SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL

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

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

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

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

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

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

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

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

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

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

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

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

(1) 10 CFR 30.1, "Scope;"

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

(3) 10 CFR [~~30.3,~~] 30.3(a), (c), and (d), "Activities requiring [~~license;"~~] license," except that references to 10 CFR 30.3(b)(1), (b)(2), and (b)(3) shall not apply;

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

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

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

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

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

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

(10) 10 CFR 30.13, "Carriers;"

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

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

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

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

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

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

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

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

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

(20) 10 CFR 30.33, "General requirements for issuance of specific licenses," except the agency [~~may base the issuance of a specific license on information and evaluations made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51, and the agency~~] shall issue a "Radioactive Materials [~~License" in lieu of Form NRC 374;~~] License." In the event an "environmental document," as defined by G.S. 113A-9.(2), has been prepared in accordance with 15A NCAC 01C .0206, the agency may base the issuance of a specific license on information and evaluations made in that environmental document;

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

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

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

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

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

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

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

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

(29) 10 CFR 30.51, "Records;"

(30) 10 CFR 30.52, "Inspections;"

(31) 10 CFR 30.53, "Tests;"

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

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

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

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

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

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

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

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

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

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

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

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

(A) legal business name and mailing address;

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

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Applications specified in this Rule are available at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

supporting material shall be submitted to the agency by e-mail at Licensing.ram@dhhs.nc.gov, or at the address shown in Rule .0111 of this Chapter in lieu of the [~~NRC.~~] United States Nuclear Regulatory Commission. The following information shall appear on the application:

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

(2) type of device;

(3) device manufacturer;

(4) device model numbers and serial numbers;

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

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

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

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

(9) describe the method of device disposal; and

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

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

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

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

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

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

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

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

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

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

(a) All persons manufacturing or initially transferring items or devices containing exempt quantities or exempt concentrations of byproduct material, as described in Subparagraphs .0301(a)(11) and .0301(a)(13) of this Chapter, generally licensed and specifically licensed items or devices containing byproduct material, items or devices containing byproduct material for medical use in humans, and persons requesting safety evaluations of sealed sources or devices for registration with the national Sealed Source and Device Registry shall comply with the following requirements of 10 CFR 32:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) requests for safety evaluations and registration of product information under this Paragraph and inactivation of certificates of registration of sealed sources and devices issued by the agency shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of this Chapter in lieu of the NRC.

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

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

(A) legal business name and mailing address;

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

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Applications specified in this Rule are available at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Applications shall be made on forms provided by the agency. One copy of the application and supporting material shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of this Chapter in lieu of the [~~NRC:~~] United States Nuclear Regulatory Commission:

(1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive materials licenses, shall submit an Application for Radioactive Materials License. The instructions

for completing the application printed on the application form shall be followed. The following information shall appear on the application:

(A) legal business name and mailing address;

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

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Applications specified in this Rule are available at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

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

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

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

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

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

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

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

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

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

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

(2) 10 CFR 35.2, "Definitions;"

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

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

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

(6) 10 CFR 35.10, "Implementation;"

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) the range of radiopharmaceutical dosages;

(2) the method used to determine the dosage;

(3) the route of administration;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(13) 10 CFR [~~35.2203,~~] 35.2204, "Records of molybdemum-99, strontium-82, and strontium-85 concentrations;"

(14) 10 CFR 35.2310, "Records of safety instruction;"
(15) 10 CFR 35.2404, "Records of surveys after source implant and removal;"
(16) 10 CFR 35.2406, "Records of brachytherapy source accountability;"
(17) 10 CFR 35.2432, "Records of calibration measurements of brachytherapy sources;"
(18) 10 CFR 35.2433, "Records of decay of strontium-90 sources for ophthalmic treatments;"
(19) 10 CFR 35.2605, "Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"
(20) 10 CFR 35.2610, "Records of safety procedures;"
(21) 10 CFR 35.2630, "Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units;"
(22) 10 CFR 35.2632, "Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations;"
(23) 10 CFR 35.2642, "Records of periodic spot-checks for teletherapy units;"
(24) 10 CFR 35.2643, "Records of periodic spot-checks for remote afterloader units;"
(25) 10 CFR 35.2645, "Records of periodic spot-checks for gamma stereotactic radiosurgery units;"
(26) 10 CFR 35.2647, "Records of additional technical requirements for mobile remote afterloader units;"
(27) 10 CFR 35.2652, "Records of surveys of therapeutic treatment units;" and
(28) 10 CFR 35.2655, "Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units."

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

(1) 10 CFR 35.3045, "Report and notification of a medical event;"
(2) 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child;"
(3) 10 CFR 35.3067, "Report of a leaking source;" and
(4) 10 CFR 35.3204, "Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations."

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

(1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive materials licenses, shall submit an Application for Radioactive Materials License. The following information shall appear on the application:
(A) legal business name and mailing address;

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

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Applications specified in this Rule are available free of charge at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(10) 10 CFR 36.25, "Shielding;"

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

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

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

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

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

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

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

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

(19) 10 CFR 36.51, "Training;"

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) legal business name and mailing address;

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

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Applications specified in this Rule are available at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
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Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024.

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

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

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

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

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

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

(1) 10 CFR 40.1, "Purpose;"

(2) 10 CFR 40.2, "Scope;"

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(18) 10 CFR 40.31(a), (b), (d), (f) – (i), "Application for specific licenses," except that the requirements of Paragraph (b) of this Rule shall be met, [~~the agency may require information and evaluations made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51,~~] and reports required by 10 CFR 40.31(g) shall be submitted to the NRC in lieu of the [~~agency;~~] agency. In the event an "environmental document," as defined by G.S. 113-9.(2), has been prepared in accordance with 15A NCAC 01C .0206, the agency may base the issuance of a specific license on information and evaluations made in that environmental document;

(19) 10 CFR 40.32, "General requirements for issuance of specific licenses," except that [~~the agency may base the issuance of a specific license on information and evaluations made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51, and~~]10 CFR 40.32(d), (g), and references to and requirements for uranium enrichment and uranium hexafluoride facilities shall not [~~apply;~~] apply. In the event an "environmental document," as defined by G.S. 113A-9.(2), has been prepared in accordance with 15A NCAC 01C .0206, the agency may base the issuance of a specific license on information and evaluations made in that environmental document;

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

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

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

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

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

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

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

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

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

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

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

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

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

(33) 10 CFR 40.61, "Records;"

(34) 10 CFR 40.62, "Inspections;"

(35) 10 CFR 40.63, "Tests;"

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

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

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

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

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

(A) legal business name and mailing address;

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

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Applications specified in this Rule are available at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

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

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

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

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

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

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

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

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

(2) 10 CFR 70.2, "Scope;"

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

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

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

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

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

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

(9) 10 CFR 70.12, "Carriers;"

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) legal business name and mailing address;

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

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

(3) Applications specified in this Rule are available at: https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm.

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 2005;
Transferred and Recodified from 15A NCAC 11 .0310 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024.

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

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0312 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

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

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

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

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0314 - .0315 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

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

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

10A NCAC 15 .0318 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE

10A NCAC 15 .0319 SPECIFIC LICENSES: HUMAN USE IN HOSPITALS

10A NCAC 15 .0320 SPECIFIC LICENSES: HUMAN USE BY INDIVIDUAL PHYSICIANS

10A NCAC 15 .0321 SPECIFIC LICENSES: GENERAL REQUIREMENTS FOR HUMAN USE OF UNSEALED RADIOACTIVE MATERIALS

10A NCAC 15 .0322 SPECIFIC LICENSES: HUMAN USE OF SEALED SOURCES

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

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

10A NCAC 15 .0324 SPECIFIC LICENSES: BROAD SCOPE

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

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

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

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

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

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

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

10A NCAC 15 .0339 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING

10A NCAC 15 .0340 RENEWAL OF LICENSES

10A NCAC 15 .0341 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE

10A NCAC 15 .0342 AGENCY ACTION ON APPLICATIONS TO RENEW OR AMEND

10A NCAC 15 .0343 TRANSFER OF MATERIAL

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

History Note: *Authority G.S. 104E-7; 104E-10(b); 104E-13; 104E-18;*
Eff. February 1, 1980;
Amended Eff. June 1, 1993; May 1, 1993; May 1, 1992; June 1, 1989;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. October 1, 2013; April 1, 1999; August 1, 1998; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0337 - .0344 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2024.

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

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

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

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

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

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

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

10A NCAC 15 .0352 EMERGENCY PLANS

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

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

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

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

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

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

10A NCAC 15 .0357 REPORTING REQUIREMENTS

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

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

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

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

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

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

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

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

10A NCAC 15 .0362 DECAY-IN-STORAGE

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

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

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

10A NCAC 15 .0364 MEDICAL EVENTS

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

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

10A NCAC 15 .0501 is amended as published in 38:05 NCR 255-258 as follows:

SECTION .0500 - ~~SAFETY REQUIREMENTS FOR~~ INDUSTRIAL RADIOGRAPHY ~~OPERATIONS~~ X-RAY MACHINES

Codifier's Note: 10 NCAC 03G .2600 was transferred to 15A NCAC 11 .0500 effective January 4, 1990. Recodification pursuant to G.S. 143B-279.3.

10A NCAC 15 .0501 ~~PURPOSE AND SCOPE~~ INDUSTRIAL RADIOGRAPHIC OPERATIONS OF ELECTRONIC RADIATION MACHINES FOR NON-HUMAN USE

~~(a) The rules in this Section establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of this Section are in addition to and not in substitution for the other requirements of this Chapter.~~

~~(b) The rules in this Section apply to all licensees or registrants who use sources of radiation for industrial radiography; provided, however that nothing in this Section shall apply to the use of sources of radiation in the healing arts.~~

(a) Persons conducting industrial radiographic operations using radiation machines shall comply with the following provisions of 10 CFR 34, which are hereby incorporated by reference including subsequent amendments and editions, except references to and the requirements of 10 CFR 30, 37, 71, 150 and 171 contained therein shall not apply:

(1) 10 CFR 34.1, "Purpose and Scope;"

(2) 10 CFR 34.3, "Definitions;" except that the definition of becquerel, control (drive) cable, control drive mechanism, control tube, exposure head, field station, guide tube (projection sheath), S-tube, source assembly, source changer, and storage container, shall not apply. Prior to using industrial radiography all persons shall be registered in accordance with Rules in Section .0200 of this Chapter. The following terms apply:

(A) "agreement state" shall have the same meaning as "agency" as defined in G.S 104E-5(2);

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

(C) "licensed" shall have the same meaning as "registered" pursuant to the Rules in Section .0200 of this Chapter;

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

(E) "radiation source" shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

(F) "radiographic exposure device" shall have the same meaning as "radiation machine" in G.S 104E-5(13); and

(G) "sealed source" shall have the same meaning as "radiation machine" in G.S 104E-5(13).

(3) 10 CFR 34.25, "Radiation survey instruments." The term "radioactive material" used in 10 CFR 34.25 shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

(4) 10 CFR 34.31(a), (b)(1), and (c), "Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments;"

(5) 10 CFR 34.33, "Permanent radiographic installations." The term "radioactive source" used in 10 CFR 34.33 shall have the same meaning as "radiation machine" in G.S. 104E-5(13);

(6) 10 CFR 34.35(c), "Labeling, storage, and transportation;"

(7) 10 CFR 34.41, "Conducting industrial radiographic operations;"

(8) 10 CFR 34.42, "Radiation Safety Officer for industrial radiograph;"

(9) 10 CFR 34.43, "Training;"

(10) 10 CFR 34.45(a)(1) through (a)(3), (a)(5), (a)(7) through (a)(11), (a)(13), and (b), "Operating and emergency procedure;"

(11) 10 CFR 34.46, "Supervision of radiographers' assistants;"

(12) 10 CFR 34.47, "Personnel monitoring;"

(13) 10 CFR 34.49, "Radiation surveys;"

(14) 10 CFR 34.51, "Surveillance;"

(15) 10 CFR 34.53, "Posting;"

(16) 10 CFR 34.61, "Records of the specific license for industrial radiography;"

(17) 10 CFR 34.65, "Records of radiation survey instrument;"

(18) 10 CFR 34.71, "Utilization logs;"

(19) 10 CFR 34.73, "Records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments;"

(20) 10 CFR 34.75, "Record of alarm system and entrance control checks at permanent radiographic installations;"

(21) 10 CFR 34.79, "Records of training and certification;"

(22) 10 CFR 34.81, "Copies of operating and emergency procedures;"

(23) 10 CFR 34.83, "Records of personnel monitoring procedures;"

(24) 10 CFR 34.85, "Records of radiation surveys;"

(25) 10 CFR 34.87, "Form of records;"

(26) 10 CFR 34.89(a), (b)(1 through 10), "Location of documents and records;" and

(27) Appendix A to 10 CFR 34-Radiographer Certification.

(b) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-collections/cfr/part034/index.html.

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. May 1, 1993;
Transferred and Recodified from 15A NCAC 11 .0501 Eff. February 1,2015;

Pursuant to G.S.150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;

Amended Eff. May 1, 2024.

10A NCAC 15 .0502 is repealed as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0502 DEFINITIONS

History Note: *Authority G.S. 104E-7; 10 CFR 34.3;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1989;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0502 Eff. February 1, 2015;
Amended Eff. October 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0503 - .0505 are repealed through readoption as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0503 EQUIPMENT RADIATION LEVEL LIMITS

10A NCAC 15 .0504 RADIOGRAPHIC EXPOSURE DEVICES AND STORAGE CONTAINERS

10A NCAC 15 .0505 STORAGE, LABELS AND TRANSPORTATION PRECAUTIONS

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Amended Eff. May 1, 1992;
Filed as a Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0503 - .0505 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0506 is repealed as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0506 SURVEY INSTRUMENTS

History Note: *Authority G.S. 104E-7; 104E-12(a)(1);*
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0506 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0507 - .0508 are repealed through readoption as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0507 LEAK TESTING AND REPLACEMENT OF SEALED SOURCES

10A NCAC 15 .0508 QUARTERLY INVENTORY

History Note: *Authority G.S. 104E-7; 104E-12(a)(1);*
Eff. February 1, 1980;
Amended Eff. June 1, 1993;
Filed as a Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0507 - .0508 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0509 - .0517 are repealed as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0509 UTILIZATION LOGS
10A NCAC 15 .0510 LIMITATIONS
10A NCAC 15 .0511 INSPECTION AND MAINTENANCE
10A NCAC 15 .0512 PERSONNEL MONITORING
10A NCAC 15 .0513 OPERATING AND EMERGENCY PROCEDURES
10A NCAC 15 .0514 SECURITY
10A NCAC 15 .0515 RADIATION SURVEYS AND SURVEY RECORDS
10A NCAC 15 .0516 POSTING
10A NCAC 15 .0517 SUPERVISION OF RADIOGRAPHERS' ASSISTANTS

History Note: *Authority G.S. 104E-7;104E 12(a)(1); 104E-12(a)(2); 10 C.F.R. Chapter 1, Commission Notices, Policy Statements, Agreement States, 46 F.R. 7540; 10 C.F.R. 34.43; 10 C.F.R. Appendix A;*
Eff. February 1, 1980;
Amended Eff. January 1, 1994; June 1, 1993; June 1, 1989; October 1, 1980;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. January 1, 2005; April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0509 - .0517 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0519 is repealed as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0519 SUBJECTS TO BE COVERED DURING INSTRUCTION OF RADIOGRAPHERS

History Note: *Authority G.S. 104E-7;*
Eff. February 1, 1980;
Temporary Amendment Eff. August 20, 1994 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0519 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0520 is repealed as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0520 PERMANENT RADIOGRAPHIC INSTALLATIONS

History Note: *Authority G.S. 104E-7; 104E-12(a)(1);*
Eff. October 1, 1980;
Amended Eff. January 1, 1994;
Temporary Amendment Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. April 1, 1999; May 1, 1995;
Transferred and Recodified from 15A NCAC 11 .0520 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0521 is repealed through readoptionas published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0521 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT

History Note: *Authority G.S. 104E-7;*
Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0521 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0522 - .0523 are repealed as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0522 REPORTING REQUIREMENTS

10A NCAC 15 .0523 RECORDS OF INDUSTRIAL RADIOGRAPHY

History Note: *Authority G.S. 104E-7;*
Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. May 1, 1995;
Amended Eff. January 1, 2005; April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0522 - .0523 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, ~~2019.~~ 2019;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0524 is repealed through readoption as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0524 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0524 Eff. February 1, ~~2015.~~ 2015;
Repealed Eff. May 1, 2024.

10A NCAC 15 .0525 is repealed as published in 38:05 NCR 255-258 as follows:

10A NCAC 15 .0525 RADIOGRAPHER CERTIFICATION

History Note: *Authority G.S. 104E-7; 104E-10(b); 10 C.F.R. 34.43; 10 C.F.R. 34, Appendix A;*
Eff. April 1, 1999;
Transferred and Recodified from 15A NCAC 11 .0525 Eff. February 1, 2015;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 22, 2019. 2019;
Repealed Eff. May 1, 2024.

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

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

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

10A NCAC 15 .0701 SCOPE

10A NCAC 15 .0702 MANUAL BRACHYTHERAPY

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