

This is an amendment to 20.3.3.315 NMAC, Sub-Section J effective XX/XX/2022.

20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL:

A. Introduction of radioactive material in exempt concentrations into products or materials.

(1) **Licensing.** A specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the radioactive material to be transferred to persons exempt under Paragraph (1) of Subsection A of 20.3.3.302 NMAC will be issued by NRC pursuant to 10 CFR 32.11.

(2) **Prohibition of introduction.** No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Subsection A of 20.3.3.302 NMAC or equivalent regulations of the NRC or an agreement state, except in accordance with a license issued by NRC pursuant to 10 CFR 32.11.

B. Radioactive material in exempt quantities or in certain items.

(1) **Manufacture, distribution and transfer of exempt quantities of byproduct material.**

An application for a specific license to manufacture, process, produce, package, repackage or transfer exempt quantities of byproduct material for commercial distribution to persons exempt pursuant to Subsection B of 20.3.3.302 NMAC or the equivalent regulations of the NRC or an agreement state shall be issued by NRC pursuant to 10 CFR 32.18.

(2) **Certain items containing byproduct material.** An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in Paragraph (1) of Subsection C of 20.3.3.302 NMAC or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to Paragraph (1) of Subsection C of 20.3.3.302 NMAC to persons exempt from 20.3 NMAC shall be submitted to NRC pursuant to 10 CFR 32.14.

(3) Except as specified in Paragraphs (1) and (2) of this subsection, in addition to the requirements set forth in 20.3.3.308 NMAC, an application for a specific license to manufacture, process, produce, package, repackage or initially transfer naturally occurring or accelerator produced radioactive material (NARM) in exempt quantities as specified in 20.3.3.330 NMAC of this part to persons exempt from licensing pursuant to Subsection B of 20.3.3.302 NMAC will be approved if:

(a) the radioactive material is not contained in any food, beverage, cosmetic, drug or other commodity designed for ingestion or inhalation by, or application to, a human being;

(b) the radioactive material is in the form of processed chemical elements, compounds, mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product or device intended for commercial distribution; and

(c) the applicant submits copies of prototype labels and brochures and the department approves such labels and brochures.

(4) The license issued under Paragraph (3) of Subsection B of this subsection is subject to the following conditions:

(a) no more than 10 exempt quantities shall be sold or transferred in any single transaction; however, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity;

(b) each exempt quantity shall be separately and individually packaged; no more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to Subsection B of 20.3.3.302 NMAC; the outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour;

(c) the immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable and legible label which:

(i) identifies the radionuclide and the quantity of radioactivity; and

(ii) bears the words "*radioactive material*"; and

(d) in addition to the labeling information required by Subparagraph (c) of this paragraph, the label affixed to the immediate container, or an accompanying brochure shall

(i) state that the contents are exempt from these regulations;

(ii) bear the words "*radioactive material - not for human use - introduction into foods, beverages, cosmetics, drugs or medicinal product, or into products manufactured for commercial*

distribution is prohibited - exempt quantities shall not be combined"; and

(iii) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage and disposal of the radioactive material.

(5) Each person licensed under Subsection B of 20.3.3.315 NMAC shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under Subsection B of 20.3.3.302 NMAC and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the department. Each report shall cover the year ending June 30 and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to Subsection B of 20.3.3.315 NMAC, during the report period, the report shall so indicate.

C. Licensing of byproduct material by NRC.

(1) **Gas and aerosol detectors.** An application for a specific license to manufacture, process or produce gas and aerosol detectors containing byproduct material and designed to protect life or property from fires and airborne hazards, or to initially transfer such products for use pursuant to Paragraph (4) of Subsection C of 20.3.3.302 NMAC or equivalent regulations of the NRC or an agreement state, shall be submitted to NRC pursuant to 10 CFR 32.26.

(2) **Self-luminous products.** An application for a specific license to manufacture, process or produce self-luminous products containing tritium, krypton-85, promethium-147 or radium-226, or to initially transfer such products for use pursuant to Paragraph (2) of Subsection C of 20.3.3.302 NMAC or equivalent regulations of the NRC or an agreement state, shall be submitted to NRC pursuant to 10 CFR 32.22 and for distribution submit to the NRC pursuant to 10 CFR 32.53.

(3) **Capsules containing carbon-14.** An application for a specific license to manufacture, prepare, process, produce, package, repack or transfer for commercial distribution capsules containing 1 microcurie (37 kilobecquerels) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for *in vivo* diagnostic use, to persons exempt from licensing under Subsection D of 20.3.3.302 NMAC or the equivalent regulations of the NRC or an agreement state shall be submitted to NRC pursuant to 10 CFR 32.21.

D. [RESERVED]

E. Licensing the manufacture and distribution of devices to persons generally licensed under Subsection B of 20.3.3.305 NMAC.

(1) **Requirements for approval of a license application.** An application for a specific license to manufacture or initially transfer devices containing radioactive material to persons generally licensed under Subsection B of 20.3.3.305 NMAC or equivalent regulations of the NRC or an agreement state will be approved if:

(a) the applicant satisfies the general requirements of 20.3.3.308 NMAC;
(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions and potential hazards of the device to provide reasonable assurance that:

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

(ii) under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of ten percent of the limits specified in Subsection A of 20.3.4.405 NMAC; and

(iii) under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses: 1) whole body, head and trunk, active blood-forming organs, gonads or lens of eye: 15 rems (150 millisieverts); 2) hands and forearms, feet and ankles, and localized areas of skin averaged over areas no larger than 1 square centimeter: 200 rems (2 sieverts); and 3) other organs: 50 rems (500 millisieverts);

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

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

(ii) the requirement, or lack of requirement, for leak testing, or for testing

any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity; and date of determination of the quantity; and

(iii) the information called for in the following statement in the same or substantially similar form:

The receipt, possession, use and transfer of this device model _____, serial number _____, are subject to general license or the equivalent and the regulations of the United States nuclear regulatory commission or a state with which the nuclear regulatory commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. The model, serial number, and name of manufacturer or distributor may be omitted from this label provided this information is specified elsewhere in labeling affixed.

Caution-radioactive material

(name of manufacturer or distributor)

(d) each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, “*caution-radioactive material*,” the radiation symbol described in 20.3.4.427 NMAC, and the name of the manufacturer or initial distributor; and

(e) each device meeting the criteria of Item (i) in Subparagraph (m) of Paragraph (3) of Subsection B of 20.3.3.305 NMAC, bears a permanent (e.g., embossed, etched, stamped or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, “*caution-radioactive material*,” and, if practicable, the radiation symbol described in 20.3.4.427 NMAC.

(f) The device has been registered in the Sealed Source and Device Registry.

(2) **Requests for lengthening of test intervals:** In the event the applicant desires that the device be required to be tested at longer intervals than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in its application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the department will consider information which includes, but is not limited to:

- (a) primary containment (source capsule);
- (b) protection of primary containment;
- (c) method of sealing containment;
- (d) containment construction materials;
- (e) form of contained radioactive material;
- (f) maximum temperature withstood during prototype test;
- (g) maximum pressure withstood during prototype test;
- (h) maximum quantity of contained radioactive material;
- (i) radiotoxicity of contained radioactive material; and
- (j) operating experience with identical devices or similarly designed and

constructed devices.

(3) **Authorizations for general licensees to perform certain activities.** In the event the applicant desires that the general licensee under Subsection B of 20.3.3.305 NMAC, or under equivalent regulations of the NRC or an agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator or remove the device from installation, the applicant shall include in its application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities and the bases for such estimates. The submitted information must demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license, is unlikely to cause that individual to receive a yearly dose in excess of ten percent of the limits specified in Subsection A of 20.3.4.405 NMAC.

(4) **Transfer provisions:**

(a) [Reserved]

(b) If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an agreement state, each person that is licensed under this subsection shall provide the information specified in this subparagraph to each person to whom a device is to be transferred. This information

shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i) a copy of the NRC's or agreement state's regulations equivalent to Subsection B of 20.3.3.305 NMAC, Subsection F of 20.3.3.317 NMAC, 20.3.3.326 NMAC, 20.3.4.451 NMAC, and 20.3.4.452 NMAC or a copy of 10 CFR Sections 31.5, 31.2, 30.51, 20.2201 and 20.2202; if a copy of the NRC regulations is provided to a prospective general licensee in lieu of the agreement state's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the agreement state; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

(ii) a list of the services that can only be performed by a specific licensee;

(iii) information on acceptable disposal options including estimated costs of disposal; and

(iv) the name or title, address and phone number of the contact at the agreement state regulatory agency from which additional information may be obtained.

(c) An alternative approach to informing customers may be proposed by the licensee for approval by the department.

(d) Each device shall meet the labeling requirements in Subparagraphs (c) through (e) of Paragraph (1) of this Subsection.

(e) If a notification of bankruptcy is submitted under Subsection E of 20.3.3.317 NMAC of this part and each specific licensee or the license is to be terminated, each person licensed under Paragraph (1) of this subsection shall provide, upon request, to the department, NRC and any agreement state, records of final disposition required under 10 CFR30.34(h).

(5) Material transfer reports and records: Each person licensed under 20.3.3.305 NMAC of this subsection to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

(a) The person shall report to the department in accordance with 20.3.1.116 NMAC, all transfers of such devices to persons for use under the general license in Subsection B of 20.3.3.305 NMAC and all receipts of devices from persons licensed under Subsection B of 20.3.3.305 NMAC. The report shall be clear and legible, submitted on a quarterly basis containing all of the following data.

(i) The required information for transfers to general licensees includes: 1) the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use; 2) the name, title and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements; 3) the date of transfer; 4) the type, model number, and serial number of the device transferred; and 5) the quantity and type of radioactive material contained in the device.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(iii) For devices received from a person licensed pursuant to Subsection B of 20.3.3.305 NMAC, the report shall include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(iv) If the licensee makes changes to a device possessed by a person licensed pursuant to Subsection B of 20.3.3.305 NMAC, such that the label must be changed to update required information, the report shall identify the general licensee, the device and the changes to information on the device label.

(v) The report shall cover each calendar quarter, shall be filed within 30 days of the end of the calendar quarter, and shall clearly indicate the period covered by the report.

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

(vii) If no transfers have been made to or from persons generally licensed under Subsection B of 20.3.3.305 NMAC during the reporting period, the report shall so indicate.

(b) The person shall report all transfers of devices to persons for use under a general license under NRC's or an agreement state's regulations that are equivalent to Subsection B of 20.3.3.305 NMAC, and all receipts of devices from general licensees in the NRC's or agreement state's jurisdiction, to the responsible

NRC or agreement state agency. The report shall be clear and legible, containing all of the data required as described below.

(i) The required information for transfers to general licensees includes: 1) the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use; 2) the name, title and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements; 3) the date of transfer; 4) the type, model number and serial number of the device transferred; and 5) the quantity and type of radioactive material contained in the device.

(ii) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report shall include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(iii) For devices received from a general licensee, the report shall include the identity of the general licensee by name and address, the type, model number, serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

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

(v) The report shall cover each calendar quarter, shall be filed within 30 days of the end of the calendar quarter, and shall clearly indicate the period covered by the report.

(vi) The report shall clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(vii) If no transfers have been made to or from NRC or a particular agreement state during the reporting period, this information shall be reported to NRC or the responsible agreement state agency upon request of the agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by Subparagraphs (a) and (b) of this paragraph. Records required by this paragraph shall be maintained for a period of three years following the date of the recorded event.

F. Special requirements for the manufacture, assembly, repair or initial transfer of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under Subsection C of 20.3.3.305 NMAC will be approved subject to the following conditions:

(1) the applicant satisfies the general requirements specified in 20.3.3.308 NMAC;

(2) the applicant satisfies the requirements of 10 CFR 32.53, 10 CFR 32.54, 10 CFR 32.55 and 10 CFR 32.56 or their equivalent;

(3) each person licensed under 10 CFR 32.53 shall file an annual report with the director, office of Nuclear Materials Safety and Safeguards, ATTN: document control desk/GLTS by an appropriate method listed in 10 CFR 30.6(a) which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under 10 CFR 31.7. The report must identify each general licensee by name, state the kinds and number of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within 30 days thereafter. If no transfers have been made to persons generally licensed under 10 CFR 31.7 during the reporting period, the report must so indicate; and

(4) each person licensed under 10 CFR 32.53 shall report annually all transfers of devices to persons for use under a general license in an agreement state's regulations that are equivalent to 10 CFR 31.7 of this paragraph to the responsible agreement state agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular agreement state during the reporting period, this information must be reported to the responsible agreement state agency upon request of the agency.

G. Special requirements for license to manufacture or initially transfer calibration or reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under Subsection D of 20.3.3.305 NMAC. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under Subsection D of 20.3.3.305 NMAC will be approved subject to the following conditions:

- NMAC, and
- (1) the applicant satisfies the general requirements of 20.3.3.307 NMAC and 20.3.3.308 NMAC, and
 - (2) the applicant satisfies the requirements of 10 CFR 32.57, 10 CFR 32.58, 10 CFR 32.59 and 10 CFR 70.39 or their equivalent.

H. Manufacture and distribution of radioactive material for certain in-vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of Subsection F of 20.3.3.305 NMAC will be approved if:

- (1) the applicant satisfies the general requirements specified in 20.3.3.307 NMAC and 20.3.3.308 NMAC;
- (2) the radioactive material is to be prepared for distribution in prepackaged units of:
 - (a) iodine-125 in units not exceeding 10 microcuries (370 kilobecquerels) each;
 - (b) iodine-131 in units not exceeding 10 microcuries (370 kilobecquerels) each;
 - (c) carbon-14 in units not exceeding 10 microcuries (370 kilobecquerels) each;
 - (d) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 megabecquerels) each;
 - (e) iron-59 in units not exceeding 20 microcuries (740 kilobecquerels) each;
 - (f) cobalt-57 in units not exceeding 10 microcuries (370 kilobecquerels) each;
 - (g) selenium-75 in units not exceeding 10 microcuries (370 kilobecquerels) each; or
 - (h) mock iodine-125 reference or calibration sources in units not exceeding 0.05 microcurie (1.85 kilobecquerels) of iodine-129 and 0.005 microcurie (185 becquerels) of americium-241 each;
- (3) each prepackaged unit bears a durable, clearly visible label:
 - (a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kilobecquerels) of iodine-125, iodine-131, carbon-14, cobalt-57 or selenium-75; 50 microcuries (1.85 megabecquerels) of hydrogen-3 (tritium); 20 microcuries (740 kilobecquerels) of iron-59; or 0.05 microcurie (1.85 kilobecquerels) of iodine-129 and 0.005 microcurie (185 becquerels) of americium-241; and
 - (b) displaying the radiation caution symbol described in Paragraph (1) of Subsection A of 20.3.4.427 NMAC and the words, “*caution, radioactive material*” and “*not for internal or external use in humans or animals*”;

(4) the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in-vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the United States nuclear regulatory commission or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

(name of manufacturer); and

- (5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling, storing and disposal of such radioactive material; in the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 20.3.4.433 NMAC.

I. Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under Subsection G of 20.3.3.305 NMAC will be approved subject to the following conditions:

- (1) the applicant satisfies the general requirements of 20.3.3.307 NMAC and 20.3.3.308 NMAC; and
- (2) the criteria of 10 CFR 32.61 and 32.62 are met.

J. Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct [~~radioactive~~] material for medical use under 20.3.7 NMAC.

- (1) An application for a specific license to manufacture, prepare or transfer for commercial distribution, radioactive material for use by persons authorized pursuant to 20.3.7 NMAC will be approved if the following conditions are met.

and 20.3.3.308 NMAC;

(a) The applicant satisfies the general requirements specified in 20.3.3.307 NMAC and 20.3.3.308 NMAC;

(b) The applicant submits evidence that the applicant is at least one of the following:

(i) registered with the FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding or processing of a drug under 21 CFR 207.20(a);

(ii) registered or licensed with a state agency as a drug manufacturer;

(iii) licensed as a pharmacy by a state board of pharmacy;

(iv) operating as a nuclear pharmacy within a federal medical institution; or

(v) a PET drug production facility registered with a state agency.

(c) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees.

(d) The applicant commits to [~~satisfies~~] the following labeling requirements.

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic or other material, of a radioactive drug to be transferred for commercial distribution; the label must include the radiation symbol and the words “*caution, radioactive material*” or “*danger, radioactive material*”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

(ii) A label is affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution; the label must include the radiation symbol and the words “*caution, radioactive material*” or “*danger, radioactive material*” and an identifier that ensures that the syringe, vial or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by Items (iii) or (iv) of Subparagraph (b) of Paragraph (1) of this subsection:

(a) may prepare radioactive drugs for medical use, as defined in 20.3.7.7 NMAC, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in Subparagraphs (b) and (d) of this paragraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in Subsection F of 20.3.7.702 NMAC;

(b) may allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) the individual qualifies as an authorized nuclear pharmacist as defined in 20.3.7.7 NMAC;

(ii) the individual meets the requirements specified in Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(b) and Subsection E of 20.3.7.714 NMAC, incorporating 10 CFR 35.59, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) the individual is designated as an authorized nuclear pharmacist in accordance with Subparagraph (d) of this paragraph;

(c) may conduct the actions authorized in Subparagraphs (a) and (b) of this paragraph in spite of more restrictive language in license conditions;

(d) may designate a pharmacist (as defined in 20.3.7.7 NMAC) as an authorized nuclear pharmacist if:

(i) the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(ii) the individual practiced at a pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies in non-licensing states, as defined in 20.3.1.7 NMAC, before August 8, 2009, or an earlier date as noticed by the NRC;

(e) may designate a pharmacist (as defined in 20.3.7.7 NMAC) as an authorized nuclear pharmacist if the individual is identified as of May 3, 1995, as an “authorized user” in a nuclear pharmacy license issued by the department under this part; and

(f) shall provide to the Commission a copy of

(i) each individual’s certification by a specialty board whose certification process has been recognized by the Commission [~~department, NRC~~] or agreement state as specified in 10 CFR 35.55(a) [~~Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(a), with the written attestation signed by a~~]

preceptor as required by Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(b)(2); or

- (ii) the Commission [~~department, NRC~~] or agreement state license, or
- (iii) Commission[~~the permit issued by a NRC~~] master material licensee

permit, or

- (iv) the permit issued by a licensee or Commission [~~department, NRC or agreement state licensee, or NRC~~] master materials permittee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

- (v) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies in non-licensing states, as defined in 20.3.1.7 NMAC, before August 8, 2009, or an earlier date as noticed by the NRC; and

- (vi) the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under Items (i) and (iii) of Subparagraph (b) of this paragraph, the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta or photon emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

- (a) perform tests before initial use, periodically and following repair, on each instrument for accuracy, linearity and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

- (b) check each instrument for constancy and proper operation at the beginning of each day of use.

(4) A licensee shall satisfy the labeling requirements in paragraph J(1)(d) of this section [~~Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.~~].

(5) Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.

K. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 20.3.7 NMAC for use as a calibration, transmission or reference source or for the uses listed in 20.3.7.710 NMAC, 20.3.7.711 NMAC and 20.3.7.712 NMAC will be approved if:

- (1) the applicant satisfies the general requirements in 20.3.3.307 NMAC and 20.3.3.308 NMAC; and

- (2) the applicant satisfies the requirements in 10 CFR 32.74.

L. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass-volume applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Subsection E of 20.3.3.304 NMAC or equivalent regulations of the NRC or an agreement state will be approved if:

- (a) the applicant satisfies the general requirements specified in 20.3.3.307 NMAC and 20.3.3.308 NMAC;

- (b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling and marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in one year a radiation dose in excess of ten percent of the limits specified in Subsection A of 20.3.4.405 NMAC; and

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

(2) In the case of an industrial product or device whose unique benefits are questionable, the department will approve an application for a specific license under this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant

quantities of depleted uranium into the environment.

(3) The department may deny application for a specific license under this subsection if the end use of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to this subsection shall:

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

(b) label or mark each unit to:

(i) identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

(ii) state that the receipt, possession, use and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or of an agreement state;

(c) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "*depleted uranium*";

(d) furnish a copy of the general license contained in Subsection C of 20.3.3.304 NMAC and a copy of the department form to each person to whom they transfer depleted uranium in a product or device for use pursuant to the general license contained in Subsection C of 20.3.3.304 NMAC; or furnish a copy of the general license contained in the NRC or agreement state's regulation equivalent to Subsection C of 20.3.3.304 NMAC and a copy of the NRC or agreement state's certificate; or alternatively, furnish a copy of the general license contained in Subsection C of 20.3.3.304 NMAC and a copy of department form to each person to whom they transfer depleted uranium in a product or device for use pursuant to the general license of the NRC or an agreement state, with a note explaining that use of the product or device is regulated by the NRC or an agreement state under requirements substantially the same as those in Subsection C of 20.3.3.304 NMAC;

(e) report to the department all transfers of industrial products or devices to persons for use under the general license in Subsection C of 20.3.3.304 NMAC; such report shall identify each general licensee by name and address, an individual by name and (or) position who may constitute a point of contact between the department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device; the report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person; if no transfers have been made to persons generally licensed under Subsection C of 20.3.3.304 NMAC during the reporting period, the report shall so indicate;

(f) report to the director of the office of nuclear material safety and safeguards, by an appropriate method listed in 10 CFR 40.5 all transfers of industrial products or devices to persons for use under the U.S. nuclear regulatory commission general license in 10 CFR 40.25; the report shall contain all information described in Subparagraph (e) of this paragraph;

(g) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to Subsection L of 20.3.3.315 NMAC for use under a general license in that agreement state's regulations equivalent to Subsection C of 20.3.3.304 NMAC; the report shall contain all information described in Subparagraph (e) of this paragraph;

(h) keep records showing the name, address and point of contact for each general licensee to whom they transfer depleted uranium in industrial products or devices for use pursuant to the general license provided in Subsection C of 20.3.3.304 NMAC or equivalent regulations of the NRC or of an agreement state; the records shall be retained for three years and show the date of each transfer, the quantity of depleted uranium in each product or device transferred and compliance with the report requirements of this subsection.

M. Licensing the manufacture, assembly, repair or distribution of commodities, products or devices which contain radioactive material other than those enumerated above. The department shall require substantially the same information as required for licensing of similar items by 10 CFR Part 32 not specifically named in this section.

N. Serialization of nationally tracked sources. Each licensee who manufactures a nationally tracked source, as defined in 20.3.4.7 NMAC, after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

[20.3.3.315 NMAC - Rp, 20.3.3.315 NMAC, 04/30/2009; A, X/XX/2022]

This is an amendment to 20.3.3.317 NMAC, Sub-Section I effective XX/XX/2022.

20.3.3.317 TERMS AND CONDITIONS OF LICENSES:

A. Each license issued pursuant to the requirements in this part shall be subject to all the provisions of the act, now or hereafter in effect, and to all rules, regulations and orders of the board or department.

(1) No right to the special nuclear material shall be conferred by the license except as defined by the license;

(2) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of 20.3.3.317 NMAC;

(3) The license shall be subject to and the licensee shall observe, all applicable rules, regulations, and orders of the department.

B. No license issued or granted under this part nor any right under a license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily, or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the department shall, after securing full information, find that the transfer is in accordance with the provisions of the act, and shall give its consent in writing. An application for transfer of license must include:

(1) the identity, technical and financial qualifications of the proposed transferee; and

(2) financial assurance for decommissioning information required by 20.3.3.311 NMAC.

C. Each person licensed by the department pursuant to this part shall confine their use and possession of material licensed to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the rules in this part shall carry with it the right to receive, acquire, own and possess radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of 20.3.3.306 NMAC, incorporating 10 CFR 71.

D. Each license issued pursuant to the regulations in this part shall be deemed to contain the applicable provisions set forth in the act and 20.3 NMAC, whether or not these provisions are expressly set forth in the license.

E. Filing for bankruptcy.

(1) Each general licensee that is required to register by Paragraph (m) of Subsection B of 20.3.3.305 NMAC and each specific licensee shall notify the department and appropriate NRC Regional Administrator in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (bankruptcy) of the United States Code by or against:

(a) the licensee;

(b) an entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

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

(2) The notification must indicate:

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

(b) the date of the filing of the petition.

F. The general licenses provided in this part are subject to the provisions in 20.3.1 NMAC, Paragraph (4) of Subsection A of 20.3.3.302 NMAC, Subsection A of 20.3.3.317 NMAC, 20.3.3.322 NMAC, 20.3.3.323 NMAC, 20.3.3.326 NMAC, 20.3.4 NMAC and 20.3.10 NMAC unless indicated otherwise by a particular provision of the general license.

G. Licensees required submitting emergency plans by 20.3.3.309 NMAC shall follow the emergency plan approved by the department. The licensee may change the approved plan without department approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the department and to affected offsite response organizations prior to the effective date of the change. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the department.

H. Security requirements for portable gauges. Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

I. Generators. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 20.3.7.706 NMAC of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the

permissible concentration listed in 10 CFR 35.204(a) at the time of generator elution, in accordance with 10 CFR 35.3204.

J. PET drugs for non-commercial distribution.

(1) Authorization under Subsection J of 20.3.3.307 NMAC to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.

(2) Each licensee authorized under Subsection J of 20.3.3.307 NMAC to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium shall:

(a) satisfy the labeling requirements in Subparagraph (d) of Paragraph (1) of Subsection J of 20.3.3.315 NMAC for each PET radioactive drug transport radiation shield and each syringe, vial or other container used to hold a PET radioactive drug intended for non-commercial distribution to members of its consortium; and

(b) possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for non-commercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check and instrument adjustment requirements in Paragraph (3) of Subsection J of 20.3.3.315 NMAC.

(3) A licensee that is a pharmacy authorized under Subsection J of 20.3.3.307 NMAC to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(a) an authorized nuclear pharmacist that meets the requirements in Subparagraph (b) of Paragraph (2) of Subsection J of 20.3.3.315 NMAC; or

(b) an individual under the supervision of an authorized nuclear pharmacist as specified in Subsection F of 20.3.7.702 NMAC.

(4) A pharmacy, authorized under Subsection J of 20.3.3.307 NMAC to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Subparagraph (e) of Paragraph (2) of Subsection J of 20.3.3.315 NMAC.

[20.3.3.317 NMAC - Rp, 20.3.3.317 NMAC, 4/30/2009; A, 6/30/2011; A, 6/13/2017; A, XX/XX/2022]