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/.

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