(8) Each person specifically licensed to initially transfer generally licensed devices to other persons shall comply with the requirements of this Paragraph.

(a) The person shall report, on a quarterly basis, all transfers of devices to persons for use under a general license and all receipts of devices from generally licensed persons. For devices transferred for use under the general license granted in Rule .0309(c)(12) of this Chapter, the reports shall be provided to the agency at the address listed in Rule .0111. For devices transferred outside the jurisdiction of the agency, the reports shall be provided to the Nuclear Regulatory Commission or to the Agreement State which has jurisdiction over the general licensee. The information shall be provided either on the Nuclear Regulatory Commission's Form 653 "Transfers of Industrial Devices Report" or in a clear and legible report that contains all of the information required by the form. The required information includes:

(i) the identity of each general licensee by name and mailing address for the location of use. If there is no mailing address at the location of use, an alternate address for the general licensee shall be submitted along with the information on the actual location of use;

(ii) the name, title and telephone number of the person identified by the general licensee as having knowledge of, and authority to ensure compliance with, these rules;

(iii) the date of transfer;

(iv) the type, model number, and serial number of the device transferred; and

~~(v) the quantity and type of radioactive material contained in the device.~~

~~(b) If one or more intermediate persons will temporarily possess the device at the intended use location prior to its use by the end user, the report shall include the same information for both the intended end user and each intermediate person, and designate the intermediate person(s).~~

~~(c) If the licensee makes changes to a device possessed by a general licensee such that the label must be changed to update required information, the report shall identify the general licensee, the device, and the changes to the information on the label.~~

~~(d) The report shall cover a calendar quarter and must be filed within 30 days of the end of the calendar quarter. The report shall identify the period covered by the report.~~

~~(e) The report shall identify the specific licensee submitting the report and include the license number of the specific licensee.~~

~~(f) In providing information on devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number and serial number of the device received, and, in the case of devices not initially transferred by the licensee submitting the report, the name of the manufacturer or initial transferor.~~

~~(g) If no transfers have been made to or from persons generally licensed during the reporting period, the report shall so indicate.~~

~~(9) The person providing the reports shall maintain all information concerning the transfers and receipts of devices required by this Rule for a period of three years following the date of the recorded event.~~

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.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0316 is proposed for amendment as follows:

10A NCAC 15 .0316 GENERAL LICENSES: TRANSPORTATION

(a) Any person transporting or storing byproduct material for transportation shall be exempt as authorized by 10 CFR 30.13.

(b) Any person transporting or storing source material for transportation shall be exempt as authorized by 10 CFR 40.12. Any person not exempt under 10 CFR 40.12 shall be issued a general license in accordance with Rule .0306(a) of this Section.

(c) Any person transporting or storing special nuclear material for transportation shall be exempt as authorized by 10 CFR 70.12. Any person not exempt shall be issued a general license in accordance with Rule .0306(a) of this Section.

(d) Any person preparing radioactive material for shipment or transporting radioactive material shall be subject to the provisions of 10 CFR Part 71 as applicable to the shipment and mode of transportation. Notwithstanding Rule .0117(a)(2)(J) of this Chapter, 10 CFR 71.85(a) through (c), and 71.91(b) are excluded from incorporation by reference.

(e) Notifications required by 10 CFR 71.97 and 10 CFR 73.37(b)(2) shall be made to the Governor's designee as follows:

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

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

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

(f) Transportation of special nuclear material by aircraft shall be prohibited in accordance with 10 CFR 150.21.

(g) Notifications of incidents, accidents, or the loss of control of radioactive material while in transit or while being stored for transportation shall be made to the agency in accordance with Rule .0357 of this Section. Notification of the theft, or loss of radioactive material while in transit, or while being stored for transportation shall be made to the agency in accordance with Rule .1645 of this Chapter.

(h) 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) Except for persons exempt from these Rules, a general license is hereby issued to any common, contract or other carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident thereto; provided the transportation and storage is in accordance with the applicable requirements of the regulations appropriate to the mode of transport of the U.S. Department of Transportation in 49 CFR Part 170-189 and the U.S. Postal Service in the Postal Service Manual, (Domestic Mail Manual), Section 124.3; insofar as, such regulations relate to the packaging of radioactive material, marking and labeling of the package, loading and storage of packages, placarding of the transportation vehicle, monitoring requirements and accident reporting. Any common, contract or other carrier transporting nuclear waste or spent nuclear fuel under this general license shall comply with the provisions in Paragraph (c) of this Rule. Persons who transport and store radioactive material pursuant to the general license in this Paragraph are exempt from the requirements of Sections .1000 and .1600 of this Chapter.~~

~~(b) Except for persons exempt from these Rules, a general license is hereby issued to any private carrier to transport radioactive material; provided, the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport of the U.S. Department of Transportation in 49 CFR Part 170-189 and the U.S. Postal Service in the Postal Service Manual, (Domestic Mail Manual), Section 124.3; insofar as, such regulations relate to the packaging, loading and storage of packages, placarding of the transportation vehicle, monitoring~~

~~requirements and accident reporting. The following exemptions and requirements shall apply to transportation of radioactive material under this general license:~~

~~(1) Persons who transport radioactive material pursuant to the license in Paragraph (b) of this Rule are exempt from the requirements in Sections .1000 and .1600 of this Chapter to the extent that they transport radioactive material. Any notification of incidents referred to in those requirements shall be filed with, or made to, the agency.~~

~~(2) Physicians, as defined in Rule .0104 of this Chapter, are exempt from the requirements in Paragraph (b) of this Rule to the extent that they transport in their private vehicle radioactive material for use in the practice of medicine.~~

~~(3) Any person who transports nuclear waste within or through this state under this general license shall comply with the provisions in Paragraph (c) of this Rule.~~

~~(c) No carrier shall transport within or through this state any nuclear waste or spent nuclear fuel unless the shipper has notified the "governor's designee" in accordance with the requirements of 10 CFR Part 71.97 for nuclear waste and 10 CFR 73.37(f) for spent nuclear fuel. The governor's designee and contact information is as follows:~~

~~(1) designee: N.C. Highway Patrol Headquarters, Operations Officer;~~

~~(2) mailing address: P.O. Box 27687, Raleigh, North Carolina 27611-7687;~~

~~(3) telephone 919/733-4030 from 8 a.m. to 5 p.m. workdays and 919/733-3861 all other times.~~

~~(d) As used in Paragraphs (a) through (c) of this Rule:~~

~~(1) "Shipment" means any single vehicle carrying one or more containers of nuclear waste.~~

~~(2) "Nuclear Waste" means:~~

~~(A) any quantity of radioactive material required by 10 CFR Part 71 to be in Type B packaging or subject to advance notification requirements of 10 CFR §§ 71.97 while transported within or through this state to a disposal site, or to a collection point for transport to a disposal site; or~~

~~(B) any quantity of irradiated fuel required by 10 CFR Part 71 to be in Type B packaging while transported within or through this state irrespective of destination if the quantity of irradiated fuel is less than that subject to advance notification requirements of 10 CFR Part 73.~~

~~(3) "Spent Nuclear Fuel" means a quantity of irradiated reactor fuel in excess of 100 grams in net weight of irradiated fuel exclusive of cladding or other structural or packaging material which has a total external radiation dose rate in excess of 100 rems per hour at a distance of three feet from any accessible surface without intervening shielding.~~

History Note: *Authority G.S. 20-167.1; 104E-7; 104E-10(b); 104E-15(a); 150B-21.6;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; May 1, 1992; October 1, 1982;
Transferred and Recodified from 15A NCAC 11 .0316 Eff. February 1, ~~2015.~~ 2015;

Amended Eff. March 1, 2017.

10A NCAC 15 .0317 is proposed for amendment as follows:

10A NCAC 15 .0317 SPECIFIC LICENSES: FILING APPLICATION AND GENERAL REQUIREMENT

(a) Applications for specific licenses shall be filed on an agency form in accordance with G.S. 104E-10(b) in lieu of NRC Form 313, and shall meet the requirements of 10 CFR 30.32, 30.37, or 30.38 as applicable for the type of licensing action, except that:

(1) 10 CFR 30.32(e), 35.18(a)(2), the portions of 36.11 and 39.11 pertaining to payment of fees, 40.31(e), 61.20(c) and 70.21(e) are not incorporated by reference;

(2) the agency may require an applicant to submit an environmental impact statement to the agency in accordance with Rule .0108 of this Chapter in lieu of the requirements of 10 CFR 30.32(f), 40.31(f), 40.32(e), 61.10, or 70.23(a); and

(3) applications for activities listed in 10 CFR 150.7 or excepted activities listed in 10 CFR 150.10 shall be filed on NRC Form 313 and submitted to the U.S. Nuclear Regulatory Commission at the address shown in 10 CFR 150.4 in lieu of the agency.

(b) In addition to Paragraph (a) of this Rule, applications for a specific license to:

(1) manufacture items containing exempt quantities of radioactive material or to manufacture exempt quantities of radioactive material that is not incorporated into a manufactured item shall meet the applicable requirements of 10 CFR Part 32, Subpart A;

(2) manufacture or initially transfer generally licensed devices containing byproduct material shall meet the applicable requirements of 10 CFR Part 32, Subpart B;

(3) manufacture radioactive drugs, sources, or devices not containing exempt quantities of radioactive material for medical use shall meet the applicable requirements of 10 CFR Part 32, Subpart C;

(4) conduct broad scope activities shall meet the requirements of 10 CFR 33.12 and 33.16, as applicable to licensed activities. Broad scope medical licensees meeting the criteria of 10 CFR 33.13(a) shall be exempt from certain licensing and regulatory requirements as specified in 10 CFR 35.15. 10 CFR 33.11 is not incorporated by reference;

(5) perform industrial radiography shall meet the requirements of 10 CFR 34.11;

(6) administer radioactive material or radiation from a licensed source to humans for medical use when a license is required by 10 CFR 35.11 shall meet the requirements of 10 CFR 35.12 and 35.13, as applicable to licensed activities. Notifications required by 10 CFR 35.14 shall be sent to the agency at the address shown in Rule .0111 of this Chapter;

(7) irradiate material using gamma radiation from sealed sources in facilities listed in 10 CFR 36.1(b) shall meet the requirements of 10 CFR 36.1;

(8) conduct well logging activities shall meet the requirements of 10 CFR 39.11;

(9) possess, use, or transfer source material shall meet the requirements of 10 CFR 40.31;

(10) dispose of radioactive waste received from another person shall meet the requirements of Section .1200 of this Chapter;

(11) receive, possess, or use special nuclear material shall meet the requirements of 10 CFR 70.22(a), 70.22(d), and 70.22(e), 70.33, or 70.34 as applicable to licensed activities; or

(12) manufacture or initially transfer calibration or reference sources containing plutonium to persons generally licensed under Rule .0312 of this Section shall meet the requirements of 10 CFR 70.39.

(c) Applications for sealed source and device registration certification, amendment of sealed source and device registration certificates, and inactivation of previously issued sealed source and device registration certificates shall comply with the provisions of 10 CFR Part 32, Subpart D.

(d) Completed applications shall be sent to the agency at the address shown in Rule .0111 of this Chapter.

(e) 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) Applications for specific licenses shall be filed on an agency form. Completed applications shall include the following information and other information necessary for the agency to determine if the applicant meets the requirements for that license:~~

~~(1) name, address and use location of the applicant;~~

~~(2) training and experience of radioactive material users and of the person responsible for radiation protection;~~

~~(3) types, quantities and uses of radioactive materials;~~

~~(4) description of facilities, equipment and safety program;~~

~~(5) procedures for disposal of radioactive material; and~~

~~(6) how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practical, the generation of radioactive waste.~~

~~(b) The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.~~

~~(c) Each application shall be signed by the applicant or licensee or a person authorized to act on his behalf.~~

~~(d) An application for a license may include a request for a license authorizing one or more activities.~~

~~(e) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must:~~

~~(1) identify the source or device by manufacturer and model number as registered with the US Nuclear Regulatory Commission under 10 CFR 32.210, with an Agreement State. A source or device~~

~~containing radium-226 or accelerator-produced radioactive material must identify the manufacturer and model number if registered with a state under provisions comparable to 10 CFR 32.210;~~

~~(2) contain the information identified in 10 CFR 32.210(c); or~~

~~(3) for sources or devices containing naturally occurring or accelerator-produced radioactive material manufactured prior to November 30, 2007 that are not registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the applicant must provide:~~

~~(A) all available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and~~

~~(B) sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.~~

~~(f) Applications and documents submitted to the agency shall be made available for public inspection except as are determined otherwise by the agency pursuant to the provisions of G.S. 104E-9(4).~~

~~(g) A license application shall be approved if the agency determines that:~~

~~(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules in such a manner as to minimize danger to public health and safety or property;~~

~~(2) the applicant's proposed equipment, facilities, and procedures are adequate to protect public health from radiation hazards and minimize radiological danger to life or property;~~

~~(3) the issuance of the license will not be inimical to the health and safety of the public; and~~

~~(4) the applicant satisfies any applicable special requirements in Rules .0318 to .0336 of this Section.~~

~~(h) If required by Rule .0353 of this Section, applications for specific licenses filed under this Section must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.~~

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-12; 104E-18;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; April 1, 1999; May 1, 1992; November 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0317 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. August 1, 2016.

10A NCAC 15 .0327 is proposed for amendment as follows:

10A NCAC 15 .0327 SPECIFIC LICENSES: EXEMPT GAS AND AEROSOL DETECTORS

An application for a specific license authorizing the manufacture and initial distribution of devices containing byproduct material to persons exempt from licensing under Rule .0305(c) of this Section shall comply with the provisions of Rule .0317(a), (b)(1), (c), and (d) of this Section as applicable to licensed activities.

~~An application for a specific license authorizing the incorporation of radioactive material other than source material into gas and aerosol detectors to be distributed to persons exempt under Rule .0305(d) of this Section will be approved if the application satisfies requirements contained in Section 32.26 of 10 CFR Part 32 for source and byproduct material.~~

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0327 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0328 is proposed for amendment as follows:

10A NCAC 15 .0328 SPECIFIC LICENSES: MANUFACTURE DEVICES TO PERSONS LICENSED

An application for a specific license authorizing the manufacture and initial transfer of devices containing byproduct material to persons generally licensed under Rule .0309 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to licensed activities.

~~(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Rule .0309 of this Section or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state shall be approved if:~~

~~(1) the applicant satisfies the general requirements of Rule .0317 of this Section;~~

~~(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:~~

~~(A) the device can be safely operated by persons not having training in radiological protection;~~

~~(B) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar year a dose in excess of 10 percent of the limits specified in the table of Rule .1604 of this Chapter; and~~

~~(C) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:~~

(i) whole body, head and trunk, active blood-forming organs, gonads, or lens of eye: 15 rems;

(ii) hands and forearms, feet and ankles, localized areas of skin averaged over areas no larger than one square centimeter: 200 rems; or

(iii) other organs: 50 rems; and

(3) each device bears a durable, legible, visible label or labels approved by the agency, which contain in a clearly visible and separate statement:

(A) instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(B) the requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(C) the information called for in the following statement in the same or substantially similar form: "The receipt, possession, use, and transfer of this device Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited."

"CAUTION—RADIOACTIVE MATERIAL

(name of manufacturer or distributor)"

The model, serial number, and name of manufacturer or distributor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) If the applicant desires that the device be tested at intervals longer than six months, either for proper operation of any on-off mechanism and indicator, or for leakage of radioactive material, he or she shall include in his or her application sufficient information to demonstrate that a longer interval is justified by performance characteristics of the device or similar devices and by design features which have a bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency shall consider information which includes:

(1) primary containment (source capsule);

(2) protection of primary containment;

(3) method of sealing containment;

(4) containment construction materials;

(5) form of contained radioactive material;

(6) maximum temperature withstood during prototype test;

(7) maximum pressure withstood during prototype tests;

(8) maximum quantity of contained radioactive material;

(9) radiotoxicity of contained radioactive material; and

(10) the applicant's operating experience with identical devices or similarly designed and constructed devices.

(c) If the applicant desires that the general licensee under Rule .0309 of this Section, or under equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state, be authorized to install the device, collect the sample for analysis by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, he or she shall include in his or her application:

(1) Written instructions for each activity to be followed by the general licensee;

(2) Estimated calendar year doses associated with the activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license; and

(3) information to demonstrate that performance of the activity or activities is unlikely to cause that individual to receive a calendar year dose in excess of 10 percent of the limits specified in Rule .1604 of this Chapter.

(d) Each person licensed under this Rule to distribute devices shall furnish a copy of the general license contained in Section 31.5 of 10 CFR Part 31 to each person to whom he or she directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Rule .0309 of this Section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The copy of Section 31.5 of 10 CFR Part 31 shall be accompanied by a note explaining that the use of the device is regulated by agreement states under requirements substantially the same as those in Section 31.5 of 10 CFR Part 31. Alternatively, when transferring the devices to persons in a specific agreement state, a copy of that agreement state's equivalent regulations shall be furnished by the licensee.

(e) Each person licensed under this Rule to distribute devices shall report to the agencies specified in Subparagraphs (e)(1), (2) and (3) of this Rule all transfers of the devices to persons generally licensed under the rules of those agencies. The reports shall cover each calendar quarter and shall be filed within 30 days thereafter. If no transfers have been made to generally licensed persons during the reporting period, the reports shall so indicate. Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a contact with the general licensee, the type and model number of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will possess the device at the intended place of use prior to its possession by the user, the reports shall include identification of each intermediate person by name, address, contact and relationship to the intended user. The reports shall be submitted to:

(1) the agency for devices transferred to persons generally licensed under Rule .0309 of this Section;

~~(2) each agreement state for devices transferred to persons generally licensed under rules equivalent to Rule .0309 of this Section; and~~

~~(3) the U.S. Nuclear Regulatory Commission for devices transferred to persons generally licensed under Section 31.5 of 10 CFR Part 31.~~

~~(f) Each person licensed under this Rule to distribute devices shall maintain for agency inspection either copies of all reports required in Paragraph (e) of this Rule or a record containing the same information. Such copies or records of transfer shall be maintained for at least five years after the date of each transfer of a device to a generally licensed person.~~

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0328 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0329 is proposed for amendment as follows:

10A NCAC 15 .0329 SPECIFIC LICENSES: LUMINOUS SAFETY DEVICES IN AIRCRAFT

An application for a specific license authorizing the manufacture, assembly, repair, and initial transfer devices containing byproduct material to persons generally licensed under Rule .0311 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to licensed activities.

~~An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under Rule .0311 of this Section will be approved subject to the following conditions:~~

~~(1) the applicant satisfies the general requirements specified in Rule .0317 of this Section; and~~

~~(2) the applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32 or their equivalent.~~

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0329 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0330 is proposed for amendment as follows:

10A NCAC 15 .0330 SPECIFIC LICENSES: MANUFACTURE OF CALIBRATION SOURCES

An application for a specific license authorizing the manufacture and initial transfer of calibration or reference sources for distribution to persons generally licensed under Rule .0312 of this Section shall comply with the provisions of:

(1) Rule .0317(a), (c), and (d) of this Section;

(2) Rule .0317(b)(2) of this Section for calibration or reference sources containing byproduct material; and

(3) Rule .0317(b)(12) of this Section for calibration or reference sources containing plutonium.

~~An application for a specific license to manufacture calibration sources containing americium-241 and plutonium for distribution to persons generally licensed under Rule .0312 of this Section will be approved subject to the following conditions:~~

~~(1) the applicant satisfies the general requirements of Rule .0317 of this Section; and~~

~~(2) the applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, 32.60 and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.~~

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0330 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0331 is proposed for amendment as follows:

10A NCAC 15 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS

An application for a specific license authorizing the manufacture and initial transfer of devices containing byproduct material to persons generally licensed under Rule .0314 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to licensed activities.

~~An application for a specific license to manufacture or distribute radioactive material for use under the general license in Rule .0314 of this Section shall be approved if all of the following requirements are satisfied:~~

~~(1) The applicant satisfies the general requirements specified in Rule .0317 of this Section.~~

~~(2) The radioactive material is to be prepared for distribution in prepackaged units of:~~

~~(a) iodine-125 in units not exceeding 10 microcuries each;~~

~~(b) iodine-131 in units not exceeding 10 microcuries each;~~

~~(c) carbon-14 in units not exceeding 10 microcuries each;~~

~~(d) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;~~

~~(e) iron-59 in units not to exceed 20 microcuries each;~~

~~(f) cobalt-57 in units not to exceed 10 microcuries each;~~

~~(g) selenium-75 in units not exceeding 10 microcuries each; or~~

~~(h) mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.~~

~~(3) Each prepackaged unit bears a durable, visible label:~~

~~(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed the appropriate limit in Item (2) of this Rule; and~~

~~(b) displaying the radiation caution symbol described in Rule .1623 of this Chapter and the words, "CAUTION, RADIOACTIVE MATERIAL," and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS."~~

~~(4) The following statement, or a statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:~~

~~This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or a state with which the Commission has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer.)~~

~~(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Rule .1628 of this Chapter.~~

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0331 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0332 is proposed for amendment as follows:

10A NCAC 15 .0332 SPECIFIC LICENSES: MANUFACTURE OF ICE ~~DETECTOR~~ DETECTION DEVICES

An application for a specific license authorizing the manufacture and initial transfer of generally licensed ice detection devices for transfer to a person generally licensed under Rule .0315 of this Section shall comply with the provisions of Rule .0317(a), (b)(2), (c), and (d) of this Section as applicable to licensed activities.

~~An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Rule .0315 of this Section will be approved subject to the following conditions:~~

~~(1) the applicant satisfies the general requirements of Rule .0317 of this Section, and~~

~~(2) the applicant satisfies the requirements of Sections 32.61, 32.62, 32.63 and 32.103 of 10 CFR Part 32 or their equivalent.~~

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Transferred and Recodified from 15A NCAC 11 .0332 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0335 is proposed for amendment as follows:

10A NCAC 15 .0335 SPECIFIC LICENSES: PRODUCTS CONTAINING DEPLETED URANIUM

An application for a specific license authorizing the manufacture and initial transfer of products containing depleted uranium to persons generally licensed under Rule .0307(b) of this Section, shall comply with the provisions of Rule .0317(a), (b)(9), (c), and (d) of this Section as applicable to licensed activities.

~~(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Rule .0307(e) of this Section or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:~~

~~(1) the applicant satisfies the general requirements specified in Rule .0317 of this Section;~~

~~(2) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of ten percent of the limits specified in Rule .1604 of this Chapter; and~~

~~(3) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.~~

~~(b) In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under this Rule only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.~~

~~(c) The agency may deny any application for a specific license under this Rule if the end use(s) of the industrial product or device cannot be reasonably foreseen.~~

~~(d) Each person licensed pursuant to Paragraph (a) of this Rule shall:~~

~~(1) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;~~

~~(2) label or mark each unit to:~~

~~(A) identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and~~

~~(B) state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an agreement state;~~

~~(3) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium".~~

~~(e) Each person, licensed under this Rule to distribute devices, shall furnish a copy of the general license contained in Section 40.25 of 10 CFR Part 40 to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in Rule .0307(e) of this Section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The copy of Section 40.25 of 10 CFR Part 40 shall be accompanied by a note explaining that the use of the device is regulated by agreement states under requirements substantially the same as those in Section 40.25 of 10 CFR Part 40. Alternatively, when transferring the devices to persons in a specific agreement state, a copy of that agreement state equivalent regulations shall be furnished.~~

~~(f) Each person, licensed under this Rule to distribute devices, shall report to the agencies specified in Subparagraphs (f)(1),(2) and (3) of this Rule all transfers of the devices to persons generally licensed under the rules of those agencies. Such reports shall identify each general licensee by name and address, an individual by name or position who may constitute a contact with the general licensee, the type and model number of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the reports shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to generally licensed persons during the reporting period, the reports shall so indicate. The reports shall cover each calendar quarter and shall be filed within 30 days thereafter. The reports shall be submitted to:~~

~~(1) the agency for devices transferred to persons generally licensed under Rule .0307(e) of this Section;~~

~~(2) each agreement state for devices transferred to persons generally licensed under rules equivalent to Rule .0307(e) of this Section; and~~

~~(3) the U.S. Nuclear Regulatory Commission for devices transferred to persons generally licensed under Section 40.25 of 10 CFR Part 40.~~

~~(g) Each person, licensed under this Rule to distribute devices, shall maintain for agency inspection either copies of all reports required in Paragraph (f) of this Rule or a record containing substantially the same information. Such copies or records of transfer shall be maintained for at least five years after the date of each transfer of a device to a generally licensed person.~~

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 .0335 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0337 is proposed for amendment as follows:

10A NCAC 15 .0337 ISSUANCE OF SPECIFIC LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES

(a) An application for a specific license shall be approved, and a specific license issued, or amended by the agency if the agency determines that the applicant satisfies the provisions of 10 CFR 30.33(a)(1) through (4), 30.39, 40.32(a) through (f), and 70.23(a)(1) through (6) as applicable to licensed activities, and any additional requirements in:

(1) 10 CFR 32.11, 32.14, 32.18, 32.21, 32.22, 32.26, and 32.30 as applicable to the manufacture of exempt concentrations of byproduct material, and items containing exempt concentrations of byproduct material listed in 10 CFR Part 32, Subpart A;

(2) 10 CFR 32.51, 32.53, 32.57, 32.61, and 32.71 as applicable to the manufacturing and distribution of generally licensed items and devices listed in 10 CFR Part 32, Subpart B;

(3) 10 CFR 32.72 and 32.74 as applicable to the manufacturing and distribution of radioactive drugs, sources, or devices listed in 10 CFR Part 32, Subpart C;

(4) 10 CFR 33.13 through 33.15, and 33.17 as applicable to activities of broad scope;

(5) 10 CFR 34.13 for industrial radiography;

(6) 10 CFR 35.18 for the medical use of radioactive materials;

(7) 10 CFR 36.13 for the use of sealed sources to irradiate materials;

(8) 10 CFR 39.13, 39.15, and 39.17 for the use of radioactive materials in well logging;

(9) 10 CFR 40.34 for the use of source material in the manufacture and initial transfer of devices containing depleted uranium to a person generally licensed under Rule .0307(b) of this Section;

(10) 10 CFR 40.52 for the use of source material in the manufacture of exempt devices listed in Rule .0305 of this Section;

(11) 10 CFR 40.54 for the initial transfer of source material to a person generally licensed under .0307(a) of this Section;

(12) 10 CFR 61.23(a) through (h), and (k), and Section .1200 of this Chapter for the receipt, possession, transfer, or disposal of radioactive waste received from another person; and

(13) 10 CFR 70.31(a) and (b) for the use of special nuclear material.

(b) An application for a new or amended Sealed Source and Device Registration certificate shall be approved by the agency, and a new or amended Sealed Source and Device Registration certificate issued in accordance with 10 CFR 32.210(d) and (e).

(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) Upon a determination that an application meets the requirements of the Act and the rules of this Section, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.~~

~~(b) The agency may amend any license, when not in conflict with any law, to waive any requirement in these Rules or to impose additional requirements in accordance with 46 FR 7540, with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to the rules in this Chapter as it deems appropriate or necessary in order to:~~

~~(1) minimize danger to public health and safety or property;~~

~~(2) require such reports and the keeping of such records, and provide for such inspections of activities under the license as may be appropriate or necessary; and~~

~~(3) prevent loss or theft of radioactive material subject to this Section.~~

History Note: *Authority G.S. 104E-7; 104E-10(b); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0337 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0338 is proposed for amendment as follows:

10A NCAC 15 .0338 SPECIFIC TERMS AND CONDITIONS OF LICENSES

(a) All licenses issued by the agency for activities authorized under the Rules of this Section are subject to the terms and conditions listed in 10 CFR 30.34(a) through (d), and 30.34(e)(2) through (j)(4). In addition to these terms and conditions, licenses of broad scope are subject to the terms and conditions listed in 10 CFR 33.17.

(b) All licenses issued by the agency authorizing the possession and use of source material are subject to the terms and conditions listed in in 10 CFR 40.35, 40.41, 40.46, 40.53, 40.55, and 40.56.

(c) All licenses issued by the agency authorizing the receipt, possession, or disposal of radioactive waste received from another person are subject to the terms and conditions listed in 10 CFR 61.24, 61.25, and the Rules in Section .1200 of this Chapter.

(d) All licenses issued by the agency authorizing the possession and use of special nuclear material are subject to the terms and conditions of 10 CFR 70.32.

(e) 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) Each person licensed by the agency pursuant to this Section shall confine his or her use and possession of the radioactive material licensed to the locations and purposes authorized in the license.~~

~~(b) Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:~~

~~(1) the licensee;~~

~~(2) an entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the license or licensee as property of the estate; or~~

~~(3) an affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.~~

~~(c) The notification in Paragraph (b) of this Rule shall indicate:~~

~~(1) the bankruptcy court in which the petition for bankruptcy was filed; and~~

~~(2) the date of the filing of the petition.~~

~~(d) Licensees required to submit emergency plans pursuant to Rule .0352 of this Section shall follow the emergency plan approved by the agency. The licensees may change the approved plan without prior agency approval only if the licensee believes the changes do not decrease the effectiveness of the plan and are submitted to the agency no later than 20 calendar days after the changes are made. The licensee shall furnish the change to affected off-site response organizations within six months after the change is made. Proposed changes that the licensee believes are likely to decrease, or may potentially decrease, the effectiveness of the approved emergency plan shall not be implemented without prior application to and approval by the agency.~~

~~(e) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule .0361 of this Section. The licensee shall record the results of each test and retain each record for three years after the record is made.~~

~~(f) Each portable nuclear gauge licensee shall use at least two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever portable gauges are not under the control and constant surveillance of the licensee.~~

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; May 1, 1993; May 1, 1992; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0338 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0343 is proposed for amendment as follows:

10A NCAC 15 .0343 TRANSFER OF MATERIAL

(a) Any person licensed under the Rules of this Section transferring byproduct material shall comply with the provisions of 10 CFR 30.41.

(b) Any person licensed under the Rules of this Section transferring source material shall comply with the provisions of 10 CFR 40.51.

(c) Any person licensed under the Rules of this Section transferring special nuclear material shall comply with the provisions of 10 CFR 70.42.

(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) No licensee shall transfer radioactive material except as authorized pursuant to this Section.~~

~~(b) Except as otherwise provided in his license and subject to the provisions of Paragraphs (c), (d) and (e) of this Rule any licensee may transfer radioactive material to:~~

- ~~(1) the agency;~~
- ~~(2) the U.S. Department of Energy;~~
- ~~(3) any person exempt from the rules in this Section to the extent permitted under the exemption;~~
- ~~(4) any person authorized to receive the radioactive material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state, or any person otherwise authorized to receive the radioactive material by the federal government or any agency thereof, the agency, or an agreement state; or~~
- ~~(5) as otherwise authorized by the agency in writing.~~

~~(c) A licensee may transfer material to the agency only after receiving prior approval from the agency.~~

~~(d) Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, or an agreement state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, or an agreement state prior to receipt of the radioactive material, the licensee~~

~~transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.~~

~~(e) The following methods for the verification required by Paragraph (d) of this Rule are acceptable:~~

~~(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;~~

~~(2) The transferor may have in his possession a written certificate by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;~~

~~(3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided the oral certification is confirmed in writing within 10 days after the date of the oral certification;~~

~~(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an agreement state as to the identity of licensees and the scope and expiration dates of licenses and registration; or~~

~~(5) When none of the methods of verification described in this Rule are readily available or when a transferor desires to verify that information received by one of the methods is correct or updated, the transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an agreement state that the transferee is licensed to receive the radioactive material.~~

~~(f) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Rule .0346 of this Section.~~

History Note: *Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
Authority G.S. 104E-7; 104E-10(b);
Eff. February 1, 1980;
Amended Eff. May 1, 1995; May 1, 1993; June 1, 1989;
Transferred and Recodified from 15A NCAC 11 .0343 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0344 is proposed for amendment as follows:

10A NCAC 15 .0344 MODIFICATION: REVOCATION: AND TERMINATION OF LICENSES AND SEALED SOURCE AND DEVICE REGISTRATION CERTIFICATES

(a) All licenses authorizing the receipt, possession, use, and transfer of byproduct material, and all sealed source and device registration certificates issued by the agency under the Rules of this Section, are subject to modification by the agency in accordance with 10 CFR 30.61.

(b) All licenses issued by the agency for the receipt, possession, use, and transfer of source material under the Rules of this Section, are subject to modification by the agency in accordance with 10 CFR 40.71.

(c) All licenses issued by the agency for the receipt, possession, transfer, or disposal of radioactive waste from another person are subject to modification by the agency in accordance with the provisions of 10 CFR 61.24.

(d) All licenses issued by the agency for the receipt, possession, use, and transfer of special nuclear material are subject to modification by the agency in accordance with 10 CFR 70.81.

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

- ~~(1) amendments to the Act,~~
- ~~(2) rules adopted pursuant to provisions of the Act, or~~
- ~~(3) orders issued by the agency pursuant to provisions of the Act and rules adopted pursuant to provisions of the Act.~~

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

- ~~(1) for any material false statement in the application or in any statement of fact required by provisions of this Section;~~
- ~~(2) because of conditions which would warrant the agency to refuse to grant a license or an original application revealed by:~~
  - ~~(A) the application;~~
  - ~~(B) any statement of fact;~~
  - ~~(C) any report, record, inspection or other means; or~~
- ~~(3) for violation of, or failure to observe any of the terms and conditions of the Act, the license, the rules of this Chapter, or order of the agency.~~

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

- ~~(1) call to the attention of the licensee in writing the facts or conduct which may warrant these actions, and~~
- ~~(2) provide an opportunity for the licensee to demonstrate or achieve compliance with all lawful requirements.~~

~~(d) The agency may terminate a specific license upon request submitted by the licensee to the agency in writing.~~

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-13;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0344 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0353 is proposed for amendment as follows:

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

(a) Applications for a new license filed with the agency under Rule .0317 of this Section, and applications for the renewal of a license filed with the agency under Rule .0340 of this Section, shall include an evaluation of the need for financial assurance based upon the quantity of radioactive material requested in the application.

(b) Applications for amendment of a license filed with the agency under Rule .0341 of this Section, changing the quantity of radioactive material authorized for possession by a licensee, shall include an evaluation of the need for financial assurance based upon the quantity of radioactive material that shall be authorized by the amended license.

(c) Evaluation of the need for financial assurance shall be performed by the applicant based upon the type of application listed in Paragraph (a) or (b) of this Rule, using one or more the methods shown in Paragraph (d) of this Rule.

(d) Applicants shall require financial assurance to possess the following types and quantities of radioactive material:

(1) byproduct material in the quantities shown in 10 CFR 30.35(a) or (b);

(2) source material in the quantities shown in 10 CFR 40.36(a) or (b); and

(3) special nuclear material in the quantities shown in 10 CFR 70.25(a)(2) or (b).

(e) Applicants requiring financial assurance shall:

(1) comply with the provisions of 10 CFR 30.35(c) for the possession of byproduct material;

(2) comply with the provisions of 10 CFR 40.36(c) for the possession of source material; and

(3) comply with the provisions of 10 CFR 70.25(c) for the possession of special nuclear material.

(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) For the purposes of this Rule, R is defined as the sum of the ratios of the quantity of each isotope with half-life greater than 120 days to the applicable value in the table in Appendix C to 10 CFR §§ 20.1001 – 20.2401, as shown in the following formula:~~

$$R = \sum_{1}^{n} \left(\frac{\text{Possession limit of Isotope 1}}{\text{Appendix C value for Isotope 1}} + \frac{\text{Possession limit of Isotope 2}}{\text{Appendix C value for Isotope 2}} \cdots + \frac{\text{Possession limit of Isotope } n}{\text{Appendix C value for Isotope } n} \right)$$

(b) For unsealed radioactive materials, other than source material, the quantities requiring financial assurance and the financial assurance amounts are as follows:

(1) If R divided by 10^5 is greater than one, then the minimum financial assurance amount is one million one hundred twenty-five thousand dollars ($1,125,000) and shall be as stated in a decommissioning funding plan as described in Paragraph (i) of this Rule;

(2) If R divided by 10^4 is greater than one, but R divided by 10^5 is less than or equal to one, then the financial assurance amount is one million one hundred twenty-five thousand dollars ($1,125,000); or

(3) If R divided by 10^3 is greater than one, but R divided by 10^4 is less than or equal to one, then the financial assurance amount is two hundred twenty-five thousand dollars ($225,000).

(c) For sealed radioactive materials, the quantities requiring financial assurance and the financial assurance amounts are as follows:

(1) If R divided by 10^{12} is greater than one, the licensee shall submit a decommissioning funding plan in accordance with Paragraph (i) of this Rule; or

(2) If R divided by 10^{10} is greater than one, but R divided by 10^{12} is less than or equal to one, then the financial assurance amount is one hundred thirteen thousand dollars ($113,000).

(d) For source material in a readily dispersible form, the quantities requiring financial assurance and the financial assurance amounts are as follows:

(1) If a specific license authorizes possession and use of more than 100 millicuries, then the minimum financial assurance amount is one million one hundred twenty-five thousand dollars ($1,125,000) and shall be as stated in a decommissioning funding plan as described in Paragraph (i) of this Rule; or

(2) If a specific license authorizes possession and use of more than 10 millicuries, but less than or equal to 100 millicuries, then the licensee shall either:

(a) submit a decommissioning funding plan in accordance with Paragraph (i) of this Rule; or

(b) submit certification of financial assurance in the amount of two hundred twenty five thousand dollars ($225,000).

(e) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Paragraphs (b) or (c) or source material in quantities specified in Paragraph (d) of this Rule shall either:

(1) submit a decommissioning funding plan as described in Paragraph (i) of this Rule; or

(2) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Paragraphs (b) through (d) of this Rule using one of the methods described in Rule .0354 of this Section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt

of licensed material. As part of the certification, the applicant shall submit to this agency, a copy of the financial instrument obtained to satisfy the requirements of Paragraph (i) of this Rule.

(f) Each holder of a specific license issued before the effective date of this Rule, and of a type described in Paragraphs (b)(1), (b)(2), (c)(1), or (d)(1) of this Rule shall submit, no later than May 1, 2007, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this Rule.

(g) Each holder of a specific license issued before the effective date of this Rule, and of a type described in Paragraphs (b)(3), (c)(2) or (d)(2) of this Rule shall submit, no later than November 1, 2007, a certification of financial assurance in accordance with the criteria set forth in this Rule.

(h) Each holder of a specific license issued on or after the effective date of this Rule, which is of a type described in Paragraphs (b) through (d) of this Rule, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this Rule.

(i) Each decommissioning funding plan shall contain a cost estimate for decommissioning and documentation of an approved method assuring funds for decommissioning as referenced in Rule .0354 of this Section, including means of adjusting cost estimates and associated funding levels at intervals not to exceed three years.

(j) Each person licensed under this Section of this Chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning includes:

(1) Records of spills or other occurrences involving the spread of contamination in and around the facility, equipment, or site.

(A) These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete.

(B) These records shall include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As built drawings and modifications of structures and equipment in restricted areas where radioactive materials are being used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination.

(A) If required drawings are referenced, each relevant document need not be indexed individually.

(B) If drawings are not available, the licensee shall substitute records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Except for areas containing only sealed sources (provided the sealed sources have not leaked or no contamination remains after cleanup of any leak) or radioactive materials having only half-lives of

~~less than 65 days, or depleted uranium used only for shielding, licensees shall be required to establish and maintain a list, contained in a single document. The list shall be updated every two years, and include the following information:~~

~~(A) All areas designated and formerly designated as restricted areas as defined in Rule .0104 of this Chapter;~~

~~(B) All areas outside of restricted areas that require documentation under Paragraph (j) of this Rule;~~

~~(C) All areas outside of restricted areas where current and previous wastes have been buried as documented in Rule .1642 of this Chapter; and~~

~~(D) All areas outside of restricted areas which contain material that, if the license expired, the licensee would be required to decontaminate either the area to unrestricted release levels or to apply to the agency for approval for disposal as required in Rule .1629 of this Chapter.~~

~~(k) Prior to license termination, each licensee authorized to possess radioactive material in an unsealed form, shall forward to the agency the records required in Paragraph (j) of this Rule.~~

~~(l) Before licensed activities are transferred, licensees shall transfer all records required in Paragraph (j) of this Rule. In this case, the new licensee shall maintain the records until the license is terminated.~~

History Note: *Authority G.S. 104E-7; 104E-18;*
Eff. May 1, 1992;
Amended Eff. May 1, 2006; April 1, 1999; August 1, 1998; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0353 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0354 is proposed for amendment as follows:

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

(a) Licensees or applicants for a radioactive materials license authorizing the use of:

(1) byproduct material shall provide for financial assurance in compliance with 10 CFR 30.35(f);

(2) source material shall provide for financial assurance in compliance with 10 CFR 40.36(e); and

(3) special nuclear material shall provide for financial assurance in compliance with 10 CFR 70.25(f).

(b) Licensees or applicants for a radioactive materials license authorizing the use of any combination of radioactive material listed in Paragraph (a) of this Rule, shall provide for financial assurance in accordance with the evaluation performed for Rule .0353(c) of this Section.

(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) Financial assurance for decommissioning as required by Rule .0353 of this Section must be provided by one or more of the following methods:~~

~~(1) prepayment, where:~~

~~(A) Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs; and~~

~~(B) Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.~~

~~(2) a surety method, insurance, or other guarantee method, where:~~

~~(A) These methods guarantee that decommissioning costs will be paid should the licensee default;~~

~~(B) A surety method may be in the form of a surety bond, letter of credit, or line of credit;~~

~~(C) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the parent company and guarantee meet the criteria contained in Rule .0355 of this Section;~~

~~(D) A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this Section; and~~

~~(E) Any surety method or insurance used to provide financial assurance for decommissioning shall contain the following conditions:~~

~~(i) The surety method or insurance shall be open-ended or, if written for a specified term, such as five years, shall be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew;~~

~~(ii) The surety method or insurance shall provide that the full face amount be paid to the beneficiary automatically prior to the expiration date without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation;~~

~~(iii) The surety method or insurance shall be payable to a trust established for decommissioning costs. The trustee and trust shall be acceptable to the agency. An acceptable trust includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency;~~

~~(iv) The surety method or insurance shall remain in effect until the agency has terminated the license.~~

~~(3) an external sinking fund where:~~

~~(A) Deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund;~~

~~(B) An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected;~~

~~(C) An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit or deposits of government securities; and~~

~~(D) The surety or insurance provisions shall be as stated in Subparagraph (a)(2) of this Rule.~~

~~(4) in the case of federal, state or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the provisions of Rule .0353 of this Section, and indicating that funds for decommissioning shall be obtained when required by the agency.~~

History Note: *Authority G.S. 104E-7; 104E-18;*
Eff. May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0354 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0355 is proposed for amendment as follows:

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

(a) Licensees or applicants for a radioactive materials license requiring financial assurance under Rule .0353 of this Section may self-guarantee funds, or provide a guarantee of funds by their parent company for decommissioning funding in accordance with the provisions of Rule .0354 of this Section, except that:

(1) parent companies guaranteeing funds for decommissioning shall have a tangible net worth of at least ten million dollars ($10,000,000) to meet the asset requirement set forth in in Section II, Paragraphs A.1(iii), or A.2(iii), of Appendix A to 10 CFR Part 30;

(2) licensees self-guaranteeing funds for decommissioning who issue bonds, and whose bonds meet the bond rating requirements of Section II, Paragraph A(3) of Appendix C to 10 CFR Part 30 shall have a tangible net worth of at least ten million dollars ($10,000,000), and at least six times the amount of decommissioning funds being assured by the self-guarantee to meet the asset requirements set forth in in Section II, Paragraph A.(2) and A.(3) of Appendix C to 10 CFR Part 30;

(3) licensees self-guaranteeing funds for decommissioning who do not issue bonds, or whose bonds do not meet the bond rating requirements of Section II, Paragraph A(3) of Appendix C to 10 CFR Part 30, shall have a tangible net worth of at least ten million dollars ($10,000,000), and at least six times

the amount of decommissioning funds being assured by the self-guarantee to meet the asset requirements set forth in in Section II, Paragraph A.(1) and A.(2) of Appendix D to 10 CFR Part 30;

(4) licensees self-guaranteeing funds for decommissioning who are nonprofit publicly funded colleges, universities, or hospitals shall meet the funding requirements set forth in 10 CFR 30.35(f)(4). For the purpose of this Rule, publicly funded trade schools, technical institutes, technical colleges, technical universities, or other publicly funded educational institutions are to be interpreted as "nonprofit publicly funded colleges;"

(5) licensees self-guaranteeing funds for decommissioning who are nonprofit privately funded, or nonprofit semi-privately funded colleges, or universities who do not issue bonds, or whose bonds do not meet the bond rating requirements of Section II, paragraph A.(1) of Appendix E to Part 30 shall have an unrestricted endowment consisting of assets worth of at least ten million dollars ($10,000,000), and at least six times the amount of decommissioning funds being assured by the self-guarantee to meet the asset requirements set forth in in Section II, Paragraph A.(2) of Appendix E to 10 CFR Part 30; or

(6) licensees self-guaranteeing funds for decommissioning who are nonprofit privately funded, or nonprofit semi-privately funded hospitals who do not issue bonds, or whose bonds do not meet the bond rating requirements of Section II, Paragraph B.(1) of Appendix E to 10 CFR Part 30 shall have a tangible net worth of at least ten million dollars ($10,000,000), and at least six times the amount of decommissioning funds being assured by the self-guarantee to meet the asset requirements set forth in in Section II, Paragraph B.(2) of Appendix E to 10 CFR Part 30.

(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) An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This Rule establishes criteria for passing the financial test and for obtaining the parent company guarantee.~~

~~(b) To pass the financial test, the parent company shall meet the criteria of either Subparagraph (b)(1) or (b)(2) of this Rule as follows:~~

~~(1) The parent company shall have:~~

~~(A) two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and~~

~~(B) net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and~~

(C) tangible net worth of at least ten million dollars ($10,000,000); and

(D) assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

(2) The parent company shall have:

(A) a current rating for its most recent bond issuance of AAA, AA, A or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's; and

(B) tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

(C) tangible net worth of at least ten million ($10,000,000); and

(D) assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

(c) The parent company's independent certified public accountant shall have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the agency within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(d) After the initial financial test, the parent company shall repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(e) If the parent company no longer meets the requirements of Paragraph (b) of this Rule, the licensee shall send notice to the agency of intent to establish alternate financial assurance as specified in this Section. The notice shall be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee shall provide alternate financial assurance within 120 days after the end of such fiscal year.

(f) The terms of a parent company guarantee which an applicant or licensee obtains shall provide that:

(1) the parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the agency. Cancellation shall not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the agency, as evidenced by the return receipts.

(2) if the licensee fails to provide alternate financial assurance as specified in this Section within 90 days after receipt by the licensee and the agency of a notice of cancellation of the parent company guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(g) The parent company guarantee and financial test provisions shall remain in effect until the agency has terminated the license.

~~(h) If a trust is established for decommissioning costs, the trustee and trust shall be acceptable to the agency. An acceptable trustee includes an appropriate state or federal agency or an entity to act as a trustee whose trust operations are regulated and examined by a federal or state agency.~~

History Note: *Authority G.S. 104E-7; 104E-18;*
Eff. May 1, 1992;
Transferred and Recodified from 15A NCAC 11 .0355 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0357 is proposed for amendment as follows:

10A NCAC 15 .0357 REPORTING REQUIREMENTS

(a) All reports required by this Rule shall be made to the agency in accordance with Rule .0111 of this Chapter.

(b) Reports of incidents involving exposure, or incidents threatening to cause exposure to radiation in excess of the annual occupational limits of Rule .1604 of this Chapter shall be made to the agency in accordance with the provisions of 10 CFR 20.2202.

(c) Reports of an event that prevents taking protective actions to avoid exposure to radiation or to radioactive material that could cause exposures in excess of the regulatory limits of this Chapter shall be made to the agency in accordance with the provisions of:

(1) 10 CFR 30.50 for licensees authorized for the possession and use of byproduct material;

(2) 10 CFR 40.60 for licensees authorized for the possession and use of source material; and

(3) 10 CFR 70.50 of this Chapter for licensees authorized for the possession and use of special nuclear material.

(d) Reports of exposure to radiation exceeding the exposure limits in Section .1600 of this Chapter, or to concentrations of radioactive material in any restricted or unrestricted area in excess of licensed or regulatory limits of 10 CFR Part 20.2203(a)(3) shall be made to the agency in accordance with 10 CFR 20.2203.

(e) Reports of incidents or events occurring at irradiation facilities licensed under the provisions of 10 CFR 36.1(b) shall be made to the agency in accordance with 10 CFR 36.83.

(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) Immediate report. Each licensee shall notify the agency as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to sources of radiation that could exceed regulatory limits or releases of licensed radioactive material that could exceed regulatory limits. These events include but are not limited to fires, explosions and toxic gas releases.~~

(b) Twenty-four hour report. Each licensee shall notify the agency within 24 hours after the discovery of any of the following events involving licensed radioactive material:

(1) an unplanned contamination event that:

(A) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(B) involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B to 10 CFR §§ 20.1001-20.2401 for the material; and

(C) causes the licensee to restrict access to the area for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination;

(2) an event in which equipment is disabled or fails to function as designed when:

(A) the equipment is required by rule or license condition to:

(i) prevent releases exceeding regulatory limits;

(ii) prevent exposures to sources of radiation exceeding regulatory limits; or

(iii) to mitigate the consequences of an accident;

(B) the equipment is required to be available and operable at the time that it is disabled or fails to function; and

(C) no redundant equipment is available and operable to perform the required safety function;

(3) an event that requires unplanned medical treatment at a medical facility of an individual with removable radioactive contamination on the individual's clothing or body; or

(4) an unplanned fire or explosion damaging any licensed material or any device, container or equipment containing licensed radioactive material when:

(A) the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B to 10 CFR §§ 20.1001-20.2401 for the material; and

(B) the damage affects the integrity of the licensed radioactive material or its container.

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this Rule shall be made as follows:

(1) Licensees shall make reports required by Paragraphs (a) and (b) of this Rule by telephone as specified in Rule .0111(b) of this Chapter. To the extent that the information is available at the time of notification, the information provided in these reports shall include:

(A) the caller's name and call back telephone number;

(B) a description of the event, including date and time;

(C) the exact location of the event;

(D) the isotopes, quantities, and chemical and physical form of the licensed radioactive material involved; and

(E) any personnel radiation exposure data available.

~~(2) Each licensee who makes a report required by Paragraph (a) or (b) of this Rule shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports shall be submitted to the agency as specified in Rule .0111(a) of this Chapter. The reports shall include the following:~~

~~(A) a description of the event, including the probable cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned;~~

~~(B) the exact location of the event;~~

~~(C) the isotopes, quantities and chemical and physical form of the licensed material involved;~~

~~(D) the date and time of the event;~~

~~(E) the corrective actions taken or planned and the result of any evaluations or assessments; and~~

~~(F) the extent of exposure of individuals to sources of radiation without identification of individuals by name.~~

History Note: *Authority G.S. 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;
Transferred and Recodified from 15A NCAC 11 .0357 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .0359 is proposed for amendment as follows:

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

(a) Licensees shall comply with the provisions of 10 CFR 35.63, except that dosage determination shall be made by direct measurement for all unsealed photon-emitting radioactive drugs prior to administration to any person. Licensees shall ensure that instruments used to measure dosages under this Rule are calibrated in accordance with the provisions of 10 CFR 35.60.

(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) A licensee shall possess and use a dose calibrator to measure the radioactivity of dosages of photon-emitting radionuclides prior to administration to each individual. A licensee shall:~~

~~(1) develop, maintain, and implement written procedures for use of the dose calibrator;~~

~~(2) calibrate each dose calibrator in accordance with the requirements of 10 CFR 35.60(b).~~

~~(b) A licensee shall retain a record of each check, test, and calibration performed in accordance with this Rule for a period of three years following the test.~~

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

10A NCAC 15 .0521 is proposed for amendment as follows:

10A NCAC 15 .0521 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT

(a) Equipment used in industrial radiographic operations shall meet the performance requirements of 10 CFR 34.20.

(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.

~~Equipment used in industrial radiographic operations shall meet the following minimum criteria:~~

~~(1) Each radiographic exposure device, source assembly or sealed source, and all associated equipment shall meet the requirements specified in American National Standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography". This publication is incorporated by reference in Rule .0117 of this Chapter.~~

~~(2) Engineering analysis may be submitted to the agency to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review by the agency, this may be an acceptable alternative to actual testing of the component pursuant to the above referenced standard.~~

~~(3) In addition to the requirements specified in Item (1) of this Rule, the following requirements apply to radiographic exposure devices, source changers, source assemblies, and sealed sources:~~

~~(a) Each radiographic exposure device shall have attached to it by the user a durable, legible, clearly visible label bearing the following:~~

~~(i) Chemical symbol and mass number of the radionuclide in the device;~~

~~(ii) Activity and the date on which this activity was last measured;~~

~~(iii) Model number (or product code) and serial number of the sealed source;~~

~~(iv) Manufacturer's identity of the sealed source; and~~

(v) Licensee's name, address, and telephone number.

(b) Radiographic exposure devices intended for use as Type B transport containers shall meet the applicable requirements of 10 CFR Part 71.

(c) Modification of radiographic exposure devices, source changers and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including sealed source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(4) In addition to the requirements specified in Items (1) and (3) of this Rule, the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the sealed source to be moved out of the device for radiographic operations or to source changers.

(a) The coupling between the source assembly and the control cable shall be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(b) The device shall automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system shall be designed to only allow release of the sealed source by means of a deliberate operation on the exposure device.

(c) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers which shall be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(d) Each sealed source or source assembly shall have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER--RADIOACTIVE." The label shall not interfere with the safe operation of the exposure device or associated equipment.

(e) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(f) Guide tubes shall be used when moving the sealed source out of the device.

(g) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube shall be attached to the outermost end of the guide tube during radiographic operations.

(h) The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432.

(i) Source changers shall provide a system for assuring that the sealed source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

~~(5) All associated equipment acquired after January 10, 1996 shall be labeled to identify that the components have met the requirements of this Rule.~~

History Note: *Filed as a Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;*
Authority G.S. 104E-7;
Eff. May 1, 1995;
Amended Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0521 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .1004 is proposed for amendment as follows:

10A NCAC 15 .1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS

(a) Licensees and registrants shall report radiation exposure data for any occupationally exposed person to that person or their designee in accordance with the provisions of 10 CFR 19.13, except that the report shall contain the following statement in lieu of the statement appearing in 19.13(a): "This report is furnished to you under the provisions of Section 10A NCAC 15 .1000: NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS. You should preserve this report for future reference."

(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) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of any individual shall be reported to the individual as specified in this Rule. The information reported shall include data and results obtained pursuant to rules of this Chapter, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to provisions of this Chapter. Each notification and report shall:~~

~~(1) be in writing;~~

~~(2) include identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's social security number;~~

~~(3) include the individual's exposure information; and~~

~~(4) contain the following statement: This report is furnished to you under the provisions of Section 15A NCAC 11 .1000: NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS. You should preserve this report for further reference.~~

~~(b) Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of Rule .1640 of this Chapter. The licensee or registrant shall provide an annual report to each individual monitored under Rule .1614 of this Chapter of the dose received in that monitoring year if:~~

~~(1) the individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or~~

~~(2) the individual requests his or her annual dose report.~~

~~(c) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's radiation dosage and exposure to radioactive materials. The report shall:~~

~~(1) be furnished within 30 days from the time any request is made, or within 30 days after the information has been obtained by the licensee or registrant, whichever is later;~~

~~(2) cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the agency; and~~

~~(3) include the dates and locations of work under the license or registration in which the worker participated during this period.~~

~~(d) When a licensee or registrant is required pursuant to Rules .1646, .1647, or .1648 of this Chapter to report to the agency any overexposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his or her exposure data included in the report to the agency. The reports shall be transmitted at a time no later than the transmittal to the agency.~~

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-12;*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .1004 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .1613 is proposed for amendment as follows:

10A NCAC 15 .1613 SURVEYS

(a) Licensees and registrants shall conduct surveys, and monitor for radiation and radiation exposure in accordance with the provisions of 10 CFR 20.1501.

(b) The exposure of individual monitoring devices, individual monitoring equipment, or personnel monitoring equipment to radiation from any source for the purpose of falsifying exposure records shall be prohibited.

(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) Each licensee or registrant shall make or cause to be made, surveys that:~~

~~(1) may be necessary for the licensee or registrant to comply with the rules in this Section; and~~

~~(2) are reasonable under the circumstances to evaluate:~~

~~(A) the magnitude and extent of radiation levels;~~

~~(B) concentrations or quantities of radioactive material; and~~

~~(C) the potential radiological hazards that could be present.~~

~~(b) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated at the frequency committed to in accordance with the requirements of Rules .0207 or .0317 of this Chapter for the radiation measured.~~

~~(c) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with Rule .1604 of this Section, with other applicable provisions of this Chapter, or with conditions specified in a license shall be processed and evaluated by a dosimetry processor:~~

~~(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and~~

~~(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.~~

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

History Note: *Authority G.S. 104E-7(a)(2);*
Eff. January 1, 1994;
Amended Eff. August 1, 2002;
Transferred and Recodified from 15A NCAC 11 .1613 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .1645 is proposed for amendment as follows:

10A NCAC 15 .1645 REPORTS OF THEFT OR LOSS OF LICENSED RADIOACTIVE MATERIAL

(a) Reports of the theft or loss of radioactive material shall be made to the agency in accordance with the provisions of 10 CFR 20.2201, at the telephone numbers and addresses shown in Rule .0111 of this Chapter.

(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) Each licensee shall report by telephone as follows:~~

~~(1) immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to 10 CFR §§ 20.1001 – 20.2401 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or~~

~~(2) within 30 days after the occurrence of any lost, stolen, or missing licensed radioactive material becomes known to the licensee, all licensed radioactive material in a quantity greater than 10 times the quantity specified in Appendix C to 10 CFR §§ 20.1001 – 20.2401 that is still missing at this time.~~

~~(b) Telephone reports in Paragraph (a) of this Rule shall be made to the agency as specified in Rule .0111 of this Chapter.~~

~~(c) Each licensee required to make a report under Paragraph (a) of this Rule shall, within 30 days after making the telephone report, make a written report setting forth the following information:~~

~~(1) a description of the licensed radioactive material involved, including kind, quantity, and chemical and physical form;~~

~~(2) a description of the circumstances under which the loss or theft occurred;~~

~~(3) a statement of disposition, or probable disposition, of the licensed radioactive material involved;~~

~~(4) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;~~

~~(5) actions that have been taken, or will be taken, to recover the material; and~~

~~(6) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed radioactive material.~~

~~(d) Written reports shall be addressed to the agency as specified in Rule .0111 of this Chapter.~~

~~(e) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.~~

~~(f) The licensee shall prepare any report filed with the agency pursuant to this Rule so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.~~

History Note: *Authority G.S. 104E-7(a)(2); 104E-12(a);*
Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .1645 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.

10A NCAC 15 .1653 is proposed for amendment as follows:

10A NCAC 15 .1653 RADIOLOGICAL REQUIREMENTS FOR LICENSE TERMINATION

(a) Licensees shall comply with the provisions of 10 CFR Part 20, Subpart E, to meet the requirements for license termination and decommissioning.

(b) The agency shall not publish a notice in the Federal Register of the receipt of a license termination plan or decommissioning plan as required by 10 CFR 20.1405(b), but shall make other notices and solicit comments from interested parties as required by 10 CFR 20.1405.

(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) General provisions and scope:~~

~~(1) The requirements in this Rule apply to the decommissioning of facilities licensed under the rules of this Chapter. For low-level radioactive waste disposal facilities licensed under Section .1200 of this Chapter, the requirements apply only to ancillary surface facilities that support radioactive waste disposal facilities.~~

~~(2) The requirements in this Rule do not apply to sites which:~~

~~(A) have been decommissioned prior to the effective date of this Rule in accordance with criteria approved by the agency; or~~

~~(B) have previously submitted and received agency approval for a license termination plan or for a decommissioning plan.~~

~~(3) After a site has been decommissioned and the license terminated in accordance with the requirements set forth in this Rule, the agency may require additional cleanup only if, based on new information, the agency determines that the requirements of this Rule were not met and residual radioactivity remaining at the site could result in a significant threat to the public health and safety.~~

~~(4) When calculating Total Effective Dose Equivalent (TEDE) to the average member of the critical group, the licensee shall determine the peak annual TEDE expected within the first 1,000 years after decommissioning.~~

~~(b) Radiological criteria for unrestricted use of a site shall be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radioactivity results in a TEDE to an average member of the critical group that does not exceed 25 millirem (0.25 millisievert) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels, which are ALARA, may take into account consideration of detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.~~

~~(c) A site shall be considered acceptable for license termination under restricted conditions if:~~

(1) the licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of Paragraph (b) of this Rule would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA may take into account consideration of detriments, such as traffic accidents, expected to result from decontamination and waste disposal;

(2) the licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background radioactivity, to the average member of the critical group, will not exceed 25 millirem (0.25 millisievert) per year;

(3) the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms to meet the requirements of Subparagraph (e)(3) of this Rule are described in Rule .0354 of this Chapter.

(4) the licensee has submitted to the agency a decommissioning plan or license termination plan, as described in Rule .0339 of this Chapter, indicating the licensee's intent to decommission in accordance with the requirements of this Chapter, and specifying that the licensee intends to decommission by restricting use of the site;

(5) the licensee has documented in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice:

(A) licensees proposing to decommission by restricting use of the site shall have sought advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(i) whether provisions for institutional controls proposed by the licensee will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background radioactivity to the average member of the critical group will not exceed 25 millirem (0.25 millisievert) TEDE per year, will be enforceable and will not impose undue burdens on the community or other affected parties; and

(ii) whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(B) the licensee has provided for:

(i) participation by representatives of a broad cross-section of community interests who may be affected by the decommissioning;

(ii) an opportunity for a comprehensive, collective discussion of the issues by the participants represented; and

(iii) a publicly available summary of the results of all such discussions, and the extent of agreement and disagreement among the participants on the issues.

(6) residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background radioactivity to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(A) 100 millirem (1 millisievert) per year; or

(B) 500 millirem (5 millisievert) per year provided the licensee:

(i) demonstrates that further reductions in residual radioactivity necessary to comply with the 100 millirem per year (1 millisievert per year) value described in Part (c)(6)(A) of this Rule, are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) makes provisions for durable institutional controls; or

(iii) provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the requirements of Subparagraph (c)(2) of this Rule and to assume and carry out responsibilities for any necessary control and maintenance of those controls.

(d) Alternate criteria for license termination:

(1) The agency may terminate a license using alternate criteria greater than the dose requirements of Paragraph (b), Subparagraph (c)(2), and Subpart (c)(5)(A)(i) of this Rule, if the licensee:

(A) provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than 100 millirem TEDE per year (1 millisievert per year) limit described in Rule .1611 of this Section, by submitting an analysis of possible sources of exposure;

(B) has employed, to the extent practical, restrictions on site use according to the provisions of Paragraph (c) of this Rule in minimizing exposures at the site;

(C) reduces doses to ALARA levels, taking into consideration detriments such as traffic accidents expected to potentially result from decontamination and waste disposal;

(D) has submitted a decommissioning plan or license termination plan to the agency indicating the licensee's intent to decommission in accordance with the requirements of this Chapter, and specifying that the licensee proposes to decommission by use of alternate criteria;

(E) has documented in the decommissioning plan or license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed; and

(F) in seeking such advice, the licensee has provided for:

~~(i) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;~~

~~(ii) an opportunity for a comprehensive, collective discussion of the issues by the participants represented; and~~

~~(iii) a publicly available summary of the results of such discussions, including a description of the extent of agreement and disagreement among the participants on the issues.~~

~~(2) The use of alternate criteria to terminate a license requires the consideration of any comments provided by any other interested state agencies and any public comments submitted pursuant to Paragraph (e) of this Rule.~~

~~(e) Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Paragraphs (c) and (d) of this Rule, or whenever the agency deems such notice to be in the public interest, the agency shall notify and solicit comments from:~~

~~(1) local governments in the vicinity of the site, appropriate state agencies, the U.S. Environmental Protection Agency, and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and~~

~~(2) publish a notice in a forum, such as local newspapers, letters to state or local organizations or other appropriate forum that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.~~

History Note: *Authority G.S. 104E-7(a)(2); 104E-10(b);*
Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .1653 Eff. February 1, ~~2015.~~ 2015;
Amended Eff. March 1, 2017.