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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) legal business name and mailing address;

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

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

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

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

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

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

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

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

(A) the license number;

(B) amendment number of the current license;

(C) expiration date of the license;

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

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

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

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

(H) explanation of the action requested; and

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

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

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

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