This is an amendment to 20.3.3.301 NMAC, Sub-Section C and D effective XX/XX/XXXX.

20.3.3.301 EXEMPTIONS - UNIMPORTANT QUANTITIES OF SOURCE MATERIAL:

A. Any person is exempt from the requirements in this part to the extent that such person receives, possesses, uses, transfers or delivers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than one twentieth of one percent of the mixture, compound, solution or alloy. The exemption contained in this subsection does not include *byproduct material* as defined in Paragraph (2) of Subsection F of 20.3.1.7 NMAC.

B. Any person is exempt from the requirements in this part to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

C. Any person is exempt from the requirements for a license set forth in the Radiation Protection Act, NMSA 1978, Sections 74-3-1 through 16 (1953, as amended through 2003)[~~section 62 of the Atomic Energy~~] and from the regulations in this part and in 10 CFR Parts 19, 20, and 21 to the extent that such person receives, possesses, uses or transfers:

(1) any quantities of thorium contained in:

(a) incandescent gas mantles;

(b) vacuum tubes;

(c) welding rods;

(d) electric lamps for illuminating purposes; provided, that each lamp does not contain more than 50 milligrams of thorium;

(e) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting; provided, that each lamp does not contain more than two grams of thorium;

(f) rare earth metals and compounds, mixtures and products containing not more than one fourth of one percent by weight, thorium, uranium or any combination of these; or

(g) personnel neutron dosimeters; provided, that each dosimeter does not contain more than 50 milligrams of thorium;

(2) source material contained in the following products:

(a) glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze does not contain more than twenty percent by weight source material;

(b) glassware, containing not more than two percent by weight source material or, for glassware manufactured before August 27, 2013, ten percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction;

(c) glass enamel or glass enamel frit containing not more than ten percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983 (On July 25, 1983, the exemption of glass enamel frit was suspended. The exemption was eliminated on September 11, 1984); or

(d) piezoelectric ceramic containing not more than two percent by weight source material;

(3) photographic film, negatives and prints containing uranium or thorium;

(4) any finished product or part fabricated of, or containing, tungsten or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part;

(5) uranium contained in counterweights installed in aircraft, rockets, projectiles and missiles, or stored or handled in connection with installation or removal of such counterweights; provided, that:

(a) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: “depleted uranium.” (the requirements specified in Subparagraphs (a) and (b) of this paragraph need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, “caution - radioactive material - uranium”);

(b) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: “unauthorized alterations prohibited”; (the requirements specified in Subparagraphs (a) and (b) of this paragraph need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, “caution - radioactive material - uranium”);

(c) the exemption contained in this paragraph shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of such counterweights other than repair or restoration of any plating or other covering; and

(d) consistent with 10 CFR 40.56, the counterweights are not manufactured for military purpose using Australian-obligated source material;

(6) natural or depleted uranium metal used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend, “caution - radioactive shielding - uranium” and the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth of an inch (3.2 millimeters);

(7) thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than ten percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, thirty percent by weight of thorium; and that the exemption contained in this paragraph does not authorize either:

(a) the shaping, grinding or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alternation of the lens; or

(b) the receipt, possession, use or transfer of uranium or thorium contained in contact lenses, spectacles, eyepieces in binoculars or other optical instruments;

(8) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

(9) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided, that:

(a) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium-dioxide); and

(b) the thorium content in the nickel-thoria alloy does not exceed four percent by weight.

D. No person may initially transfer for sale or distribution a product containing source material to persons exempt in accordance with 10 CFR 40.13(c), or equivalent regulations of an agreement state, unless authorized by a license issued pursuant to 10 CFR 40.52 to initially transfer such products for sale or distribution.

(1) Persons initially distributing source material in products covered by the exemptions in this paragraph 10 CFR 40.13(c) before August 27, 2013, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the NRC commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

(2) Persons authorized to manufacture, process, or produce these materials or products containing source material by an agreement state, and persons who import finished products of parts, for sale or distribution must be authorized by a license issued pursuant to 10 CFR 40.52 for distribution only and are exempt from the requirements of 10 CFR 19 and 10 CFR 20 [~~20.3.3 NMAC and 20.3.4 NMAC~~], and 10 CFR 40.32(b) and (c).

E. The exemptions in Subsection C of this section do not authorize the manufacture of any of the products described.

[20.3.3.301 NMAC - Rp, 20.3.3.301 NMAC, 4/30/2009; A, XX/XX/XXXX]

This is an amendment to 20.3.3.302 NMAC, Sub-Section C effective XX/XX/XXXX.

20.3.3.302 EXEMPTIONS - RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL:

A. Exempt concentrations.

(1) Except as provided in Paragraphs (3) and (4) of this subsection, any person is exempt from the license requirements in this part to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in 20.3.3.329 NMAC.

(2) This subsection shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(3) A manufacturer, processor or producer of a product or material is exempt from the license requirements in this part to the extent that they transfer radioactive material contained in a product or material in concentrations not in excess of those specified in 20.3.3.329 NMAC and introduced into the product or material by a licensee holding a specific license issued by the NRC expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(4) 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 this subsection or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued pursuant to Paragraph (1) of Subsection A of 20.3.3.315 NMAC.

B. Exempt quantities.

(1) Except as provided in Paragraphs (3) through (5) of this subsection, any person is exempt from the license requirements in this part to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in 20.3.3.330 NMAC.

(2) Any person who possesses byproduct material received or acquired prior to September 25, 1971 under the general license then provided in 10 CFR 31.4 or similar general license of an agreement state, is exempt from the requirements for a license set forth in this part to the extent that such person possesses, uses, transfers or owns byproduct material.

(3) This subsection does not authorize for the purposes of commercial distribution the production, packaging, repackaging or transfer of radioactive material or the incorporation of radioactive material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in 20.3.3.330 NMAC, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this subsection or equivalent regulations of the NRC or an agreement state, except in accordance with a specific license issued by the NRC pursuant to 10 CFR 32.18 which license states that the radioactive material may be transferred by the licensee to persons exempt under this subsection or the equivalent regulations of the NRC or an agreement state.

(5) No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceed the limits set forth in 20.3.3.330 NMAC, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this chapter.

C. Exempt items.

(1) Certain items containing radioactive material. Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in this paragraph, or who desires to initially transfer for sale or distribution such products containing byproduct material, shall apply for a specific license to NRC pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to this paragraph or equivalent NRC or agreement state regulations. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution (specifically licensed by NRC pursuant to 10 CFR 32.14) the following products containing radioactive material, any person is exempt from the license requirements in this part to the extent that such person receives, possesses, uses, transfers, owns or acquires the following products:

(a) timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(i) 25 millicuries (925 megabecquerels) of tritium per timepiece;

(ii) 5 millicuries (185 megabecquerels) of tritium per hand;

(iii) 15 millicuries (555 megabecquerels) of tritium per dial (bezels when used shall be considered as part of the dial);

(iv) 100 microcuries (3.7 megabecquerels) of promethium-147 per watch hand or 200 microcuries (7.4 megabecquerels) of promethium-147 per any other timepiece;

(v) 20 microcuries (0.74 megabecquerel) of promethium-147 per watch hand or 40 microcuries (1.48 megabecquerels) of promethium-147 per other timepiece hand;

(vi) 60 microcuries (2.22 megabecquerels) of promethium-147 per watch dial or 120 microcuries (4.44 megabecquerels) of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

(vii) the levels of radiation from hands and dials containing promethium-147 shall not exceed, when measured through 50 milligrams per square centimeter of absorber: *1)* for wrist watches, 0.1 millirad (1 milligray) per hour at 10 centimeters from any surface; *2)* for pocket watches, 0.1 millirad (1 milligray) per hour at 1 centimeter from any surface; or *3)* for any other timepiece, 0.2 millirad (2 milligray) per hour at 10 centimeters from any surface; or

(viii) 1 microcurie (37 kilobecquerels) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007;

(b) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 megabecquerels) of polonium-210 per device.

(c) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 megabecquerels) of polonium-210 per device or a total of not more than 50 millicuries (1.85 gigabecquerels) of hydrogen-3 (tritium) per device.

(d)[~~**(c)**~~] precision balances containing not more than 1 millicurie (37 megabecquerels) of tritium per balance or not more than 0.5 millicurie (18.5 megabecquerels) of tritium per balance part manufactured before December 17, 2007;

(e)[~~(d)~~] [RESERVED];

(f) **[~~(e)~~]** marine compasses containing not more than 750 millicuries (27.8 gigabecquerels) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 gigabecquerels) of tritium gas manufactured before December 17, 2007;

(g)[~~(f)~~] ionization chamber smoke detectors containing not more than 1 microcurie (37 kilobecquerels) of americium-241 per detector in the form of a foil and designed to protect life and property from fires;

(h)[~~(g)~~] electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material (for purposes of this exemption, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwaves tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents):

(i) 150 millicuries (5.55 gigabecquerels) of tritium per microwave receiver protector tube or 10 millicuries (370 megabecquerels) of tritium per any other electron tube;

(ii) 1 microcurie (37 kilobecquerels) of cobalt-60;

(iii) 5 microcuries (185 kilobecquerels) of nickel-63;

(iv) 30 microcuries (1.11 megabecquerels) of krypton-85;

(v) 5 microcuries (185 kilobecquerels) of cesium-137;

(vi) 30 microcuries (1.11 megabecquerels) of promethium-147; and

provided further, that the levels of radiation from each electron tube containing radioactive materials do not exceed 1 millirad (10 milligray) per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber; and

(i)[~~(h)~~] ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material; provided, that:

(i) each source contains no more than one exempt quantity set forth in 20.3.3.330 NMAC;

(ii) each instrument contains no more than ten exempt quantities; for this requirement, an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 20.3.3.330 NMAC provided that the sum of such fractions shall not exceed unity; and

(iii) for purposes of this subparagraph, 0.05 microcurie (1.85 kilobecquerels) of americium-241 is considered an exempt quantity under 20.3.3.330 NMAC.

(2) Self-luminous products containing tritium, krypton-85, promethium-147 or radium-226.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, promethium-147 or radium-226, and except as provided in Subparagraph (c) of this paragraph, any person is exempt from the license requirements in this part to the extent that such person receives, possesses, uses, transfers, owns or acquires tritium, krypton-85, promethium-147 or radium-226 in self-luminous products manufactured, processed, produced or initially transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR 32.22 which license authorizes the initial transfer of the product for use under this paragraph.

(b) Any person who desires to manufacture, process or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85 or promethium-147 for use pursuant to Subparagraph (a) of this paragraph, shall apply to NRC for a license pursuant to 10 CFR 32.22, and for a certificate of registration in accordance with 10 CFR 32.210, [~~which license states that the product may be transferred by the licensee to persons exempt from the regulations pursuant to Subparagraph (a) of this paragraph or equivalent regulations of the NRC or an agreement state~~].

(c) The exemption in this paragraph does not apply to tritium, krypton-85, promethium-147 or radium-226 used in products primarily for frivolous purposes or in toys or adornments.

(3) Radium-226 acquired previously. Any person is exempt from the licensing requirements in this part to the extent that such person possesses, uses or transfers, articles containing less than 0.1 microcurie (3.7 kilobecquerels) of radium-226 which were acquired prior to May 3, 1995 (the date when these rules were codified).

(4) Gas and aerosol detectors containing radioactive material.

(a) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the licensing requirements in this part to the extent that such person receives, possesses, uses, transfers, owns or acquires byproduct material, in gas and aerosol detectors designed to protect life or property [~~from fires and airborne hazards~~], and manufactured, processed, produced or initially transferred in accordance with a specific license issued by the NRC, pursuant to 10 CFR 32.26, which license authorizes the initial transfer of the product for use under this paragraph. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by the department, agreement state or non-agreement state under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

(b) Any person who desires to manufacture, process or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant to Subparagraph (a) of this paragraph, shall apply for a license to the NRC pursuant to 10 CFR 32.26, [~~which license states that the product may be initially transferred by the licensee to persons exempt from the regulations pursuant to Subparagraph (a)~~] of this paragraph and for a certificate of registration in accordance with 10 CFR 32.210.

(5) Certain industrial devices.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in section 81 of the Atomic Energy Act of 1954, as amended and from the regulations in 10 CFR parts 19, 20, 21, 30 through 36, and 39 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30 of this chapter, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under subparagraph (a) of this

paragraph, should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

D. Radioactive drug - capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

(1) Except as provided in Paragraphs (2) and (3) of this subsection, any person is exempt from the requirements for a license set forth in this part and 20.3.7 NMAC provided that such person receives, possesses, uses, transfers, owns or acquires capsules containing 1microcurie (37 kilobecquerels) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(2) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 20.3.7 NMAC.

(3) Any person who desires to manufacture, prepare, process, produce, package, repackage or transfer for commercial distribution such capsules shall apply for and receive a specific license by NRC pursuant to 10 CFR 32.21.

(4) Nothing in this section relieves persons from complying with applicable FDA, other federal and state requirements governing receipt, administration and use of drugs.

[20.3.3.302 NMAC - Rp, 20.3.3.302 NMAC, 4/30/2009; A, XX/XX/XXXX]

This is an amendment to 20.3.3.304 NMAC, Sub-Section B and F effective XX/XX/XXXX.

20.3.3.304 GENERAL LICENSES - SOURCE MATERIAL:

A. General license to receive title to source material or byproduct material (as defined in Paragraph (2) of Subsection F of 20.3.1.7 NMAC). A general license is hereby issued authorizing the receipt of title to source material or byproduct material (as defined in Paragraph (2) of Subsection F of 20.3.1.7 NMAC) without regard to quantity. This general license does not authorize any person to receive, possess, deliver, use or transfer source material or byproduct material (as defined in Paragraph (2) of Subsection F of 20.3.1.7 NMAC).

B. Small quantities of source material.

A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and federal, state, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under Subsection B of this section may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of August 27, 2013, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the department takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2014, or until the department takes final action on a pending application submitted on or before August 27, 2014, for a specific license for such material; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under Subsection B of this section may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits of Subsection B(1) of this section; or

(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under Subsection B of this section; or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under Subsection B of this section may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

C. Any person who receives, possess, uses, or transfers source material pursuant to the general license in Subsection B of this section:

(1) is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the department in a specific license;

(2) shall not abandon such source material. Source material may be disposed of as follows:

(a) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under a general license to persons receiving the material for permanent disposal.

(b) The recipient of source material transferred under the provisions of this section is exempt from the requirements to obtain a license under this part to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter or in accordance with 20.3.4.433 NMAC.

(3) is subject to the provisions in accordance with 10 CFR 40.1 through 40.10, 10 CFR 40.41(a) through (e), 10 CFR 40.46, 10 CFR 40.51, 10 CFR 40.56, 10 CFR 40.60 through 40.63, 10 CFR 40.71, 10 CFR 40.81, and the equivalent regulations in 20.3.3 NMAC; and

(4) shall not export such source material except in accordance with 10 CFR 110.

D. Any person who receives, possesses, uses, or transfers source material in accordance with subsection B of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the department by an appropriate method

listed in 20.3.1.116 NMAC about such contamination and may consult with the department as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 20.3.4.426.B NMAC.

E. Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in Subsection B of this section is exempt from the provisions of 20.3.10 NMAC, and 20.3.4 NMAC to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 20.3.4.426.A NMAC and 20.3.4.433 NMAC to the extent necessary to meet the provisions of 20.3.3.304.B NMAC. However, this exemption does not apply to any person who also holds a specific license issued under 20.3.3 NMAC.

F. No person may initially transfer or distribute source material to persons generally licensed under Subsection B(1) and (2) of this section, or equivalent regulations of an agreement state, unless authorized by a specific license in accordance with 10 CFR 40.54 [~~and~~] or equivalent provisions of an agreement state [~~regulations under 20.3.3.307 NMAC~~]. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by Subsection A of this section before August 27, 2013, without specific authorization may continue for 1 year beyond this date. Distribution may also be continued until the NRC takes final action on a pending application for a license or license amendment to specifically authorize distribution submitted on or before August 27, 2014.

G. Depleted uranium in industrial products and devices.

(1) A general license is hereby issued to receive, acquire, possess, use or transfer, in accordance with the provisions in Paragraphs (2), (3), (5) and (6) of this subsection, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in Paragraph (1) of this subsection applies only to industrial products or devices which have been manufactured or initially transferred either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to Subsection L of 20.3.3.315 NMAC or in accordance with a specific license issued by the NRC or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the NRC or an agreement state.

(3) Persons who receive, acquire, possess or use depleted uranium pursuant to the general license established by Paragraph (1) of this subsection shall file a form, *registration certificate - use of depleted uranium under general license*, with the department. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on the registration form the following information and such other information as may be required by that form:

(a) name and address of the general licensee;

(b) a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in Paragraph (1) of this subsection and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(c) name and title, address and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in Subparagraph (b) of this paragraph.

(4) The general licensee possessing or using depleted uranium under the general license established by Paragraph (1) of this subsection shall report in writing to the department any changes in information furnished by them in the form *registration certificate-use of depleted uranium under general license*. The report shall be submitted within 30 days after the effective date of such change.

(5) A person, who receives, acquires, possesses or uses depleted uranium pursuant to the general license established by Paragraph (1) of this subsection:

(a) shall not introduce such depleted uranium, in any form, into a chemical, physical or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(b) shall not abandon such depleted uranium;

(c) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 20.3.3.323 NMAC; in the case where the transferee receives the depleted uranium pursuant to the general license established by Paragraph (1) of this subsection, the transferor shall furnish the transferee a copy of this subsection and a copy of the registration form; in cases where the transferee receives the depleted uranium pursuant to a general license contained in the NRC or agreement state's regulation equivalent to this subsection,

Subsection C of 20.3.3.304 NMAC, the transferor shall furnish the transferee a copy of this subsection and a copy of the registration form accompanied by a note explaining that use of the product or device is regulated by the NRC or agreement state under requirements substantially the same as those in this subsection;

(d) shall report in writing, within 30 days of any transfer, to the department the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(e) shall not export such depleted uranium except in accordance with a license issued by the NRC pursuant to 10 CFR 110.

(6) Any person receiving, acquiring, possessing, using or transferring depleted uranium pursuant to the general license established by Paragraph (1) of this subsection is exempt from the requirements of 20.3.4 NMAC and 20.3.10 NMAC with respect to the depleted uranium covered by that general license.

[20.3.3.304 NMAC - Rp, 20.3.3.304 NMAC, 4/30/2009; A, XX/XX/XXXX]

This is an amendment to 20.3.3.305 NMAC, Sub-Section A, B, and C, effective XX/XX/XXXX.

20.3.3.305 GENERAL LICENSES - RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL:

A. Reserved [~~Certain devices and equipment.~~ ~~A general license is hereby issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with the specifications in a specific license issued to the manufacturer by the NRC.~~

~~**(1) Static elimination device.** Devices designed for use as static eliminators which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 megabecquerels) of polonium-210 per device.~~

~~**(2) Ion generating tube.** Devices designed for ionization of air which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 megabecquerels) of polonium-210 per device or a total of not more than 50 millicuries (1.85 gigabecquerels) of hydrogen-3 (tritium) per device.~~

~~**(3)** Devices authorized before October 23, 2012 for use under the general license provided in 10 CFR 31.3 and in this section and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the NRC or an agreement state.~~]

B. Certain detecting, measuring, gauging or controlling devices and certain devices for producing light or an ionized atmosphere.

(1) A general license is hereby issued as required by Subparagraph (m) of Paragraph (3) of this subsection to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state or local government agencies to receive, acquire, possess, use or transfer, in accordance with the provisions of Paragraphs (2), (3), and (4) of this subsection, [~~radioactive~~] byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere, and the device has been registered in the sealed source and device registry.

(2) The general license in Paragraph (1) of this subsection applies only to [~~radioactive~~] byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

(a) a specific license issued by the department pursuant to Subsection E of 20.3.3.315 NMAC; or

(b) an equivalent specific license issued by the NRC or an agreement state; or

(c) an equivalent specific license issued by a state with provisions comparable to Subsection E of 20.3.3.315 NMAC. The devices must have been received from one of the specific licensees described in this paragraph, or through a transfer made under Subparagraph (h) of Paragraph (3) of this subsection.

(3) Any person who receives, acquires, possesses, uses or transfers [~~radioactive~~] byproduct material in a device pursuant to the general license in Paragraph (1) of this subsection shall comply with the following.

(a) The general licensee shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels.

(b) The general licensee shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six month intervals or at such other intervals as are specified in the label; however:

(i) devices containing only krypton need not be tested for leakage of radioactive material; and

(ii) devices containing only tritium or not more than 100 microcuries (3.7 megabecquerels) of other beta or gamma emitting material or 10 microcuries (0.37 megabecquerel) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(c) The general licensee shall assure that the test required by Subparagraph (b) of Paragraph (3) of this subsection and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment are performed:

(i) in accordance with the instructions provided by the labels; or

(ii) by a person holding a specific license pursuant to this part from the department, the NRC, or an agreement state to perform such activities.

(d) The general licensee shall maintain records showing compliance with the requirements of Subparagraphs (b) and (c) of Paragraph (3) of this subsection. The records must show the results of tests. The records must also show the dates of performance of, and the names of persons performing, testing, installing, servicing and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(i) each record of a test for leakage or radioactive material required by Subparagraph (b) of Paragraph (3) of this subsection shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;

(ii) each record of a test of the on-off mechanism and indicator required by Subparagraph (b) of Paragraph (3) of this subsection shall be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of; and

(iii) each record that is required by Subparagraph (c) of Paragraph (3) of this subsection shall be retained for 3 years from the date of the recorded event or until the device is transferred or disposed of.

(e) The general licensee shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcuries (185 becquerels) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued pursuant to this part by the department, the NRC or an agreement state. The device and any radioactive material from the device, shall only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device, or as otherwise approved by the department. A report shall be furnished to the department within 30 days containing a brief description of the event and the remedial action taken. In the case of detection of 0.005 microcurie or more removable radioactive material or failure of, or damage to, a source likely to result in contamination of the premises or the environs, the report shall include a plan for ensuring that the premises and environs are acceptable for unrestricted use. Under these circumstances, the criteria set out in Subsection B of 20.3.4.426 NMAC, *radiological criteria for unrestricted use*, shall be applicable, as determined by the department on a case-by-case basis.

(f) The general licensee shall not abandon the device containing radioactive material.

(g) The general licensee shall not export the device containing radioactive material except in accordance with 10 CFR 110.

(h) Device transfer requirements.

(i) The general licensee shall transfer or dispose of the device containing radioactive material only by export as provided by Subparagraph (g) of this paragraph, by transfer to another general licensee as authorized in Subparagraph (i) of this paragraph , or to a person authorized to receive the device by a specific license issued by the department pursuant under this part, or by a specific license issued by the department authorizing waste collection pursuant to this part, or equivalent provisions of the NRC or an agreement state, or as otherwise approved under Item (iii) of this subparagraph.

(ii) The general licensee shall within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the department at the address indicated in 20.3.1.116 NMAC. The report shall contain the identification of the device by manufacturer's (or initial transferor's) name, model number and serial number; the name, address and license number of the person receiving the device (license number not applicable if exported); and the date of the transfer.

(iii) The general licensee shall obtain written department approval before transferring the device to any other specific licensee not specifically identified in Item (i) of this subparagraph. However, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder: verifies that the specific license authorizes the possession and use, or applies for and obtains amendment to the license authorizing the possession and use; removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by Subparagraph (a) of this paragraph) so that the device is labeled in compliance with 20.3.4.430 NMAC, however, the manufacturer, model number, and serial number must be retained; obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and reports the transfer under Item (ii) of this subparagraph.

(i) The general licensee shall transfer the device to another general licensee only if:

(i) the device remains in use at a particular location, in which case: *1)* the transferor shall give the transferee a copy of this subsection (Subsection B of 20.3.3.305 NMAC), a copy of Subsection F of 20.3.3.317 NMAC, a copy of 20.3.3.326 NMAC, a copy of 20.3.4.451 NMAC, a copy of 20.3.4.452 NMAC and any safety documents identified in the label of the device; *2)* within 30 days of the transfer, the transferor shall report to the department at the address indicated in 20.3.1.116 NMAC, stating the manufacturer's (or initial transferor's) name, the model number and the serial number of the device transferred, the transferee's name and mailing address for the location of use, and the name, title and phone number of the responsible individual identified by the transferee in accordance with Subparagraph (l) of this paragraph to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(ii) the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(j) The general licensee shall comply with the provisions of 20.3.4.451 NMAC and 20.3.4.452 NMAC for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of 20.3.4 NMAC and 20.3.10 NMAC.

(k) The general licensee shall respond to written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the department with a written justification for the request.

(l) The general licensee shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(m) Registration requirements.

(i) The general licensee shall register on a department registration form, in accordance with Items (ii) and (iii) of this subparagraph, devices containing at least 10 millicuries (370 megabecquerels) of cesium-137, 0.1 millicuries (3.7 megabecquerels) of strontium-90, 1 millicurie (37 megabecquerels) of cobalt-60, 0.1 millicurie (3.7 megabecquerels) of radium-226, 1 millicurie (37 megabecquerels) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address of a location of use, as described under Item (iii) of this subparagraph, represents a separate general licensee and requires a separate registration.

(ii) If in possession of a device meeting the criteria of Item (i) of this subparagraph, the general licensee shall register these devices annually with the department. Registration shall be done by verifying, correcting or adding to the information provided in a request for registration received from the department. The registration information shall be submitted to the department within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of Item (i) of this subparagraph is subject to the bankruptcy notification requirement in Subsection E of 20.3.3.317 NMAC.

(iii) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the department: *1)* name and mailing address of the general licensee; *2)* information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label); *3)* name, title and telephone number of the responsible person designated as a representative of the general licensee under Subparagraph (l) of this paragraph; *4)* address or location at which the device(s) are used or stored; for portable devices, the address of the primary place of storage; *5)* certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information; and *6)* certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(iv) Persons generally licensed by the NRC and an agreement state with respect to devices meeting the criteria in Item (i) of this subparagraph are not subject to registration requirements if the devices are used in areas subject to department jurisdiction for a period less than 180 days in any calendar year. The department will not request registration information from such licensees.

(n) The general licensee shall report changes to the mailing address for the location of use (including change in name of general licensee) to the department at the address indicated in 20.3.1.116 NMAC, within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

(o) The general licensee shall not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter shall be locked in the closed position. The testing required by Subparagraph (b) of Paragraph (3) of this subsection need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they shall be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(4) The general license in Paragraph (1) of this subsection does not authorize the manufacture or import of devices containing radioactive material.

C. Luminous safety devices for use in aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(a) each device contains not more than 10 curies (370 gigabecquerels) of tritium or 300 millicuries (11.1 gigabecquerels) of promethium-147; and

(b) each device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions [~~in~~] 10 CFR 32.53 [~~Subsection F of 20.3.3.315 NMAC~~], or manufactured or assembled in accordance with a specific license issued by the NRC [~~or an agreement state which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the NRC or an agreement state~~,] [~~and the device has been registered in the sealed source and device registry~~];

(c) quality assurance procedures are in place that are sufficient to ensure compliance with 10 CFR 32.55; and

(d) prototypes of the device have been subjected to and have satisfactorily passed the tests required in 10 CFR 32.53(e) and outlined in Subsection C(2) of this section.

(2) The applicant [~~Each person licensed under 10 CFR 32.53 or equivalent agreement state regulations~~] shall subject at least five prototypes of the device to tests [~~the required tests and satisfactorily pass the required tests~~] as follows:

(a) the devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering;

(b) the devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subparagraph C(2) of this section; and

(c) the device designs are rejected for which the following has been detected for any unit; a leak resulting in a loss of one tenth of one percent or more of the original amount of tritium or promethium-147 from the device; or surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or any other evidence of physical damage.

(3) Each person licensed under 10 CFR 32.55 or 20.3.3.305(C) NMAC [~~equivalent agreement state regulations~~] shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

(4) Each person licensed under 10 CFR 32.53 or 20.3.3.305(C) NMAC [~~equivalent agreement state regulations~~] shall:

(a) maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(b) subject inspection lots to acceptance sampling procedures, by procedures specified in Subparagraph C(2) of this section and in the license issued under 10 CFR 32.53 or 20.3.3.305(C) NMAC [~~equivalent agreement state regulations~~] to provide at least ninety-five percent confidence that the lot tolerance percent defective of five percent will not be exceeded.

(5) The licensee shall subject each inspection lot to:

(a) tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion; and

(b) inspection [~~inspect the inspection lot~~] for evidence of physical damage, containment failure, or loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective: [~~using the following methods of inspection~~]:

(i) a leak resulting in a loss of one tenth of one percent or more of the original amount of tritium or promethium-147 from the device;

(ii) levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(iii) any other criteria specified in the license issued under 10 CFR 32.53 or 20.3.3.305(C) NMAC ~~[equivalent agreement state regulations~~].

(6) No person licensed under 10 CFR 32.53 or 20.3.3.305(C) NMAC ~~[equivalent agreement state regulations~~] shall transfer [~~the following luminous safety devices~~] to persons generally licensed pursuant to 10 CFR 31.7 or under an equivalent general license of an agreement state:

(a) any luminous safety device tested and found defective under any condition of a license issued under Subsection C of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(b) any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in Subsection C(4)(b) of this section, unless a procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under 10 CFR 32.53 or 20.3.3.305(C) NMAC ~~[equivalent agreement state regulations~~] and each individual sub-lot is sampled, tested, and accepted in accordance with Subsection C(2) of this section and any other criteria that may be required as a condition of the license issued under 10 CFR 32.53 or 20.3.3.305(C) NMAC ~~[equivalent agreement state regulations~~].

(7) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to this general license are exempt from the requirements of 20.3.4 NMAC and 20.3.10 NMAC except that they shall comply with the reporting and notification provisions of 20.3.4.451 NMAC and 20.3.4.452 NMAC.

(8) This general license does not authorize the manufacture, assembly, repair or import of luminous safety containing tritium or promethium-147.

(9) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

(10) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

D. Calibration and reference sources.

(1) A general license is hereby issued to those persons listed in this paragraph to own, receive, acquire, possess, use and transfer, in accordance with the provisions of Paragraphs (4) and (5) of this subsection americium-241 in the form of calibration or reference sources.

(a) Any person who holds a specific license issued by the department which authorizes them to receive, possess, use and transfer radioactive material.

(b) Any government agency, as defined in 20.3.1.7 NMAC, which holds a specific license issued pursuant to this chapter which authorizes it to receive, possess, use and transfer radioactive material.

(2) A general license is hereby issued to those persons listed below to receive title to, own, acquire, deliver, receive, possess, use and transfer in accordance with the provisions of Paragraph (4) and (5) plutonium in the form of calibration or reference sources.

(a) Any person who holds a specific license issued by the department which authorizes them to receive, possess, use and transfer radioactive material.

(b) Any government agency, as defined in 20.3.1.7 NMAC, which holds a specific license issued pursuant to 20.3 NMAC which authorizes it to receive, possess, use and transfer radioactive material.

(c) Any person who holds a specific license issued by the NRC or an agreement state which authorizes them to receive, possess, use and transfer special nuclear material.

(3) A general license is hereby issued to receive, possess, use and transfer radium-226 in the form of calibration or reference sources in accordance with Paragraphs (4) and (5) of this subsection to any person who holds a specific license issued by the department which authorizes them to receive, possess, use and transfer radioactive material.

(4) The general licenses in Paragraphs (1), (2) and (3) of this subsection apply only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued the department pursuant to Subsection G of 20.3.3.315 NMAC or in accordance with the specifications contained in a specific license issued by the NRC or an agreement state pursuant to equivalent licensing requirements which authorizes the manufacturer of the sources for distribution to persons generally licensed by the NRC or an agreement state.

(5) The general licenses provided in Paragraphs (1), (2) and (3) of this subsection are subject to the provisions of Subsection F of 20.3.3.317 NMAC. In addition, persons who receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(a) shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kilobecquerels) of americium-241, 5 microcuries (185 kilobecquerels) of plutonium and 5 microcuries (185 kilobecquerels) of radium-226 in such sources;

(b) shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use and transfer of this source, model _____, serial number _____, are subject to a general license and the regulations of the United States nuclear regulatory commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. Caution - radioactive material - this source contains [describe one of the following radioactive materials americium-241, plutonium or radium-226 as appropriate]. Do not touch radioactive portion of this source.

_____

(name of manufacturer or initial transferor)

(c) shall not transfer, abandon or dispose of such source except by transfer to a person authorized by a license issued by the department, the NRC or an agreement state to receive the source;

(d) shall store such source, except when the source is being used, in a closed container adequately designated and constructed to contain americium-241, plutonium or radium-226 which might otherwise escape during storage; and

(e) shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture or import of calibration or reference sources containing americium-241, plutonium or radium-226.

E. General license to install devices generally licensed in Subsection B of 20.3.3.305 NMAC. Any person who holds a specific license issued by the NRC or an agreement state authorizing the holder to manufacture, install or service a device described in Subsection B of this section within such agreement state issuing the specific license or within a location subject to NRC jurisdiction, is hereby granted a general license to install and service such device in this state; provided, that:

(1) the device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or an agreement state; and

(2) such person assures that any labels required to be affixed to the device under regulations of the NRC or agreement state which licensed manufacture of the device bear a statement that removal of the label is prohibited.

F. General license for use of radioactive material for certain in-vitro clinical or laboratory testing.

(1) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of Paragraphs (2) through (6) of this subsection, the following radioactive materials in prepackaged units, each for use for in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(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, 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; and

(h) mock iodine-125 for use as reference or calibration sources not to exceed 0.05 microcurie (1.85 kilobecquerels) of iodine-129 and 0.005 microcurie (1.85 becquerels) of americium-241 each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by Paragraph (1) of this subsection unless that person

(a) has filed a form, *registration certificate-in vitro testing with radioactive material under general license,* with the department and received from the department a validated copy of the registration certificate with a registration number assigned. The physician, clinical laboratory or hospital shall furnish on the registration certificate the following information and such other information as may be required by the form:

(i) name and address of the physician, clinical laboratory or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in Paragraph (1) of this subsection and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material; or

(b) has a license that authorizes the medical use of radioactive material that was issued under 20.3.7 NMAC.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by Paragraph (1) of this subsection shall comply with the following:

(a) the general licensee shall not possess at any one time, pursuant to the general license in Paragraph (1) of this subsection at any one location of storage or use, a total amount of iodine-125, iodine-131, iron-59, cobalt-57 or selenium-75 in excess of 200 microcuries (7.4 megabecquerels);

(b) the general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;

(c) the general licensee shall use the radioactive material only for the uses authorized by Paragraph (1) of this subsection;

(d) the general licensee shall neither transfer the radioactive material except by transfer to a person authorized to receive it pursuant to a license issued by the department, the NRC or an agreement state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier; and

(e) the general licensee shall dispose of mock iodine reference or calibration sources in accordance with 20.3.4.433 NMAC.

(4) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to Paragraph (1) of this subsection:

(a) except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under Subsection H of 20.3.3.315 NMAC, or in accordance with the provisions of a specific license issued by the NRC or an agreement state, or labeled before November 30, 2007 in accordance with the provisions of a specific license issued by a state with comparable provisions to Subsection H of 20.3.3.315 NMAC, which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, cobalt-57, selenium-75, or mock iodine-125 for distribution to persons generally licensed by the NRC, the agreement state or the state with comparable provisions to Subsection H of 20.3.3.315 NMAC; and

(b) unless 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 shall be received, acquired, possessed and used only by physicians, veterinarians in the practice of veterinary medicine, 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 U.S. nuclear regulatory commission or of a State with which the commission has entered into an agreement for the exercise of regulatory authority.

_____

(name of manufacturer)

(5) The general licensee possessing or using radioactive material under the general license of Paragraph (1) of this subsection shall report in writing to the department, any changes in the information furnished by them in the *certificate-in-vitro testing with radioactive material under general license* form. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of Paragraph (1) of this subsection is exempt from the requirements of 20.3.4 NMAC and 20.3.10 NMAC with respect to radioactive

material covered by that general license except that such person using a mock iodine-125 shall comply with the provisions of 20.3.4.433 NMAC, 20.3.4.451 NMAC and 20.3.4.452 NMAC.

G. General license for strontium 90 in ice detection devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 megabecquerels) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the department, the NRC or an agreement state, which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the department, NRC or an agreement state.

(2) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in Paragraph (1) of this subsection:

(a) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the department, the NRC or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 20.3.4.433 NMAC;

(b) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereof; and

(c) are exempt from the requirement of 20.3.4 NMAC and 20.3.10 NMAC except that such persons shall comply with the provisions of 20.3.4.433 NMAC, 20.3.4.451 NMAC and 20.3.4.452 NMAC.

(3) This general license does not authorize the manufacture, assembly, disassembly, repair or import of strontium-90 in ice detection devices.

H. General license for certain items and self-luminous products containing radium-226.

(1) A general license is hereby issued to any person to acquire, receive, possess, use or transfer, in accordance with the provisions of Paragraphs (2), (3) and (4) of this subsection, radium-226 contained in the following products manufactured prior to November 30, 2007.

(a) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts and healing pads.

(b) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), non-intact timepieces, and timepiece hands and dials no longer installed in timepieces.

(c) Luminous items installed in air, marine or land vehicles.

(d) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

(e) Small radium sources containing no more than 1 microcurie (0.037 megabecquerel) of radium-226. For the purposes of this paragraph, ‘‘small radium sources’’ means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators or as designated by the department or NRC.

(2) Persons who acquire, receive, possess, use or transfer byproduct material under the general license issued in Paragraph (1) of this subsection are exempt from the provisions of 20.3.3.325 NMAC, 20.3.3.326 NMAC, 20.3.4 NMAC and 20.3.10 NMAC to the extent that the receipt, possession, use or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

(3) Any person who acquires, receives, possesses, uses or transfers radioactive material in accordance with the general license in Paragraph (1) of this section shall:

(a) notify the department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the department at the address specified in 20.3.1.116 NMAC within 30 days of the event;

(b) not abandon products containing radium-226; the product, and any radioactive material from the product, may only be disposed of according to 20.3.4.437 NMAC or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the department;

(c) not export products containing radium-226 except in accordance with 10 CFR 110;

(d) dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act, by transfer to a person authorized to receive radium-226 by a specific license issued under this part, or equivalent regulations of the NRC, an agreement state or as otherwise approved by the department or NRC;

(e) respond to written requests from the department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the department a written justification for the request.

(4) The general license in Paragraph (1) of this section does not authorize the manufacture, assembly, disassembly, repair or import of products containing radium-226, except when timepieces may be disassembled and repaired.

I. General license to own radioactive material. A general license is hereby issued to receive title to and own radioactive material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this subsection is not authorized to acquire, deliver, manufacture, produce, transfer, receive, possess, use, import or export radioactive material, except as authorized in a specific license.

[20.3.3.305 NMAC - Rp, 20.3.3.305 NMAC, 04/30/2009; A, XX/XX/XXXX]

This is an amendment to 20.3.3.307 NMAC, Sub-Section E and L effective XX/XX/2020.

20.3.3.307 FILING APPLICATION FOR SPECIFIC LICENSES:

A. Except where otherwise determined by the department, applications for specific licenses shall be filed in duplicate on a form prescribed by the department (*application for a radioactive material license*) in accordance with the instructions to the form. Additional copies of the application may be required by the department. Information contained in previous application, statements or reports filed with the department may be incorporated by reference, provided that the reference is clear and specific.

B. The department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the department to determine whether the application shall be granted or denied or whether a license shall be modified or revoked.

C. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on their behalf.

D. An application for a license may include a request for a license authorizing more than one activity, provided that the application specifies the additional activities for which licenses are requested and complies with the requirements in this chapter as to applications for such licenses. In such cases, annual fees for all types of activities authorized by the license may be charged as determined by 20.3.16 NMAC.

E. An application for a specific license of category 1 and category 2 quantities of radioactive material shall comply with 10 CFR 37. The licensee shall comply with 10 CFR 37 except as follows:

(1) any reference to the commission or NRC shall be deemed a reference to the department;

(2) 10 CFR 37.5 definitions of agreement state, byproduct material, commission and person shall not be applicable;

(3) 10 CFR 37.7, 10 CFR 37.9, 10 CFR 37.11(a) and (b), 10 CFR 37.13, 10 CFR 37.27(c), 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable; and

(4) the license required report of events or notification in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81 shall use the following address: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469.

F. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must identify the source and (or) the device by manufacturer name and model number as registered with the *sealed source and device registry*.

(1) Except as provided in Subsection (F)(2), (F)(3), and (F)(4) of this section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either:

(a) identify the source or device by manufacturer and model number registered with the NRC pursuant to 10 CFR 32.210, with an agreement state, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a state under provisions comparable to 10 CFR 32.210; or

(b) contain the information identified in 10 CFR 32.210(c).

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the NRC under 10 CFR 32.210 or with an agreement state, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the application must include:

(a) all available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

(b) sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

G. As provided by 20.3.3.311 NMAC, certain applications for a new or renewal specific license must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

H. An application for a license to receive and possess radioactive material for the conduct of any activity which the department has determined pursuant to Subpart A of 10 CFR 51 will significantly affect the

quality of the environment shall be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by an environmental impact report required pursuant to Subpart A of 10 CFR 51.

I. None of the following applications shall be accepted for review unless it is accompanied by an environmental impact report, submitted by the applicant, that specifically addresses the short-term and long-term environmental, radiological and public health and safety aspects of the applications and alternatives to the proposed action:

(1) an initial application for a radioactive material license for a commercial radioactive waste disposal site license;

(2) the first renewal of any such license not previously accompanied by an environmental impact report;

(3) an application for an amendment to an existing license that may result in additional significant impacts from radiation on the environment or public health or safety beyond those impacts addressed in the existing license and accompanying documents; and

(4) any other application that the secretary determines may have significant impacts from radiation on the environment or public health or safety.

J. The application for a radioactive material license for a commercial radioactive waste disposal site, or for any renewal thereof, or for an amendment thereto as described in Paragraph (3) of Subsection H of this section, shall demonstrate that the activity for which such license is requested will comply with all laws and regulations enforceable by the department.

K. An application from a medical facility or educational institution to produce PET radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 20.3.7 NMAC shall include:

(1) a request for authorization for the production of PET radionuclides or evidence of an existing license issued under 20.3.3 NMAC or under equivalent NRC or agreement state requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides;

(2) evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in Subparagraph (b) of Paragraph (1) of Subsection J of 20.3.3.315 NMAC;

(3) identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in Subparagraph (b) of Paragraph (2) of Subsection J of 20.3.3.315 NMAC; and

(4) information identified in Subparagraph (c) of Paragraph (1) of Subsection J of 20.3.3.315 NMAC on the PET drugs to be non-commercially transferred to members of its consortium.

L. An application for a specific license to transfer source material under this section [~~10 CFR 40~~].

(1) An application for a specific license to initially transfer source material for use under [~~10 CFR 40.22, and equivalent regulations~~] 20.3.3.307 [~~20.3.3.304.B~~] NMAC, will be approved if:

(a) the applicant satisfies the general requirements specified in this section [~~10 CFR 40.32 and equivalent regulations 20.3.3.307 NMAC~~]; and

(b) the applicant submits adequate information on, and the department [~~NRC~~] approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

(2) Each person licensed under this section [~~10 CFR 40.54~~] shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "radioactive material."

(3) Each person licensed under this section [~~10 CFR 40.54~~] shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(4) Each person licensed under this section [~~10 CFR 40.54~~] shall provide the information specified in this paragraph to each person to whom source material is transferred for use under this section [~~10 CFR 40.22 and 20.3.3.304.B NMAC~~]. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(a) a copy of 20.3.3.304.B NMAC[~~10 CFR 40.22~~] and 10 CFR 40.51 or equivalent regulations under 20.3.3.307.L [~~20.3.3.304~~] NMAC; and

(b) appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(5) Each person licensed under this section [~~10 CFR 40.54~~] shall report transfers as follows:

(a) File a report with the department under 20.3.1.116 NMAC. The report shall include the following information:

(i) The name, address, and license number of the person who transferred the source material; and

(ii) For each general licensee under 10 CFR 40.22 or [~~and~~] 20.3.3.304 [~~20.3.3.307~~] NMAC to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(b) File a report with each responsible agreement state agency that identifies all persons, operating under the provisions equivalent to 10 CFR 40.22, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the agreement state:

(i) The name, address, and license number of the person who transferred the source material;

(ii) The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(iii) The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the Agreement State.

(c) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 10 CFR 40.22 or equivalent agreement state provisions during the current period, a report shall be submitted to the NRC indicating so. If no transfers have been made to general licensees in a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon request of the agency.

(d) Each person licensed under 20.3.3.304 NMAC [~~10 CFR 40.54~~] shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the NRC or to an agreement state agency.

[20.3.3.307 NMAC - Rp, 20.3.3.307 NMAC, 04/30/2009; A, XX/XX/XXXX]

This is an amendment to 20.3.3.315 NMAC, Sub-Section C and F effective XX/XX/XXXX.

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, repackage 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.

(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) If a device containing radioactive material is to be transferred for use under the general license contained in Subsection B of 20.3.3.305 NMAC, each person that is licensed under Paragraph (1) of Subsection D of 20.3.3.315 NMAC shall provide the information specified in this paragraph 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 general license contained in Paragraph (1) of Subsection D of 20.3.3.315 NMAC; if Subparagraphs (b) through (d) of Paragraph (3) of Subsection B of 20.3.3.305 NMAC or Subparagraph (m) of Paragraph (3) of Subsection B of 20.3.3.305 NMAC do not apply to the particular device, those paragraphs may be omitted;

(ii) a copy of Subsection F of 20.3.3.317 NMAC, 20.3.3.326 NMAC, 20.3.4.451 NMAC and 20.3.4.452 NMAC;

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

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

(v) a statement indicating that improper disposal of radioactive material is subject to civil and criminal penalties pursuant to 20.3.1 NMAC.

(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 has been made under Subsection E of 20.3.3.317 NMAC 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 Subparagraph (c) of Paragraph (5) of Subsection D of 20.3.3.315 NMAC.

(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 [~~federal and state materials and environmental management programs~~], 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:

(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.

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(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 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.

(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 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 department a copy of

(i) each individual's certification by a specialty board whose certification process has been recognized by the department, NRC or agreement state as specified in 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 department, NRC or agreement state license, or

(iii) the permit issued by a NRC master material licensee, or

(iv) the permit issued by a 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) 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, XX/XX/XXXX]