Burgos, Alexander N

Subject: FW: Radiation Protection Commission Rules

From: Albright, James <james.albright@dhhs.nc.gov>
Sent: Friday, April 12, 2024 4:06 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>; Plott, Carmine M <cmplott@novanthealth.org>; Sit, Roger C <rcsit@ehs.unc.edu>
Subject: RE: Radiation Protection Commission Rules

Travis,
I am attending, and I assume Taylor is too since she's our Rulemaking Coordinator. I'd defer to her to reply, but she goes on vacation Monday next week and she's probably busy tying up loose ends today. I'm going to contact her separately about getting the final Rules to you.

Please also send invitations for:
Louis Brayboy (Louis.Brayboy@dhhs.nc.gov), Acting Section Chief and RAM Branch Manager Carmine Plott (cmplott@novanthealth.org)
Roger Sit (rcsit@ehs.unc.edu).

Carmine is the Chair and Roger is the Vice Chair of the Radiation Protection Commission.

Thank you,
James D. Albright
Environmental Programs Consultant
Radiation Protection Section
Radioactive Materials Branch
Division of Health Service Regulation
NC Department of Health and Human Services

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From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Friday, April 12, 2024 3:20 PM
To: Albright, James <james.albright@dhhs.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

James,

Thank you and Taylor Corpening for making the requested changes. Please submit all revised rules via email to oah.rules@oah.nc.gov no later than 5pm on April 19, 2024. The electronic copy must be saved as the official rule name (XX NCAC XXXX). Please include me on the email.

Are you or a representative from your agency planning to attend the RRC meeting on April 30th at 10am?

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: Radiation Protection Commission Rules
Attachments: 10A NCAC 15 .0307.docx; 10A NCAC 15 .0301.docx; 10A NCAC 15 .0309.docx

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From: Albright, James <james.albright@dhhs.nc.gov>
Sent: Friday, April 12, 2024 12:42 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

Travis,
I've amended 10A NCAC .0301, .0307, and .0309 as we discussed. Please see attached and let me know if there are other changes you'd like made to those Rules.

We appreciate your comments, they are helpful and the Rules are better for them.
Thank you,
James D. Albright
Environmental Programs Consultant
Radiation Protection Section
Radioactive Materials Branch
Division of Health Service Regulation
NC Department of Health and Human Services

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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 .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 .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.

Burgos, Alexander N

To: Wiggs, Travis C; Albright, James; Corpening, Taylor
Cc: Brayboy, Louis
Subject: RE: Radiation Protection Commission Rules

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Friday, April 12, 2024 12:17 PM
To: Albright, James <james.albright@dhhs.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

James,

I'm satisfied with your proposed edits to the rules. Please insert the discussed changes and send the updated rules to me for final review.

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: Radiation Protection Commission Rules
Attachments: ncagreements.pdf

From: Albright, James <james.albright@dhhs.nc.gov>
Sent: Friday, April 12, 2024 11:45 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

Travis,
My apology – see attached. If there's any other questions, etc., you have, please ask.

James D. Albright
Environmental Programs Consultant
Radiation Protection Section
Radioactive Materials Branch
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-814-2251
Mobile: 919-801-6048
james.albright@dhhs.nc.gov
Pronouns: he/him/his

Physical Address:
5505 Creedmoor Rd
Raleigh NC 27612

Mailing Address:
1645 Mail Service Center
Raleigh, NC 27699-1645

AGREEMENT
BETWEEN THE
UNITED STATES ATOMIC ENERGY COMMISSION
AND THE
STATE OF NORTH CAROLINA
FOR
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY AND RESPONSIBILITY WITHIN THE STATE PURSUANT TO SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

WHEREAS, The United States Atomic Energy Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended, (hereinafter referred to as the Act) to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and

WHEREAS, The Governor of the State of North Carolina is authorized under North Carolina General Statutes (G.S. 104C-5; 1963, c. 1211) to enter into this Agreement with the Commission; and

WHEREAS, The Governor of the State of North Carolina certified on May 15, 1964, that the State of North Carolina (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and

WHEREAS, The Commission found on July 8, 1964, that the program of the State for the regulation of the materials covered by this Agreement is compatible

with the Commission's program for the regulation of such materials and is adequate to protect the public health and safety; and

WHEREAS, The State recognizes the desirability and importance of maintaining continuing compatibility between its program and the program of the Commission for the control of radiation hazards in the interest of public health and safety; and

WHEREAS, The Commission and the State recognize the desirability of reciprocal recognition of licenses and exemption from licensing of those materials subject to this Agreement; and

WHEREAS, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, It is hereby agreed between the Commission and Governor of the State, acting in behalf of the State, as follows:

ARTICLE I

Subject to the exceptions provided in Articles II, III, and IV, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

A. Byproduct materials;

B. Source materials; and

C. Special nuclear materials in quantities not sufficient to form a critical mass.

ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of:

A. The construction and operation of any production or utilization facility;

B. The export from or import into the United States of byproduct, source, or special nuclear material, of any production or utilization facility;

C. The disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;

D. The disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission.

ARTICLE III

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE IV

This Agreement shall not affect the authority of the Commission under subsection 161 b. or i. of the Act to issue rules, regulations, or orders to protect the

common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

ARTICLE V

The Commission will use its best efforts to cooperate with the State and other agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State will use its best efforts to cooperate with the Commission and other agreement States in the formulation of standards and regulatory program of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of like materials. The State and the Commission will use their best efforts to keep each other informed of proposed changes in their respective rules and regulations and licensing, inspection and enforcement policies and criteria, and to obtain the comments and assistance of the other party thereon.

ARTICLE VI

The Commission and the State agree that it is desirable to provide for reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any agreement State. Accordingly, the Commission and the State agree to use their best effort to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

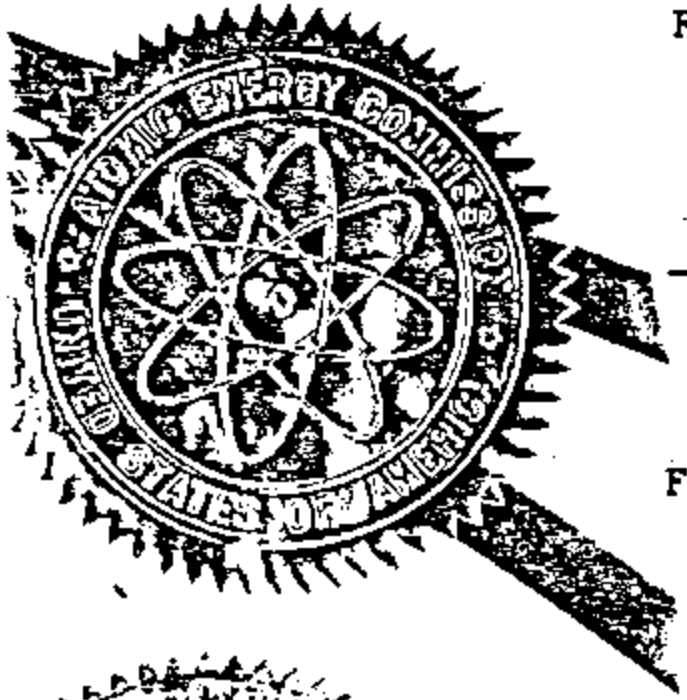
ARTICLE VII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that such termination or suspension is required to protect the public health and safety.

ARTICLE VIII

This Agreement shall become effective on August 1, 1964, and shall remain in effect unless, and until such time as it is terminated pursuant to Article VII.

Done at Raleigh, State of North Carolina, in triplicate, this 21st day of July, 1964.



FOR THE UNITED STATES ATOMIC ENERGY COMMISSION

James T. Ramey, Commissioner

FOR THE STATE OF NORTH CAROLINA

Terry Sanford, Governor

Burgos, Alexander N

Subject: FW: Radiation Protection Commission Rules

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Friday, April 12, 2024 8:55 AM
To: Albright, James <james.albright@dhhs.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

Thanks, James. I don't see an attachment with the Agreement you mentioned below. Please send me the Agreement.

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: Radiation Protection Commission Rules

From: Albright, James <james.albright@dhhs.nc.gov>
Sent: Thursday, April 11, 2024 6:34 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

Travis,
Thank you VERY much for all your prompt replies. Your insights help make the rules better, and I appreciate them. Like any profession, you get into the lingo and you know what you think they mean, but that's not a universal understanding.

See below –
James

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Thursday, April 11, 2024 4:56 PM
To: Albright, James <james.albright@dhhs.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

James,

Thank you for the reply. Your proposed solution for 10A NCAC 15 .0301,(20) and .0309, (18) and (19) is acceptable with a few minor edits. Based on your changes, you don't need to incorporate 15A NCAC 01C .0103 and .0206 by reference. You can delete the last sentence. You can cite the definition of "environmental document" directly to G.S. 113A-9 (2), and not through 15A NCAC 01C .0103 , since you don't need to incorporate by reference. There is no need to cite 113A as an Authority under History Notes.

I do have a question about my comment and your response below:
In reference to when the agency "may" use this exception, your response describes when the agency may need to use it ("in the event the agency has concerns…."). Will you insert similar language into the rule so the regulated public will better understand when this exception will apply? 15A NCAC 01C .0206 sets the bar whether an "environmental document" (defined by 15A NCAC 01C .0103, through referencing GS 113A-9.(2)) is required. If one isn't required by .0206, we would not require it. If an environmental document is not required by .0206, would your agency use Subpart A to 10 CFR 50 to determine if a specific license should be issued? Yes, and here is where it gets highly unlikely that environmental concerns will impact the issuance of a North Carolina radioactive materials license under 10 CFR 50. The only activities we regulate under the auspice of the "Agreement" are the possession and use of (1) byproduct material, (2) source material, and (3) special nuclear material in quantities less than what you'd need to form a "critical mass" (a self-sustaining nuclear reaction – such as power generation). We are also prohibited from regulating any kind of uranium processing or milling facility, and there are none in the state. I attached a copy of the Agreement so you can have a look at it, Article I lays everything out that we can do. We'd use the criteria in 10 CFR 51.20 – 51.22 to determine if an environmental assessment (or etc.) is required. Because of the restrictions placed on us by the Agreement, only the activities covered by 10 CFR 51.20(b)(11), (12) or (14) would trigger the need for an environmental assessment. Both 51.20(b)(11) and (12) have to do with 10 CFR Part 61, which is the licensing of a land disposal facility for low-level radioactive waste. 10 CFR

61 is incorporated by reference in 10A NCAC 15 .1203(a), and both 10 CFR 61 and GS 104E have extensive requirements for environmental assessments and whatnot, so we would not need to use either 51.20(b)(11) or (12). 51.20(b)(14) is a catchall provision where we could exercise some discretion, but if you look at the exclusions in 10 CFR 51.23(c), nearly every licensing action we perform as an agency is excluded from consideration.

For 10A NCAC 15 .0307,(c), your proposed language below is acceptable.
(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:

Thank you.

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: Radiation Protection Commission Rules

From: Albright, James <james.albright@dhhs.nc.gov>
Sent: Thursday, April 11, 2024 1:43 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>; Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Brayboy, Louis <louis.brayboy@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

Travis,
Regarding your comments about 10A NCAC 15 .0301, pg 2 (20) and .0309, pg 2, (18) and (19); I have this proposed solution. I will submit it officially on the form, but I want to get your thoughts on it first:

(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 15A NCAC 01C .0103, 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. 15A NCAC 01C .0103 and 15A NCAC 01C .0206 are hereby incorporated by reference, including subsequent amendments;

In your opinion, is this solution acceptable for .0301 and .0309? If this solution will not work, please let me know. Also let me know if I need to cite GS 113A in the 'Authorities' part of the History Note.

I also responded in red colored font to your comments in your email, below.

Thank you,
James D. Albright
Environmental Programs Consultant
Radiation Protection Section
Radioactive Materials Branch
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-814-2251
Mobile: 919-801-6048
james.albright@dhhs.nc.gov
Pronouns: he/him/his

Physical Address:
5505 Creedmoor Rd
Raleigh NC 27612

Mailing Address:
1645 Mail Service Center
Raleigh, NC 27699-1645

Burgos, Alexander N

Subject: FW: Radiation Protection Commission Rules

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Tuesday, April 9, 2024 4:38 PM
To: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Albright, James <james.albright@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

Good afternoon,

Thank you for responding to my request for changes. I have a few questions on two of the rules (.0301 and .0307) below. My questions in .0301 also apply to .0309, pg. 2, (18) and (19).

10A NCAC 15 .0301, pg. 2, (20):

- Based on your response, it seems that Subpart A to 10 CFR 51 may be used in "combination with" or "along with" information provided by NCDEQ. That language may be more accurate than "in lieu of." Do you agree?
- In reference to "information made pursuant to the requirements of the N.C. Department of Environmental Quality," are you able to incorporate the specific NCDEQ "requirements" into the rule using 150B-21.6?
- In reference to when the agency "may" use this exception, your response describes when the agency may need to use it ("in the event the agency has concerns…."). Will you insert similar language into the rule so the regulated public will better understand when this exception will apply?

10A NCAC 15 .0307, pg. 2, (c):

- Will you insert language describing how a clinical procedures manual "must be submitted to the agency for review and approval as part of the licensee's policies and procedures during the license application review by the agency?" I believe the additional language will make the approval process more transparent for the regulated public.

Please let me know if you have any questions. Thank you.

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

Burgos, Alexander N

Subject: FW: Radiation Protection Commission Rules
Attachments: 4_2024_Radiation Protection Commission.docx; 10A NCAC 15 .0301.docx; 10A NCAC 15 .0302.docx; 10A NCAC 15 .0304.docx; 10A NCAC 15 .0305.docx; 10A NCAC 15 .0307.docx; 10A NCAC 15 .0308.docx; 10A NCAC 15 .0309.docx; 10A NCAC 15 .0310.docx

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From: Corpening, Taylor <taylor.corpening@dhhs.nc.gov>
Sent: Tuesday, April 9, 2024 10:42 AM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>; Albright, James <james.albright@dhhs.nc.gov>
Subject: RE: Radiation Protection Commission Rules

Hello,

Attached are our responses to your technical change requests and updated rule text.

Please let me know if you have any questions.

Best,
Taylor Corpening
Rule-making Coordinator
Division of Health Service Regulation
NC Department of Health and Human Services

Work Cell: 919-896-9371
Office: 919-855-4619
Fax: 919-733-2757
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809 Ruggles Drive, Edgerton Building
2701 Mail Service Center
Raleigh, NC 27699-2701

Request for Changes Pursuant to N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

The imposition of a question implies that the rule as written is unclear or there is some ambiguity. If the request includes questions and you do not understand the question, please contact the reviewing attorney to discuss. Failure to respond may result in a staff opinion recommending objection.

Staff may suggest the agency "consider" an idea or language in this document. This is in no way a formal request that the agency adopt the idea or language but rather is offered merely for consideration which the agency may find preferable and clarifying.

To properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 – The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 – The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 – The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

1. You must submit the revised rule via email to oah.rules@oah.nc.gov. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
2. For rules longer than one page, insert a page number.
3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
5. You cannot change just one part of a word. For example:
    - Wrong: "~~a~~Association"
    - Right: "~~association~~ Association"
6. Treat punctuation as part of a word. For example:
    - Wrong: "day~~,~~; and"
    - Right: "~~day,~~ day; and"
7. Formatting instructions and examples may be found at: www.ncoah.com/rules/examples.html.

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0301

DEADLINE FOR RECEIPT: April 17, 2024

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Line 26: Where is "byproduct material" defined?
The term "byproduct material" is defined in 10A NCAC 15 .0104(23), G.S. 104E-5.(4) and in 10 CFR 30.4. 10 CFR 30.4 is incorporated by reference in this Rule.

Line 36: What does "NRC" mean? If it's an acronym, please spell it out before using. Consider making this change throughout all the rules.
The acronym "NRC" means "the United States Nuclear Regulatory Commission or its authorized representatives," and is defined in 10A NCAC 15 .0104(96). Also, the acronym "NRC" is widely used by regulators and users of radioactive materials to refer to the US Nuclear Regulatory Commission.

The agency agrees that this is a good suggestion that clarifies the Rule and has implemented it. Refer to pg 1, (5), Lines 36 and 37. Please note that the additional line used for this revision changes the line numbers on the following pages, so those line numbers are approximate.

On pg. 2, (20), Line 17-19: Under what circumstances "may" the agency "base the issuance of a specific license on information made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51?" What is the agency's authority to make this exception?
This is a complicated situation. The regulations in 10 CFR Part 51 are environmental protection regulations that apply to the NRC and NRC licensees and fall under exclusive NRC jurisdiction. Subsequently, the agency would need to rely on environmental impact statements issued by NCDEQ or developed by licensees or applicants for a radioactive materials license using NCDEQ guidance in the event the agency has concerns that licensed activities or proposed activities requiring a radioactive materials license might have an environmental impact that needs to be assessed as part of license application review activities conducted by the agency. Instances where this could come into play would be if the licensee is proposing to construct a facility in an environmentally sensitive location. The agency does not want to be placed in the situation where the radiation protection requirements are

met and the license issued, to discover after the fact that the licensee is using the issuance of the license to attempt to force a favorable outcome regarding a decision to be made by NCDEQ regarding environmental impacts of the construction of a facility. The agency will consult with NCDEQ to make this determination prior to requiring compliance with this Rule.

The agency's authority for making this exception is based on the authority of the NC Radiation Protection Commission to promulgate rules and regulations under G.S. 104E-7.(a)(2).

On pg. 2, (20), Line 20: You refer to "Form NRC 374". Where can this form be found? The contents of forms must be contained in rule or law. Are the contents of this form in a rule or law elsewhere?
"Form NRC 374" is the term the NRC uses for their radioactive materials licenses. It is not a "form" as defined by G.S. 150B-2.(d) in so far as it does not reflect the procedure or practice requirements of the agency. An example of "NRC Form 374" may be found here: https://www.nrc.gov/docs/ML1316/ML13165A077.pdf (the form number is in the upper left-hand corner).

To clarify this Rule and resolve any ambiguity caused using the term "form," the agency is revising the Rule on pg. 2, (20), Line 20 to read simply: …the agency shall issue a "Radioactive Materials License."

On pg. 3, (b)(1)(D), Line 28: Change "may" to "shall." *Done.*

On pg. 4, (b)(2)(G), Lines 13-14: Consider changing "may" to "shall" to be consistent with similar language in (b)(1)(D). *Done on pg 4 (b)(2)(G).*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0302

DEADLINE FOR RECEIPT: April 17, 2024

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Lines 12-13: Add a comma after "items" and after "32." Done.

On pg. 2, Line 2: What does "NRC" mean? If it's an acronym, please spell it out before using.
The acronym is spelled out in the revised Rule, see pg 2, Line 2. Since this is the only place in this Rule where the acronym "NRC" is used, the parenthetical "(NRC)" was not added to the revision.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0304

DEADLINE FOR RECEIPT: April 17, 2024

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Lines 13-14: How does the regulated public determine if their items or devices contain "exempt quantities or exempt concentrations of byproduct material?" Consider inserting the appropriate source(s), i.e. 10 CFR 30.70.
The regulations in 10 CFR 32 are specific to the manufacture and initial distribution of devices containing byproduct materials. The regulations in 10 CFR 30 are general provisions that apply to all specific licenses for the use of byproduct materials. Revised the Rule to reference Rules .0301(a)(11) and .0301(a)(13) of 10A NCAC 15, to address this recommended change to the Rule.

Rules .0301(a)(11) of this Subparagraph incorporates 10 CFR 30.14 by reference and describes "exempt concentrations." 10 CFR 30.14 references 10 CFR 30.70 (Schedule A – Exempt Concentrations).

Rule .0301(a)(13) of this Subparagraph incorporates 10 CFR 30.18 by reference and describes "exempt quantities." 10 CFR 30.18 references 10 CFR 30.71 (Schedule B, also known as the "exempt quantity table").

Lines 22-23: How does the regulated public determine if their items or devices contain "exempt quantities of byproduct material?" Consider inserting the appropriate source(s), i.e. 10 CFR 30.70.
Please see the explanation for Lines 13-14, above, for the resolution of this comment.

Line 28: What does "NRC" mean? If it's an acronym, please spell it out before using.
Spelled out the acronym "NRC" as suggested: United States Nuclear Regulatory Commission (NRC). Note that the additional text moves the line numbers by one in the comments following this one.

Line 33: Add parenthesis before and after "(a)".
Please note that the correct regulatory citation in .0304(c)(2), now appearing on line 35, is '10 CFR 32.51a' as it appears in the Rule, not '10 CFR 32.51(a)'. 10 CFR 32.51a is found between 32.51 and 32.52 in the 10 CFR.

On pg. 3, (g)(1)(D), Line 6: Change "may" to "shall." Done.

On pg. 3, (g)(2)(F), Line 27: Consider changing "may" to "shall" to be consistent with similar language in (g)(1)(D). Done.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0305

DEADLINE FOR RECEIPT: April 17, 2024

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Line 21: What is meant by "engaging in activities?" Can you provide specific examples? Where is "radioactive material" defined?
Thank you for your comment. Upon a more critical reading with your comment in mind the agency finds that the part of the sentence addressing the "use of more than one type of radioactive material" is outdated and superfluous. Older versions of 10 CFR 33.13(b) noted that in addition to "a reasonable number of activities" the nature, quantity, and use of the byproduct material being requested was not well known by the applicant at the time of application for approval of licensed activities. The current 10 CFR 33 emphasizes the administrative requirements for broad scope licenses.

The concept behind the language removed from pg 1, Line 21, can be found in 10A NCAC 15 .0324(a)(1) that reflects the older language formerly in 10 CFR 33.13(b). Rule .0324 is being repealed during this rulemaking.

Broad scope licenses are typically reserved for licensees that conduct research who have the administrative processes in place to "regulate themselves" subject to inspection and regulation by the State.

The term "radioactive material" has been removed from the Rule. The term is defined in 10A NCAC 15 .0104(124).

Line 35: What does "NRC" mean? If it's an acronym, please spell it out before using.
NRC is the acronym for the United States Nuclear Regulatory Commission. It is now spelled out in the Rule where the acronym appeared on Line 35. Thank you for the suggestion, it does make the Rule easier to understand for individuals not familiar with industry standard terms and acronyms. Since this is the only place the acronym appears in this Rule, the parenthetical (NRC) is not used.

On pg. 2, Line 6: What is the purpose of the "+" in front of "Radiation?" Please delete it if it's a typo. *Thanks for catching the typo! It is fixed.*

On pg. 2, (b)(1)(D), Line 8: Change "may" to "shall." Done.

On pg. 3, (b)(2)(F), Line 30: Consider changing "may" to "shall" to be consistent with similar language in (b)(1)(D). Done.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0307

DEADLINE FOR RECEIPT: April 17, 2024

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On pg. 2, (c), Lines 22-23: What is the process for a clinical procedures manual to be "approved in writing by an authorized user?" Who is considered an "authorized user?"
The process a licensee uses to approve the clinical procedures manual is left up to the licensee to develop and implement and must be submitted to the agency for review and approval as part of the licensee's policies and procedures during license application review by the agency. The signature 'approving' the clinical procedures manual is an indication that the process and procedures the licensee is using for the administration of radioactive drugs to humans ensures that radioactive drugs are used in the most effective manner possible, used in accordance with FDA regulations and guidelines, and to provide written guidance to nuclear medicine technologists administering these radioactive drugs to human patients..

Within the context of this Rule, an "authorized user" is a physician licensed to practice medicine in the State of North Carolina and who meets the education, training, and experience requirements commensurate with their use of radioactive drugs and uses of sources of radiation to diagnose and treat disease in humans. The requirements to be an "authorized user" vary by use, and are found on pg 2, Line 14 (.0307(b)(10)), pg 3, Line 26 (.0307(e)(2)) and Line 30 (.0307(e)(5)), pg 4, Lines 3 – 10 (.0307(f)(4) – (7)), Lines 21 and 22 (.0307(g)(9) and (10)), Line 28 (.0307(h)(2)), and pg 5, Lines 16 and 17 (.0307(i)(17)). These subparagraphs incorporate 10 CFR 35.57, .190, .290, .390, .392, .394, .396, .490, .491, .590, and .690 by reference, respectively.

On pg. 4, (11), Lines 23-24: How does someone become an "Authorized Medical Physicist?"
The training and experience requirements for an "authorized medical physicist" are found on pg 2, Line 12 (.0307(b)(8)) incorporating 10 CFR 35.51 by reference, and on Line 14 (.0307(b)(10)), incorporating 10 CFR 35.57 by reference.

On pg. 7, (D), Line 5: Change "may" to "shall." *Done.*

On pg. 7, (F), Line 26: Consider changing "may" to "shall" to be consistent with similar language in (D). Done.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0308

DEADLINE FOR RECEIPT: April 17, 2024

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On pg. 2, Line 6: What does "NRC" mean? If it's an acronym, please spell it out before using.
Thank you for this suggestion. It does improve the Rule. Spelled out the acronym "NRC" to mean "United States Nuclear Regulatory Commission (NRC)."

On pg. 2, (b)(1)(D), Line 18: Change "may" to "shall." *Done.*

On pg. 3, (b)(2)(F), Line 3: Consider changing "may" to "shall" to be consistent with similar language in (b)(1)(D). *Done.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0309

DEADLINE FOR RECEIPT: April 17, 2024

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On pg. 2, (18), Lines 5-7: Under what circumstances "may" the agency "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?" What is the agency's authority to make this exception?
This is a complicated situation. The regulations in 10 CFR Part 51 are environmental protection regulations that apply to the NRC and NRC licensees and fall under exclusive NRC jurisdiction. Subsequently, the agency would need to rely on environmental impact statements issued by NCDEQ or developed by licensees or applicants for a radioactive materials license using NCDEQ guidance in the event the agency has concerns that licensed activities or proposed activities requiring a radioactive materials license might have an environmental impact that needs to be assessed as part of license application review activities conducted by the agency. Instances where this could come into play would be if the licensee is proposing to construct a facility in an environmentally sensitive location. The agency does not want to be placed in the situation where the radiation protection requirements are met and the license issued, to discover after the fact that the licensee is using the issuance of the license to attempt to force a favorable outcome regarding a decision to be made by NCDEQ regarding environmental impacts of the construction of a facility. The agency will consult with NCDEQ to make this determination prior to requiring compliance with this Rule.

The agency's authority for making this exception is based on the authority of the NC Radiation Protection Commission to promulgate rules and regulations under G.S. 104E-7.(a)(2).

On pg. 2, (19), Lines 9-12: Under what circumstances "may" the agency "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?" What is the agency's authority to make this exception?
Please see the explanation, above, for the comment made about the Rule text found on pg 2, (18), Lines 5 – 7. Thank you.

On pg. 3, (b)(1)(D), Line 16: Change "may" to "shall." Done.

On pg. 3, (b)(2)(F), Line 37: Consider changing "may" to "shall" to be consistent with similar language in (b)(1)(D). Done.

Note: The acronym "NRC" appears on pg. 1, Line 27. The agency is spelling out the acronym to read "United States Nuclear Regulatory Commission (NRC)," because it is a good idea, and the request for the change was made for previous Rules.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0310

DEADLINE FOR RECEIPT: April 17, 2024

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On pg. 2, (b)(1)(D), Line 28: Change "may" to "shall." Done.

On pg. 3, (b)(2)(F), Line 14: Consider changing "may" to "shall" to be consistent with similar language in (b)(1)(D). Done.

Note: The acronym "NRC" appears on pg. 1, Line 22. The agency is spelling out the acronym to read "United States Nuclear Regulatory Commission (NRC)," because it is a good idea, and the request for the change was made for previous Rules. Note that the change adds a line number to the comments noted above.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

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."

(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 .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;*
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Amended Eff. October 1, 2013; April 1, 1999; June 1, 1993; October 1, 1982; September 1, 1981;
Transferred and Recodified from 15A NCAC 11 .0305 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024.

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

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

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

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

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

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

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

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

(2) 10 CFR 35.2, "Definitions;"

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

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

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

(6) 10 CFR 35.10, "Implementation;"

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) the range of radiopharmaceutical dosages;

(2) the method used to determine the dosage;

(3) the route of administration;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(13) 10 CFR [~~35.2203,~~] 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);*
Eff. February 1, 1980;
Amended Eff. January 1, 2005; January 1, 1994;
Transferred and Recodified from 15A NCAC 11 .0308 Eff. February 1, 2015;
Amended Eff. March 1, ~~2017.~~ 2017;
Readopted Eff. May 1, 2024.

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

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

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

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

~~(c) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are available free of charge at http://www.ecfr.gov/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;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(33) 10 CFR 40.61, "Records;"

(34) 10 CFR 40.62, "Inspections;"

(35) 10 CFR 40.63, "Tests;"

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

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

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

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

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

(A) legal business name and mailing address;

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

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

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

Burgos, Alexander N

From: Wiggs, Travis C
Sent: Wednesday, April 3, 2024 4:58 PM
To: Corpening, Taylor
Cc: Burgos, Alexander N
Subject: Radiation Protection Commission Rules
Attachments: 4_2024_Radiation Protection Commission.docx

Good afternoon,

I'm the attorney who reviewed the Rules submitted by the Radiation Protection Commission for the April 2024 RRC meeting. The RRC will formally review these Rules at its meeting on Tuesday, April 30, 2024, at 10:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get close to the meeting. If there are any other representatives from your agency who want to attend virtually, please let me know prior to the meeting, and we will get evites out to them as well.

Attached is the Request for Changes Pursuant to G.S. 150B-21.10. Please submit the revised Rules and forms to me via email, no later than 5 p.m. on April 17, 2024.

Thank you.

Travis C. Wiggs
Rules Review Commission Counsel
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