This is an amendment to 20.3.1 NMAC, Section 7, effective 8/10/2021.

20.3.1.7 DEFINITIONS: As used in these regulations, these terms have the definitions as set forth below.

A. "Accelerator" (See particle accelerator).

B. "Accelerator produced material" means any material made radioactive by exposure to radiation from a particle accelerator.

C. "Act" means the Radiation Protection Act (Sections 74-3-1 through 74-3-16, NMSA 1978).

D. "Agreement state" means any state with which the United States nuclear regulatory commission (NRC) or the United States atomic energy commission (AEC) has entered into an effective agreement under Section 274b of the Atomic Energy Act, as amended (73 Stat. 689).

E. "Board" means the environmental improvement board.

F. "Byproduct material" means:

(1) any radioactive material, (except special nuclear material), yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

(2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes; underground ore bodies depleted by these solution extraction operations do not constitute byproduct material within this definition;

(3) any discrete source of radium-226 that is produced, extracted or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical or research activity;

(4) any material that:

(a) has been made radioactive by use of a particle accelerator; and

(b) is produced, extracted or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical or research activity; or

(5) any discrete source of naturally occurring radioactive material, other than source material, that

(a) NRC, in consultation with the administrator of the environmental protection agency (EPA), the secretary of energy, the secretary of homeland security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(b) before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical or research activity.

G. "Calibration" means the quantitative evaluation and adjustment, as deemed necessary by the department, of radiation measuring instruments by a department approved laboratory. Calibration includes the determination of:

(1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or

(2) the strength of a source of radiation relative to a standard using national institute of standards and technology (NIST) traceable sources and approved techniques.

H. "CFR" means code of federal regulations.

I. "Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid and polycarboxylic acids.

J. "Commercial waste disposal" means disposal of radioactive waste as a business enterprise.

K. "Consortium" means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

L. "Council" means the radiation technical advisory council (RTAC).

M. "Curie" means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

N. "Cyclotron" means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

O. **"Decommission"** means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

(1) release of the property for unrestricted use and termination of the license; or

(2) release of the property under restricted conditions and termination of the license.

P. **"Department"** means the environment department, its successors, or its predecessors, the environmental improvement agency, or the environmental protection [~~improvement~~] division of the [~~health and environment~~] environment department.

Q. **"Depleted uranium"** means the source material uranium which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

R. **"Discrete source"** means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical or research activities.

S. **"DOE"** means the United States department of energy established by the Department of Energy Organization Act (Public Law 95-91, 91 Stat. 565, 42 U.S.C. 7101 et. seq.) to the extent that the DOE, or its duly authorized representatives, exercises functions formerly vested in the United States atomic energy commission (AEC), its chairman, members, officers and components and transferred to the United States energy research and development administration (ERDA) and to the administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act (Public Law 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the secretary of energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

T. **"DOT"** means the United States department of transportation.

U. **"EPA"** means the United States environmental protection agency.

V. **"FDA"** means the United States food and drug administration.

W. **"Former U.S. atomic energy commission (AEC) or NRC licensed facilities"** means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants or critical mass experimental facilities where AEC or NRC licenses have been terminated.

X. **"Government agency"** means any state or federal executive department, commission, independent establishment, corporation, wholly or partly owned by any state or the United States of America which is an instrumentality of the state or United States, or any board, bureau, division, service, office, officer, authority, administration or other establishment in the executive branch of the government.

Y. **"Hazardous waste"** means those wastes designated as hazardous by EPA regulations in 40 CFR Part 261.

Z. **"Healing arts"** means those professional disciplines authorized by the laws of this state to use x-rays or radioactive material in the diagnosis or treatment of human or animal disease.

AA. **"Human use"** means the internal or external administration of radiation or radioactive material to human beings for the purpose of medical diagnosis or therapy.

BB. **"Individual"** means any human being.

CC. **"Inspection"** means an official examination or observation including, but not limited to, tests, surveys and monitoring to determine compliance with rules, regulations, orders, requirements and license or registration conditions of the department.

DD. **"License"** means a license issued by the department in accordance with 20.3 NMAC.

EE. **"Licensed material"** means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the department.

FF. **"Licensee"** means the holder of a license.

GG. **"Licensing state"** means any state with regulations equivalent to the suggested state regulations for control of radiation (SSRCR) relating to, and an effective program for, the regulatory control of NARM (as defined in 20.3.1.7 NMAC) and which has been granted final designation by the conference of radiation control program directors, incorporated (CRCPD).

HH. **"Lost or missing licensed material"** means licensed material whose location is unknown. This definition includes, but is not limited to, material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

II. **"Major processor"** means a user processing, handling or manufacturing radioactive material exceeding type A quantities as unsealed sources or material, or exceeding 4 times type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers or small industrial programs. Type A and B quantities are defined in 10 CFR Part 71.4.

JJ. **"Mixed waste"** contains both hazardous waste (as defined by Resource Conservation and Recovery Act (RCRA) and its amendments) and radioactive waste (as defined by Atomic Energy Act (AEA) and its

amendments). It is jointly regulated by NRC or NRC's agreement states and EPA or EPA's RCRA authorized states. The fundamental and most comprehensive statutory definition is found in the Federal Facilities Compliance Act (FFCA) where Section 1004(41) was added to RCRA: "The term 'mixed waste' means waste that contains both hazardous waste and source, special nuclear, or byproduct material subject to the Atomic Energy Act."

KK. "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include source or special nuclear material.

LL. "Natural radioactivity" means radioactivity of naturally occurring nuclides.

MM. "NRC" means the United States nuclear regulatory commission or its duly authorized representatives.

NN. "Ore refineries" means all processors of a radioactive material ore including uranium mills or other source material extraction facilities.

OO. "Particle accelerator" (accelerator) means any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term. Particle accelerators which intentionally produce radioactive materials or produce radioactive materials incidental to the operation of an accelerator shall be subject to the licensing requirements in 20.3.3 NMAC. Particle accelerators which produce radiation for research, diagnostic or therapeutic purposes shall be subject to the registration requirements in 20.3.2 and 20.3.9 NMAC.

PP. "Person" means:

(1) any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than NRC or DOE, any state or any political subdivision of or any political entity within a state, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) any legal successor, representative, agent or agency of the foregoing.

QQ. "PET" means positron emission tomography.

RR. "Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs; for example, individuals certified in the appropriate field by the American board of radiology (ABR), or the American board of health physics (ABHP), or the American board of medical physics (ABMP) or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy; for example, individuals certified in therapeutic radiological physics or x-ray and radium physics by the ABR, or those having equivalent qualifications. With reference to providing medical physics services to certified mammographic facilities, such individuals must meet the requirements as defined by the FDA.

SS. "Radiation" (ionizing radiation), as used in this chapter, means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons and other particles capable of producing ions. Radiation, as used in this chapter, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared or ultraviolet light.

TT. "Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

UU. "Radiation safety officer" means one who has the knowledge and responsibility to apply appropriate radiation protection regulations.

VV. "Radioactive material" means any material in any physical or chemical form which emits radiation spontaneously.

WW. "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

XX. "Radioisotope" (see radioactive material).

YY. "Radionuclide" (see radioactive material).

ZZ. "Registrant" means a holder of a registration and any person who is registered or legally obligated to register with the department pursuant to 20.3.2 NMAC or 20.3.9 NMAC.

AAA. "Registration" (certificate of registration) means a registration issued by the department pursuant to 20.3.2 NMAC or 20.3.9 NMAC.

BBB. "Regulation" means any rule adopted pursuant to the act.

CCC. "Regulations of the U.S. department of transportation" (DOT) means the regulations in 49 CFR Parts 100-185.

DDD. "Research and development" means:

(1) theoretical analysis, exploration or experimentation; or

(2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

EEE. "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

FFF. "Sealed source and device registry" means the national registry that contains all the registration certificates, generated by both NRC and the agreement states that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

GGG. "Secretary" means the secretary of the New Mexico environment department.

HHH. "SI" means the international system of units.

III. "Site boundary" means that line beyond which the land or property is not owned, leased or otherwise controlled by the licensee or registrant.

JJJ. "Source material" means:

(1) uranium or thorium, or any combination thereof, in any physical or chemical form; or

(2) ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium or any combination thereof; source material does not include special nuclear material.

KKK. "Source material milling" means any activity which results in the production of byproduct as defined in Paragraph (2) of Subsection F of this section.

LLL. "Source of radiation" means any radioactive material, device or equipment emitting or capable of producing radiation.

MMM. "Special form radioactive material" means radioactive material that satisfies the conditions in 10 CFR 71.75

NNN. "Special nuclear material" means:

(1) plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the NRC, pursuant to the provisions of Section 51 of the Atomic Energy Act determines to be special nuclear material, but does not include source material; or

(2) any material artificially enriched by any of the foregoing but does not include source material.

OOO. "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams or any combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1 (i.e. unity). For example, the following quantities in combination would not exceed the limitation and are within the formula: 175 (grams contained U-235)/350 + 50 (grams U-233)/200 + 50 (grams Pu)/200 = 1.

PPP. "Test" means a method for determining the characteristics of conditions of sources of radiation or components thereof.

QQQ. "These regulations" means all parts of 20.3 NMAC.

RRR. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing such as grinding, roasting, beneficiating or refining.

SSS. "Waste" (radioactive waste) means those low-level radioactive wastes containing radioactive material which is acceptable for disposal in a land disposal facility. For the purposes of this chapter, excluded from the definition of "waste" are:

(1) high-level radioactive waste or spent nuclear fuel as defined in section 2 of the Nuclear Waste Policy Act;

(2) transuranic waste as defined in section 11.(ee) of the Atomic Energy Act; or

(3) byproduct material as defined in Paragraphs (2), (3), (4) and (5) of the definition of *byproduct material* set forth in this section.

[20.3.1.7 NMAC - Rp, 20.3.1.7 NMAC, 4/30/2009; A, 6/13/2017; A, 8/10/2021]

This is an amendment to 20.3.3 NMAC, Sections 7, 301, 302, 304, 305, 306, 307, 310 and 315 effective 8/10/2021

20.3.3.7 DEFINITIONS:

A. "Alert" means events that may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

B. "Principal activities" means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

C. "Site area emergency" means events that may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

D. "Indian [~~tribe~~] Tribe" means an Indian or Alaska native [~~tribe~~] Tribe, band, nation, pueblo, village, or community that the secretary of the interior acknowledges to exist as an Indian [~~tribe~~] Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

E. "Tribal official" means the highest ranking individual that represents [~~tribe~~] Tribe leadership, such as the chief, president, or [~~tribe~~] Tribe council leadership.

F. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting or beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

[20.3.3.7 NMAC - N, 4/30/2009; A, 6/13/2017; A, 8/10/2021]

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 [~~section 62 of the Atomic Energy~~] the Radiation Protection Act, Sections 74-3-1 through 16 NMSA 1978 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, 8/10/2021]

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, a 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 1 microcurie (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, 8/10/2021]

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 Paragraph (1) and (2) 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 a 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 a 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, 8/10/2021]

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 <u>use in</u> 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;

(b) each device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions [~~in Subsection F of 20.3.3.315~~ NMAC] <u>10 CFR 32.53</u>, 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) [~~Each person licensed under 10 CFR 32.53 or equivalent agreement state regulations~~] <u>The applicant</u> shall subject at least five prototypes of the device to [~~the required tests and satisfactorily pass the required tests~~] <u>tests</u> 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 ~~[equivalent agreement state regulations]~~ 20.3.3.305(C) NMAC 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 ~~[equivalent agreement state regulations]~~ 20.3.3.305(C) NMAC 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 ~~[equivalent agreement state regulations]~~ 20.3.3.305(C) NMAC 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) [~~inspect the inspection lot~~] inspection for evidence of physical damage, containment failure, or loss of tritium or promethium-147 after each stage of testing, [~~using the following methods of inspection~~] using methods of inspection adequate for applying the following criteria for defective:

(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 ~~[equivalent agreement state regulations]~~ Subsection C of 20.3.3.305 NMAC.

(6) No person licensed under 10 CFR 32.53 or ~~[equivalent agreement state regulations]~~ Subsection C of 20.3.3.305 NMAC 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 ~~[equivalent agreement state regulations]~~ Subsection C of 20.3.3.305 NMAC 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 ~~[equivalent agreement state regulations]~~ Subsection C of 20.3.3.305 NMAC.

(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, 4/30/2009; A, 8/10/2021]

20.3.3.306 TRANSPORTATION OF RADIOACTIVE MATERIAL:

A. Except as specified in Subsection D of this section, the regulations of the United States NRC set forth in 10 CFR 71 are hereby incorporated by reference.

B. Shipment and transport of radioactive material shall be in accordance with the provisions of Subsection A of this section.

C. The following modifications are made to the incorporated federal regulations in this section:

(1) **"commission"** means the [~~department or~~] NRC except a specified in subsection (4) below;

(2) **"act"** means the Radiation Protection Act, Sections 74-3-1 through 74-3-16 NMSA 1978; and

(3) **"byproduct material"** means radioactive material as defined in 20.3.1.7 NMAC.

(4) all reference in 10 CFR 71 to "commission" are changed to Department as follows: 71.17(a), 71.17(b), 71.21, 71.91(b), 71.91(c), 71.91(d), 71.101(c)(1), 71.106(a), 71.106(a)(1), 71.106(b) and 71.106(b)(1).

(5) all reference in 10 CRF 71 to "certificate holder", "applicant" and "applicant for a certificate of compliance (COC)" apply to the NRC as follows 71.91(c), 71.91(d), 71.101(a), 71.101(b), 71.103(a) and 71.135.

D. The following provisions contained in 10 CFR 71 are applicable to the NRC and not incorporated in this section: 71.11, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71.85(a)-(c), 71.91(b), 71.101(c)(2), (d), and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125.

[20.3.3.306 NMAC - Rp, 20.3.3.306 NMAC & 20.3.3.325 NMAC, 4/30/2009; A, 6/30/2011, A, 8/10/2021]

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 a re 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~~] Paragraph (2), (3) and (4) of this Subsection, 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 [~~10 CFR 40~~] this section.

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

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

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

(2) Each person licensed under [~~10 CFR 40.54~~] this section 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 [~~10 CFR 40.54~~] this section shall ensure that the quantities

and concentrations of source material are as labeled and indicated in any transfer records.

(4) Each person licensed under [~~10 CFR 40.54~~] this section shall provide the information specified in this paragraph to each person to whom source material is transferred for use under [~~10 CFR 40.22 and 20.3.3.304.B NMAC~~] this section. 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 [~~10 CFR 40.22~~] 20.3.3.304.B NMAC and 10 CFR 40.51 or equivalent regulations under [~~20.3.3.304~~] Subsection L of 20.3.3.307 NMAC; and

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

(5) Each person licensed under [~~10 CFR 40.54~~] this section 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 [~~and~~] or [~~20.3.3.307~~] 20.3.3.304 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 [~~10 CFR 40.54~~] 20.3.3.304 NMAC 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, 4/30/2009; A, 8/10/2021]

20.3.3.310 PUBLIC NOTICE, PARTICIPATION AND HEARING:

A. Within 60 days following:

(1) initial receipt of a new license application, or each additional submission of information by the applicant, the secretary will either accept the application for a new license for a review and give notice pursuant to Subsection B of this section, or notify the applicant in writing of any deficiencies in the application that must be corrected in order for the application to be accepted for review;

(2) a license amendment or license renewal application requesting a change of the location where radioactive material will be stored or used, the secretary will issue notices pursuant to Subsection B of this section;

(3) a license amendment or license renewal application requesting a change of principal activity, the secretary will issue notices pursuant to Subsection B of this section.

B. Notices. The secretary shall give a notice of acceptance of a new application, license amendment or renewal license application described in Subsection A of this section:

(1) to the applicant, by certified mail; and

(2) to the public, by the publication of a notice in at least one newspaper of general circulation in the area of the proposed activity in the license application, and in other newspapers as deemed appropriate by the secretary;

(3) the secretary shall make a good faith effort to notify of acceptance of a new application, license amendment or renewal license application described in of Subsection A of this section by first-class mail:

(a) any local, state, Indian [~~tribal~~] Tribal government or federal government agency that the secretary determines may be significantly affected or interested; and

(b) any other person who, prior to such notice, has requested in writing such notices.

C. The notice specified in Paragraph (2) of Subsection B of this section shall include:

(1) the name and address of the applicant;

(2) the location of the proposed activity;

(3) a brief description of the procedures to be followed by the secretary in making a final determination;

(4) a brief description of the proposed activity;

(5) the time within which written comments and requests for public hearings will be accepted; and

(6) the means by which interested persons may obtain further information;

(7) the following sample notice satisfies the requirements of this section:

PUBLIC NOTICE

The New Mexico Environment Department (the Department) has received an application for a Radioactive Material License from_____(company name and address) for _____(proposed activity) to be located at _____(location).

During the early part of the evaluation period, the Department will review and comment upon the application. The NMED may, at its discretion, retain consultants to assist it in its evaluation of the application. Relevant comments and questions received by the NMED from various agencies and interested parties will be forwarded to the applicant for its response. Correspondence associated with the application will be on file with the Radiation Control Bureau and will be available for inspection by the applicant and any other interested parties.

The Department has required the applicant to provide complete plans and other materials addressing, among other things, the public health, safety and environmental aspects of the proposed activity.

The Department will analyze the license application carefully. During this analysis, the application will be reviewed to ensure that there are no deficiencies, that the application meets all applicable requirements and that there is no reason to believe that the operation will violate any laws or regulations. If the Department is so satisfied, it will issue a Radioactive Material License, to expire in five years.

The activities of all licensees are inspected periodically to assure compliance with regulations and license conditions.

The application is available for review at NMED's offices of the Radiation Control Bureau in Santa Fe, New Mexico.

It is anticipated that the review period will require about _____ months. Written comments and requests for public hearing will be accepted for _____ days after publication of this notice.

Written comments regarding this license application should be directed to Radiation Control Bureau, Environment Department, P.O. Box 5469, Santa Fe, New Mexico 87502-5469.

D. The department shall maintain all licensees' administrative record, which shall be available for public inspection at the department office in Santa Fe.

E. Public comment period.

(1) Following the notice pursuant to Subsections B and C of this section and prior to ruling on any new application, or amendment request or renewal license application of the type described in Subsection A of this section, the secretary shall allow for a period of at least 30 days during which written comments or questions about the license application may be submitted by any interested person. If the secretary determines that the questions are relevant to the requirements in 20.3.3.307 NMAC, 20.3.3.308 NMAC and any specific requirements for the type of license requested, the secretary shall require the applicant to answer them.

(2) Following the notice of acceptance of the license application pursuant to Subsections A through C of this section and prior to ruling on any application required to be accompanied by an environmental report pursuant to Subsection H of 20.3.3.307 NMAC, the secretary shall allow a period of at least 60 days during which written comments or questions may be submitted by any interested person. If the secretary determines that the

questions are relevant to the considerations enumerated in Subsection H of 20.3.3.307 NMAC or 20.3.3.308 NMAC, the secretary shall require the applicant to answer them.
The secretary may allow an additional written comment period upon submission of additional information to the license application, amendment request or renewal license application described by Subsection A of this section by the applicant, or upon request by members of the public. A written request for a hearing may be made by the members of the public within the time period specified in the public notice described in Subsection C of this section.

F. If the secretary determines that there is significant public interest, or that there is a need to resolve issues not resolvable in writing, the secretary shall order a public hearing be held to provide guidance on any issue relevant to the license proceeding. Notice of the public hearing shall be given at least 30 days prior to the hearing to the persons and in the manner specified in Subsection C of 20.1.4.200 NMAC. Any such public hearing shall be conducted pursuant to the hearing procedures in 20.1.4 NMAC.

[20.3.3.310 NMAC - Rp, 20.3.3.310 NMAC, 4/30/2009; A, 6/13/2017, 8/10/2021]

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.

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

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

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

(3) Authorizations for general licensees to perform certain activities. In the event the applicant desires that the general licensee under Subsection B of 20.3.3.305 NMAC, or under equivalent regulations of the NRC or an agreement state, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator or remove

the device from installation, the applicant shall include in its application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities and the bases for such estimates. The submitted information must demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license, is unlikely to cause that individual to receive a yearly dose in excess of ten percent of the limits specified in Subsection A of 20.3.4.405 NMAC.

(4) Transfer provisions:

(a) [~~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.~~] [Reserved]

(b) If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an agreement state, each person that is licensed under this subsection shall provide the information specified in this subparagraph to each person to whom a device is to be transferred. This information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

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

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

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

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

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

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

(e) If a notification of bankruptcy [~~has been made~~] is submitted under Subsection E of 20.3.3.317 NMAC of this part and each specific licensee or the license is to be terminated, each person licensed under Paragraph (1) of this subsection shall provide, upon request, to the department, NRC and any agreement state, records of final disposition required under [~~Subparagraph (c) of Paragraph (5) of Subsection D of 20.3.3.315 NMAC~~] 10 CFR 30.34(h).

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

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

legible, submitted on a quarterly basis containing all of the following data.

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

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

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

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

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

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

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

(b) The person shall report all transfers of devices to persons for use under a general license under NRC's or an agreement state's regulations that are equivalent to Subsection B of 20.3.3.305 NMAC, and all receipts of devices from general licensees in the NRC's or agreement state's jurisdiction, to the responsible NRC or agreement state agency. The report shall be clear and legible, containing all of the data required as described below.

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

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

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

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

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

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

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

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by Subparagraphs (a) and (b) of this paragraph. Records required by this

paragraph shall be maintained for a period of three years following the date of the recorded event.

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

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

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

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

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

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

(1) the applicant satisfies the general requirements of 20.3.3.307 NMAC and 20.3.3.308 NMAC, and

(2) the applicant satisfies the requirements of 10 CFR 32.57, 10 CFR 32.58, 10 CFR 32.59 and 10 CFR 70.39 or their equivalent.

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

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

(2) the radioactive material is to be prepared for distribution in prepackaged units of:

(a) iodine-125 in units not exceeding 10 microcuries (370 kilobecquerels) each;

(b) iodine-131 in units not exceeding 10 microcuries (370 kilobecquerels) each;

(c) carbon-14 in units not exceeding 10 microcuries (370 kilobecquerels) each;

(d) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 megabecquerels) each;

(e) iron-59 in units not exceeding 20 microcuries (740 kilobecquerels) each;

(f) cobalt-57 in units not exceeding 10 microcuries (370 kilobecquerels) each;

(g) selenium-75 in units not exceeding 10 microcuries (370 kilobecquerels) each; or

(h) mock iodine-125 reference or calibration sources in units not exceeding 0.05 microcurie (1.85 kilobecquerels) of iodine-129 and 0.005 microcurie (185 becquerels) of americium-241 each;

(3) each prepackaged unit bears a durable, clearly visible label:

(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kilobecquerels) of iodine-125, iodine-131, carbon-14, cobalt-57 or selenium-75; 50 microcuries (1.85 megabecquerels) of hydrogen-3 (tritium); 20 microcuries (740 kilobecquerels) of iron-59; or 0.05 microcurie (1.85 kilobecquerels) of iodine-129 and 0.005 microcurie (185 becquerels) of americium-241; and

(b) displaying the radiation caution symbol described in Paragraph (1) of Subsection A of 20.3.4.427 NMAC and the words, "*caution, radioactive material*" and "*not for internal or external use in*

humans or animals";

(4) the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in-vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the United States nuclear regulatory commission or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

_____

(name of manufacturer); and

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

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

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

(2) the criteria of 10 CFR 32.61 and 32.62 are met.

J. Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing 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~~] 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~~] 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, 4/30/2009; A, 8/10/2021]

This is an amendment to 20.3.4 NMAC, Sections 425, 462 and 466, effective 8/10/2021.

20.3.4.425 SECURITY AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION:

A. The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The licensee possessing category 1 and category 2 quantities of radioactive materials 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 37.71, 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable; and

(4) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81, the licensee shall use the following address when applicable: New Mexico environment department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.

B. The licensee shall control and maintain constant surveillance, and use devices or administrative procedures to prevent unauthorized access to licensed radioactive material that is in a controlled or unrestricted area and that is not in storage.

C. The registrant shall secure registered radiation machines from unauthorized removal.

D. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

[20.3.4.425 NMAC - Rp, 20.3.4.425 NMAC, 04/30/2009; A, 8/10/2021]

20.3.4.462 APPENDIX C - QUANTITIES[1] OF LICENSED MATERIAL REQUIRING LABELING:

A. Table 462.1.

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Hydrogen-3	1,000
Beryllium-7	1,000
Beryllium-10	1
Carbon-11	1,000
Carbon-14	[~~1,000~~] 100
Fluorine-18	1,000
Sodium-22	100
Sodium-24	100
Magnesium-28	100
Aluminum-26	10
Silicon-31	1,000
Silicon-32	1
Phosphorus-32	10
Phosphorus-33	100
Sulfur-35	100
Chlorine-36	10
Chlorine-38	1,000
Chlorine-39	1,000
Argon-39	1,000
Argon-41	1,000
Potassium-40	100
Potassium-42	1,000
Potassium-43	1,000
Potassium-44	1,000
Potassium-45	1,000
Calcium-41	100

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Calcium-45	100
Calcium-47	100
Scandium-43	1,000
Scandium-44m	100
Scandium-44	100
Scandium-46	10
Scandium-47	100
Scandium-48	100
Scandium-49	1,000
Titanium-44	1
Titanium-45	1,000
Vanadium-47	1,000
Vanadium-48	100
Vanadium-49	1,000
Chromium-48	1,000
Chromium-49	1,000
Chromium-51	1,000
Manganese-51	1,000
Manganese-52m	1,000
Manganese-52	100
Manganese-53	1,000
Manganese-54	100
Manganese-56	1,000
Iron-52	100
Iron-55	100
Iron-59	10
Iron-60	1
Cobalt-55	100
Cobalt-56	10
Cobalt-57	100
Cobalt-58m	1,000
Cobalt-58	100
Cobalt-60m	1,000
Cobalt-60	1
Cobalt-61	1,000
Cobalt-62m	1,000
Nickel-56	100
Nickel-57	100
Nickel-59	100
Nickel-63	100
Nickel-65	1,000
Nickel-66	10
Copper-60	1,000
Copper-61	1,000
Copper-64	1,000
Copper-67	1,000
Zinc-62	100
Zinc-63	1,000
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Zinc-71m	1,000
Zinc-72	100
Gallium-65	1,000
Gallium-66	100
Gallium-67	1,000
Gallium-68	1,000
Gallium-70	1,000
Gallium-72	100
Gallium-73	1,000
Germanium-66	1,000
Germanium-67	1,000
Germanium-68	10
Germanium-69	1,000
Germanium-71	1,000
Germanium-75	1,000
Germanium-77	1,000
Germanium-78	1,000
Arsenic-69	1,000
Arsenic-70	1,000
Arsenic-71	100
Arsenic-72	100
Arsenic-73	100
Arsenic-74	100
Arsenic-76	100
Arsenic-77	100
Arsenic-78	1,000
Selenium-70	1,000
Selenium-73m	1,000
Selenium-73	100
Selenium-75	100
Selenium-79	100
Selenium-81m	1,000
Selenium-81	1,000
Selenium-83	1,000
Bromine-74m	1,000
Bromine-74	1,000
Bromine-75	1,000
Bromine-76	100
Bromine-77	1,000
Bromine-80m	1,000
Bromine-80	1,000
Bromine-82	100
Bromine-83	1,000
Bromine-84	1,000
Krypton-74	1,000
Krypton-76	1,000
Krypton-77	1,000
Krypton-79	1,000
Krypton-81	1,000
Krypton-83m	1,000
Krypton-85m	1,000

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Krypton-85	1,000
Krypton-87	1,000
Krypton-88	1,000
Rubidium-79	1,000
Rubidium-81m	1,000
Rubidium-81	1,000
Rubidium-82m	1,000
Rubidium-83	100
Rubidium-84	100
Rubidium-86	100
Rubidium-87	100
Rubidium-88	1,000
Rubidium-89	1,000
Strontium-80	100
Strontium-81	1,000
Strontium-83	100
Strontium-85m	1,000
Strontium-85	100
Strontium-87m	1,000
Strontium-89	10
Strontium-90	0.1
Strontium-91	100
Strontium-92	100
Yttrium-86m	1,000
Yttrium-86	100
Yttrium-87	100
Yttrium-88	10
Yttrium-90m	1,000
Yttrium-90	10
Yttrium-91m	1,000
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Yttrium-94	1,000
Yttrium-95	1,000
Zirconium-86	100
Zirconium-88	10
Zirconium-89	100
Zirconium-93	1
Zirconium-95	10
Zirconium-97	100
Niobium-88	1,000
Niobium-89m (66 min.)	1,000
Niobium-89 (122 min.)	1,000
Niobium-90	100
Niobium-93m	10
Niobium-94	1
Niobium-95m	100
Niobium-95	100
Niobium-96	100
Niobium-97	1,000

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Niobium-98	1,000
Molybdenum-90	100
Molybdenum-93m	100
Molybdenum-93	10
Molybdenum-99	100
Molybdenum-101	1,000
Technetium-93m	1,000
Technetium-93	1,000
Technetium-94m	1,000
Technetium-94	1,000
Technetium-96m	1,000
Technetium-96	100
Technetium-97m	100
Technetium-97	1,000
Technetium-98	10
Technetium-99m	1,000
Technetium-99	100
Technetium-101	1,000
Technetium-104	1,000
Ruthenium-94	1,000
Ruthenium-97	1,000
Ruthenium-103	100
Ruthenium-105	1,000
Ruthenium-106	1
Rhodium-99m	1,000
Rhodium-99	100
Rhodium-100	100
Rhodium-101m	1,000
Rhodium-101	10
Rhodium-102m	10
Rhodium-102	10
Rhodium-103m	1,000
Rhodium-105	100
Rhodium-106m	1,000
Rhodium-107	1,000
Palladium-100	100
Palladium-101	1,000
Palladium-103	100
Palladium-107	10
Palladium-109	100
Silver-102	1,000
Silver-103	1,000
Silver-104m	1,000
Silver-104	1,000
Silver-105	100
Silver-106m	100
Silver-106	1,000
Silver-108m	1
Silver-110m	10
Silver-111	100
Silver-112	100

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Silver-115	1,000
Cadmium-104	1,000
Cadmium-107	1,000
Cadmium-109	1
Cadmium-113m	0.1
Cadmium-113	100
Cadmium-115m	10
Cadmium-115	100
Cadmium-117m	1,000
Cadmium-117	1,000
Indium-109	1,000
Indium-110m (69.1 min)	1,000
Indium-110 (4.9 h)	1,000
Indium-111	100
Indium-112	1,000
Indium-113m	1,000
Indium-114m	10
Indium-115m	1,000
Indium-115	100
Indium-116m	1,000
Indium-117m	1,000
Indium-117	1,000
Indium-119m	1,000
Tin-110	100
Tin-111	1,000
Tin-113	100
Tin-117m	100
Tin-119m	100
Tin-121m	100
Tin-121	1,000
Tin-123m	1,000
Tin-123	10
Tin-125	10
Tin-126	10
Tin-127	1,000
Tin-128	1,000
Antimony-115	1,000
Antimony-116m	1,000
Antimony-116	1,000
Antimony-117	1,000
Antimony-118m	1,000
Antimony-119	1,000
Antimony-120 (16 min.)	1,000
Antimony-120 (5.76 d)	100
Antimony-122	100
Antimony-124m	1,000
Antimony-124	10
Antimony-125	100
Antimony-126m	1,000
Antimony-126	100
Antimony-127	100

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Antimony-128 (10.4 min)	1,000
Antimony-128 (9.01 h)	100
Antimony-129	100
Antimony-130	1,000
Antimony-131	1,000
Tellurium-116	1,000
Tellurium-121m	10
Tellurium-121	100
Tellurium-123m	10
Tellurium-123	100
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	1,000
Tellurium-129m	10
Tellurium-129	1,000
Tellurium-131m	10
Tellurium-131	100
Tellurium-132	10
Tellurium-133m	100
Tellurium-133	1,000
Tellurium-134	1,000
Iodine-120m	1,000
Iodine-120	100
Iodine-121	1,000
Iodine-123	100
Iodine-124	10
Iodine-125	1
Iodine-126	1
Iodine-128	1,000
Iodine-129	1
Iodine-130	10
Iodine-131	1
Iodine-132m	100
Iodine-132	100
Iodine-133	10
Iodine-134	1,000
Iodine-135	100
Xenon-120	1,000
Xenon-121	1,000
Xenon-122	1,000
Xenon-123	1,000
Xenon-125	1,000
Xenon-127	1,000
Xenon-129m	1,000
Xenon-131m	1,000
Xenon-133m	1,000
Xenon-133	1,000
Xenon-135m	1,000
Xenon-135	1,000
Xenon-138	1,000
Cesium-125	1,000

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Cesium-127	1,000
Cesium-129	1,000
Cesium-130	1,000
Cesium-131	1,000
Cesium-132	100
Cesium-134m	1,000
Cesium-134	10
Cesium-135m	1,000
Cesium-135	100
Cesium-136	10
Cesium-137	10
Cesium-138	1,000
Barium-126	1,000
Barium-128	100
Barium-131m	1,000
Barium-131	100
Barium-133m	100
Barium-133	100
Barium-135m	100
Barium-139	1,000
Barium-140	100
Barium-141	1,000
Barium-142	1,000
Lanthanum-131	1,000
Lanthanum-132	100
Lanthanum-135	1,000
Lanthanum-137	10
Lanthanum-138	100
Lanthanum-140	100
Lanthanum-141	100
Lanthanum-142	1,000
Lanthanum-143	1,000
Cerium-134	100
Cerium-135	100
Cerium-137m	100
Cerium-137	1,000
Cerium-139	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Praseodymium-136	1,000
Praseodymium-137	1,000
Praseodymium-138m	1,000
Praseodymium-139	1,000
Praseodymium-142m	1,000
Praseodymium-142	100
Praseodymium-143	100
Praseodymium-144	1,000
Praseodymium-145	100
Praseodymium-147	1,000
Neodymium-136	1,000

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Neodymium-138	100
Neodymium-139m	1,000
Neodymium-139	1,000
Neodymium-141	1,000
Neodymium-147	100
Neodymium-149	1,000
Neodymium-151	1,000
Promethium-141	1,000
Promethium-143	100
Promethium-144	10
Promethium-145	10
Promethium-146	1
Promethium-147	10
Promethium-148m	10
Promethium-149	100
Promethium-150	1,000
Promethium-151	100
Samarium-141m	1,000
Samarium-141	1,000
Samarium-142	1,000
Samarium-145	100
Samarium-146	1
Samarium-147	100
Samarium-151	10
Samarium-153	100
Samarium-155	1,000
Samarium-156	1,000
Europium-145	100
Europium-146	100
Europium-147	100
Europium-148	10
Europium-149	100
Europium-150(12.62 h)	100
Europium-150(34.2 y)	1
Europium-152m	100
Europium-152	1
Europium-154	1
Europium-155	10
Europium-156	100
Europium-157	100
Europium-158	1,000
Gadolinium-145	1,000
Gadolinium-146	10
Gadolinium-147	100
Gadolinium-148	0.001
Gadolinium-149	100
Gadolinium-151	10
Gadolinium-152	100
Gadolinium-153	10
Gadolinium-159	100
Terbium-147	1,000

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Terbium-149	100
Terbium-150	1,000
Terbium-151	100
Terbium-153	1,000
Terbium-154	100
Terbium-155	1,000
Terbium-156m (5.0 h)	1,000
Terbium-156m (24.4 h)	1,000
Terbium-156	100
Terbium-157	10
Terbium-158	1
Terbium-160	10
Terbium-161	100
Dysprosium-155	1,000
Dysprosium-157	1,000
Dysprosium-159	100
Dysprosium-165	1,000
Dysprosium-166	100
Holmium-155	1,000
Holmium-157	1,000
Holmium-159	1,000
Holmium-161	1,000
Holmium-162m	1,000
Holmium-162	1,000
Holmium-164m	1,000
Holmium-164	1,000
Holmium-166m	1
Holmium-166	100
Holmium-167	1,000
Erbium-161	1,000
Erbium-165	1,000
Erbium-169	100
Erbium-171	100
Erbium-172	100
Thulium-162	1,000
Thulium-166	100
Thulium-167	100
Thulium-170	10
Thulium-171	10
Thulium-172	100
Thulium-173	100
Thulium-175	1,000
Ytterbium-162	1,000
Ytterbium-166	100
Ytterbium-167	1,000
Ytterbium-169	100
Ytterbium-175	100
Ytterbium-177	1,000
Ytterbium-178	1,000
Lutetium-169	100
Lutetium-170	100

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Lutetium-171	100
Lutetium-172	100
Lutetium-173	10
Lutetium-174m	10
Lutetium-174	10
Lutetium-176m	1,000
Lutetium-176	100
Lutetium-177m	10
Lutetium-177	100
Lutetium-178m	1,000
Lutetium-178	1,000
Lutetium-179	1,000
Hafnium-170	100
Hafnium-172	1
Hafnium-173	1,000
Hafnium-175	100
Hafnium-177m	1,000
Hafnium-178m	0.1
Hafnium-179m	10
Hafnium-180m	1,000
Hafnium-181	10
Hafnium-182m	1,000
Hafnium-182	0.1
Hafnium-183	1,000
Hafnium-184	100
Tantalum-172	1,000
Tantalum-173	1,000
Tantalum-174	1,000
Tantalum-175	1,000
Tantalum-176	100
Tantalum-177	1,000
Tantalum-178	1,000
Tantalum-179	100
Tantalum-180m	1,000
Tantalum-180	100
Tantalum-182m	1,000
Tantalum-182	10
Tantalum-183	100
Tantalum-184	100
Tantalum-185	1,000
Tantalum-186	1,000
Tungsten-176	1,000
Tungsten-177	1,000
Tungsten-178	1,000
Tungsten-179	1,000
Tungsten-181	1,000
Tungsten-185	100
Tungsten-187	100
Rhenium-177	1,000
Rhenium-178	1,000
Rhenium-181	1,000

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Rhenium-182 (12.7 h)	1,000
Rhenium-182 (64.0 h)	100
Rhenium-184m	10
Rhenium-184	100
Rhenium-186m	10
Rhenium-186	100
Rhenium-187	1,000
Rhenium-188m	1,000
Rhenium-188	100
Rhenium-189	100
Osmium-180	1,000
Osmium-181	1,000
Osmium-182	100
Osmium-185	100
Osmium-189m	1,000
Osmium-191m	1,000
Osmium-191	100
Osmium-193	100
Osmium-194	1
Iridium-182	1,000
Iridium-184	1,000
Iridium-185	1,000
Iridium-186	100
Iridium-187	1,000
Iridium-188	100
Iridium-189	100
Iridium-190m	1,000
Iridium-190	100
Iridium-192m (1.4 m)	10
Iridium-192 (73.8 d)	1
Iridium-194m	10
Iridium-194	100
Iridium-195m	1,000
Iridium-195	1,000
Platinum-186	1,000
Platinum-188	100
Platinum-189	1,000
Platinum-191	100
Platinum-193m	100
Platinum-193	1,000
Platinum-195m	100
Platinum-197m	1,000
Platinum-197	100
Platinum-199	1,000
Platinum-200	100
Gold-193	1,000
Gold-194	100
Gold-195	10
Gold-198m	100
Gold-198	100
Gold-199	100

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Gold-200m	100
Gold-200	1,000
Gold-201	1,000
Mercury-193m	100
Mercury-193	1,000
Mercury-194	1
Mercury-195m	100
Mercury-195	1,000
Mercury-197m	100
Mercury-197	1,000
Mercury-199m	1,000
Mercury-203	100
Thallium-194m	1,000
Thallium-194	1,000
Thallium-195	1,000
Thallium-197	1,000
Thallium-198m	1,000
Thallium-198	1,000
Thallium-199	1,000
Thallium-200	1,000
Thallium-201	1,000
Thallium-202	100
Thallium-204	100
Lead-195m	1,000
Lead-198	1,000
Lead-199	1,000
Lead-200	100
Lead-201	1,000
Lead-202m	1,000
Lead-202	10
Lead-203	1,000
Lead-205	100
Lead-209	1,000
Lead-210	0.01
Lead-211	100
Lead-212	1
Lead-214	100
Bismuth-200	1,000
Bismuth-201	1,000
Bismuth-202	1,000
Bismuth-203	100
Bismuth-205	100
Bismuth-206	100
Bismuth-207	10
Bismuth-210m	0.1
Bismuth-210	1
Bismuth-212	10
Bismuth-213	10
Bismuth-214	100
Polonium-203	1,000
Polonium-205	1,000

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Polonium-207	1,000
Polonium-210	0.1
Astatine-207	100
Astatine-211	10
Radon-220	1
Radon-222	1
Francium-222	100
Francium-223	100
Radium-223	0.1
Radium-224	0.1
Radium-225	0.1
Radium-226	0.1
Radium-227	1,000
Radium-228	0.1
Actinium-224	1
Actinium-225	0.01
Actinium-226	0.1
Actinium-227	0.001
Actinium-228	1
Thorium-226	10
Thorium-227	0.01
Thorium-228	0.001
Thorium-229	0.001
Thorium-230	0.001
Thorium-231	100
Thorium-232	100
Thorium-234	10
Thorium-natural	100
Protactinium-227	10
Protactinium-228	1
Protactinium-230	0.1
Protactinium-231	0.001
Protactinium-232	1
Protactinium-233	100
Protactinium-234	100
Uranium-230	0.01
Uranium-231	100
Uranium-232	0.001
Uranium-233	0.001
Uranium-234	0.001
Uranium-235	0.001
Uranium-236	0.001
Uranium-237	100
Uranium-238	100
Uranium-239	1,000
Uranium-240	100
Uranium-natural	100
Neptunium-232	100
Neptunium-233	1,000
Neptunium-234	100
Neptunium-235	100

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Neptunium-236 (1.15E+5 y)	0.001
Neptunium-236 (22.5 h)	1
Neptunium-237	0.001
Neptunium-238	10
Neptunium-239	100
Neptunium-240	1,000
Plutonium-234	10
Plutonium-235	1,000
Plutonium-236	0.001
Plutonium-237	100
Plutonium-238	0.001
Plutonium-239	0.001
Plutonium-240	0.001
Plutonium-241	0.001
Plutonium-242	0.001
Plutonium-243	1,000
Plutonium-244	0.001
Plutonium-245	100
Americium-237	1,000
Americium-238	100
Americium-239	1,000
Americium-240	100
Americium-241	0.001
Americium-242m	0.001
Americium-242	10
Americium-243	0.001
Americium-244m	100
Americium-244	10
Americium-245	1,000
Americium-246m	1,000
Americium-246	1,000
Curium-238	100
Curium-240	0.1
Curium-241	1
Curium-242	0.01
Curium-243	0.001
Curium-244	0.001
Curium-245	0.001
Curium-246	0.001
Curium-247	0.001
Curium-248	0.001
Curium-249	1,000
Berkelium-245	100
Berkelium-246	100
Berkelium-247	0.001
Berkelium-249	0.1
Berkelium-250	10
Californium-244	100
Californium-246	1
Californium-248	0.01
Californium-249	0.001

TABLE 462.1	
Radionuclide	**Quantity (microcuries[2])**
Californium-250	0.001
Californium-251	0.001
Californium-252	0.001
Californium-253	0.1
Californium-254	0.001
Einsteinium-250	100
Einsteinium-251	100
Einsteinium-253	0.1
Einsteinium-254m	1
Einsteinium-254	0.01
Fermium-252	1
Fermium-253	1
Fermium-254	10
Fermium-255	1
Fermium-257	0.01
Mendelevium-257	10
Mendelevium-258	0.01
Any alpha-emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001
Any radionuclide other than alpha-emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

Table 462.1 notes:

[1] the quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in columns 1 and 2 of table I of 20.3.4.461 NMAC, rounding to the nearest factor of 10, and constraining the values listed between 0.001 and 1,000 microcuries (37 becquerels and 37 megabecquerels). Values of 100 microcuries (3.7 megabecquerels) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 1,000 microcuries (37 megabecquerels) to take into account their low specific activity;

[2] to convert microcuries to kilobecquerels, multiply the microcurie value by 37.

B. Note. For purposes of Subsection E of 20.3.4.428 NMAC, Subsection A of 20.3.4.431 NMAC and Subsection A of 20.3.4.451 NMAC where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1", that is, unity.

[20.3.4.462 NMAC - Rp, 20.3.4.462 NMAC, 4/30/2009; A, 8/10/2021]

20.3.4.466 APPENDIX G - REQUIREMENTS FOR TRANSFERS OF LOW-LEVEL RADIOACTIVE WASTE INTENDED FOR DISPOSAL AT LICENSED LAND DISPOSAL FACILITIES AND MANIFESTS: LLW means low-level radioactive waste as defined in the Low-Level Radioactive Waste Policy Act.

A. Manifest.

(1) A waste generator, collector or processor who transports, or offers for transportation LLW intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a manifest [NRC OMB Control Numbers 3150-0164, -0165 and -0166] reflecting information requested on applicable NRC forms 540 (*uniform low-level radioactive waste manifest* (shipping paper) and 541 (u*niform low-level radioactive waste manifest* (container and waste description)) and, if necessary, on an applicable NRC form 542 (u*niform low-level radioactive waste manifest* (manifest index and regional compact tabulation)). NRC forms 540

and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC forms 541, 541A, 542 and 542A may be completed, transmitted and stored in electronic media with the capability for producing legible, accurate and complete records on the respective forms. Licensees are not required by NRC to comply with the manifesting requirements of this part when they ship the following:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator", as defined in this part; or

(c) radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste" unless regulated by other applicable federal or state regulations;

(d) these exclusions from manifesting requirements do not, however, exempt the licensee from complying with applicable DOT requirements for shipments referencing 49 CFR, including the preparation of shipping papers.

(2) For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this section may be legible carbon copies, photocopies or computer printouts that reproduce the data in the format of the uniform manifest.

(3) NRC forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the [~~office~~]Office of the [~~chief~~] Chief information [~~officer~~] Officer, United States nuclear regulatory commission, Washington, DC 20555-0001, telephone (301) 415-5877, or by visiting the NRC's web site at http://www.nrc.gov and selecting forms from the index found on the home page.

(4) This section includes information requirements of the DOT, as codified in 49 CFR Part 172. Additional 49 CFR requirements may be applicable. Information on hazardous, medical or other waste, required to meet EPA regulations, as codified in 40 CFR Parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, any required EPA forms must accompany the *uniform low-level radioactive waste manifest* required by this chapter.

(5) As used in this section, the following definitions apply:

(a) **"chelating agent"** has the same meaning as that given in 20.3.13.7 NMAC;

(b) **"chemical description"** means a description of the principal chemical characteristics of a low-level radioactive waste;

(c) **"computer-readable medium"** means that the department's computer can transfer the information from the medium into its memory;

(d) **"consignee"** means the designated receiver of the shipment of low-level radioactive waste;

(e) **"decontamination facility"** means a facility operating under a department, NRC or agreement state license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments;

(f) **"disposal container"** means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"); note that for some shipments, the disposal container may be the transport package;

(g) **"EPA identification number"** means the number received by a transporter following application to the administrator of EPA as required by 40 CFR Part 263;

(h) **"generator"** means a licensee operating under a department, NRC or agreement state license who *(1)* is a waste generator as defined in this part, or *(2)* is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act (e.g., waste generated as a result of decontamination or recycle activities);

(i) **"high integrity container"** (HIC) means a container commonly designed to meet the structural stability requirements of 20.3.13.1325 NMAC, and to meet DOT requirements for a type A package;

(j) **"land disposal facility"** has the same meaning as that given in 20.3.13.7 NMAC;

(k) **"NRC forms 540, 540A, 541, 541A, 542 and 542A"** are official NRC forms referenced in this section; licensees need not use originals of these NRC forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size and location of information; upon agreement between the shipper and consignee, NRC forms 541 (and 541A) and NRC forms 542 (and 542A) may be

completed, transmitted and stored in electronic media; the electronic media must have the capability for producing legible, accurate and complete records in the format of the uniform manifest;

(l) **"package"** means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport;

(m) **"physical description"** means the items called for on NRC form 541 to describe a LLW;

(n) **"residual waste"** means LLW resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators; this waste is attributable to the processor or decontamination facility, provided that other federal laws or regulations, such as those of Resource Conservation and Recovery Act (RCRA), are not applicable;

(o) **"shipper"** means the licensed entity (i.e., the waste generator, waste collector or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor or land disposal facility operator;

(p) **"shipping paper"** means NRC form 540 and, if required, NRC form 540A which includes the information required by DOT in 49 CFR part 172;

(q) **"source material"** has the same meaning as that given in 20.3.3.7 NMAC;

(r) "**special nuclear material"** has the same meaning as that given in 20.3.3.7 NMAC;

(s) **"uniform low-level radioactive waste manifest"** or **"uniform manifest"** means the combination of NRC forms 540, 541 and, if necessary, 542, and their respective continuation sheets as needed, or equivalent;

(t) **"waste collector,"** including "waste broker," means an entity, operating under a department, NRC or agreement state license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor or licensed land disposal facility;

(u) **"waste description"** means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC form 541;

(v) **"waste generator"** means an entity, operating under a department, NRC or agreement state license, who *(1)* possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and *(2)* transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal; a licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste";

(w) **"waste processor"** means an entity, operating under a department, NRC or agreement state license, whose principal purpose is to process, repackage or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility; and

(x) **"waste type"** means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

(6) **Information requirements.**

(a) **General information.** The shipper of the radioactive waste shall provide the following information on the uniform manifest:

(i) the name, facility address and telephone number of the licensee shipping the waste;

(ii) an explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor or a combination of these identifiers for purposes of the manifested shipment; and

(iii) the name, address and telephone number, or the name and EPA identification number for the carrier transporting the waste.

(b) **Shipment information.** The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

(i) the date of the waste shipment;

(ii) the total number of packages or disposal containers;

(iii) the total disposal volume and disposal weight in the shipment;

(iv) the total radionuclide activity in the shipment;

(v) the activity of each of the radionuclides H-3, C-14, Tc-99 and I-129 contained in the shipment; and

(vi) the total masses of U-233, U-235 and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

(c) Disposal container and waste information. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

(i) an alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

(ii) a physical description of the disposal container, including the manufacturer and model of any high integrity container;

(iii) the volume displaced by the disposal container;

(iv) the gross weight of the disposal container, including the waste;

(v) for waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

(vi) a physical and chemical description of the waste;

(vii) the total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(viii) the approximate volume of waste within a container;

(ix) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

(x) the identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235 and plutonium in special nuclear material, and the masses of uranium and thorium in source material, including fissile category classification; for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

(xi) the total radioactivity within each container;

(xii) for wastes consigned to a disposal facility, the classification of the waste pursuant to 20.3.13.1324 NMAC; waste not meeting the structural stability requirements of Subsection B of 20.3.13.1325 NMAC; and

(xiii) any other information required on a manifest or shipping paper by the DOT, the NRC or other regulatory agencies.

(d) Uncontainerized waste information. The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

(i) the approximate volume and weight of the waste;

(ii) a physical and chemical description of the waste;

(iii) the total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

(iv) for waste consigned to a disposal facility, the classification of the waste pursuant to 20.3.13.1324 NMAC; waste not meeting the structural stability requirements of Subsection B of 20.3.13.1325 NMAC must be identified;

(v) the identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235 and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

(vi) for wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

(e) Multi-generator disposal container information. This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators," including "waste generators," as defined in this section). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

(i) For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

(ii) For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following: (1) the volume of waste within the disposal container; (2) a physical and chemical description of the waste, including the solidification agent, if any; (3) the total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent; (4) the sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in Subsection B of 20.3.13.1325 NMAC; and (5) radionuclide identities and activities contained in the waste, the masses of U-233, U-235 and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

B. Certification. An authorized representative of the waste generator, processor or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the department, the DOT and the NRC. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

C. Control and Tracking.

(1) Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in Subparagraphs (a) through (i) of this paragraph. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of Subparagraphs (d) through (i) of this paragraph. A licensee shall:

(a) prepare all wastes so that the waste is classified according to 20.3.13.1324 NMAC, and meets the waste characteristics requirements in 20.3.13.1325 NMAC;

(b) label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is class A waste, class B waste, class C waste or greater then class C waste, in accordance with 20.3.13.1324 NMAC;

(c) conduct a quality assurance program to assure compliance with 20.3.13.1324 NMAC and 20.3.13.1325 NMAC (the program must include management evaluation of audits);

(d) prepare the NRC *uniform low-level radioactive waste manifest* as required by Subsection A of this section;

(e) forward a copy or electronically transfer the *uniform low-level radioactive waste manifest* to the intended consignee so that either *(1)* receipt of the manifest precedes the LLW shipment or *(2)* the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both delivery methods *(1)* and *(2)* is also acceptable;

(f) include NRC form 540 (and NRC form 540A, if required) with the shipment regardless of the option chosen in Subparagraph (e) of this paragraph;

(g) receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC form 540;

(h) retain a copy of or electronically store the *uniform low-level radioactive waste manifest* and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 20.3.3 NMAC; and

(i) for any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with Paragraph (5) of this subsection.

(2) Any waste collector licensee who handles only prepackaged waste shall:

(a) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC form 540;

(b) prepare a new manifest to reflect consolidated shipments that meet the requirements of this section; the waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

(c) forward a copy or electronically transfer the *uniform low-level radioactive waste manifest* to the intended consignee so that either *(1)* receipt of the manifest precedes the LLW shipment or *(2)* the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee; using both delivery methods *(1)* and *(2)* is also acceptable;

(d) include NRC form 540 (and NRC form 540A, if required) with the shipment regardless of the option chosen in Subparagraph (c) of this paragraph;

(e) receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC form 540;

(f) retain a copy of or electronically store the *uniform low-level radioactive waste manifest* and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 20.3.3 NMAC;

(g) for any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with Paragraph (5) of this subsection; and

(h) notify the shipper and the department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

(3) Any licensed waste processor who treats or repackages waste shall:

(a) acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC form 540;

(b) prepare a new manifest that meets the requirements of this section; preparation of the new manifest reflects that the processor is responsible for meeting these requirements; for each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume and the other information as required in Subparagraph (e) of Paragraph (6) of Subsection A of this section;

(c) prepare all wastes so that the waste is classified according to 20.3.13.1324 NMAC, and meets the waste characteristics requirements in 20.3.13.1325 NMAC;

(d) label each package of waste to identify whether it is class A waste, class B waste or class C waste, in accordance with 20.3.13.1324 NMAC and 20.3.13.1326 NMAC;

(e) conduct a quality assurance program to assure compliance with 20.3.13.1324 NMAC and 20.3.13.325 NMAC (the program shall include management evaluation of audits);

(f) forward a copy or electronically transfer the *uniform low-level radioactive waste manifest* to the intended consignee so that either *(1)* receipt of the manifest precedes the LLW shipment or *(2)* the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee; using both delivery methods *(1)* and *(2)* is also acceptable;

(g) include NRC form 540 (and NRC form 540A, if required) with the shipment regardless of the option chosen in paragraph Subparagraph (f) of this paragraph;

(h) receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC form 540;

(i) retain a copy of or electronically store the *uniform low-level radioactive waste manifest* and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 20.3.3 NMAC;

(j) for any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with Paragraph (5) of this subsection; and

(k) notify the shipper and the department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

(4) The land disposal facility operator shall:

(a) acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC form 540 to the shipper; the shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator; if any discrepancy exists between materials listed on the *uniform low-level radioactive waste manifest* and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

(b) maintain copies of all completed manifests and electronically store the information required by 20.3.13.1334 NMAC until the department terminates the license; and

(c) notify the shipper and the department when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

(5) Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

(a) be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

(b) be traced and reported; the investigation shall include tracing the shipment and filing a report with the department; each licensee who conducts a trace investigation shall file a written report with the department within 2 weeks of completion of the investigation.

[20.3.4.466 NMAC - Rp, 20.3.4.466 NMAC, A, 8/10/2021]

This is an amendment to 20.3.5 NMAC, Section 10, effective 8/10/2021.

20.3.5.10 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY: An application for a specific license for the use of licensed material in industrial radiography will be approved if the applicant meets the following requirements:

A. The applicant satisfies the general requirements specified in Part 3 of 20.3 NMAC for byproduct material, as appropriate, and any special requirements contained in this part.

B. 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 37.71, 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable; and

(4) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81 the licensee shall use the following address: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.

C. The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of Paragraph (1) of Subsection A of 20.3.5.11 NMAC. License applicants need not describe the initial training and examination program for radiographers in the subjects outlined in Paragraph (1) of Subsection A of 20.3.5.11 NMAC.

D. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid.

E. The applicant submits written operating and emergency procedures as described in 20.3.5.29 NMAC.

F. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographers' assistant. The intervals for these performance inspections are not to exceed six months as described in Subsection B of 20.3.5.13 NMAC.

G. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility.

H. The applicant identifies and lists the qualifications of the individual(s) designated as the RSO and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures. Refer to Subsection C of 20.3.5.11 NMAC for RSO qualification requirements.

I. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application must include a description of the procedures to be followed. The description must include the:

(1) instruments to be used;

(2) methods of performing the analysis; and

(3) pertinent experience of the person who will analyze the wipe samples.

J. If the applicant intends to perform "in-house" calibrations of survey instruments the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 20.3.5.16 NMAC.

K. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

L. The applicant identifies the location(s) where all records required by this part and other parts of 20.3 NMAC will be maintained. If a license is issued to the applicant, the licensee shall maintain copies of records required by this Part and other applicable Parts of 20.3 NMAC at the specified location(s).

[20.3.5.12 NMAC - N, 5/19/2002; A, 8/10/2021]

This is an amendment to 20.3.7 NMAC, Section 700, effective 8/10/2021.

20.3.7.700 GENERAL REGULATORY REQUIREMENTS:

A. Provisions for research involving human subjects.

(1) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on the license.

(2) If the research is conducted, funded, supported or regulated by a federal agency that has implemented the *federal policy for the protection of human subjects* (45 CFR Part 46), the licensee shall, before conducting research:

(a) obtain review and approval of the research from an "institutional review board," as defined and described in the *federal policy for the protection of human subjects*; and

(b) obtain "informed consent," as defined and described in the *federal policy for the protection of human subjects*, from the human research subject.

(3) If the research will not be conducted, funded, supported or regulated by a federal agency that has implemented the *federal policy for the protection of human subjects*, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license issued by the department. The amendment request must include a written commitment that the licensee will, before conducting research:

(a) obtain review and approval of the research from an "institutional review board," as defined and described in the *federal policy for the protection of human subjects*; and

(b) obtain "informed consent," as defined and described in the *federal policy for the protection of human subjects*, from the human research subject.

(4) Nothing in this subsection relieves licensees from complying with the other requirements in this part.

B. FDA, federal and state requirements. Nothing in this part relieves the licensee from complying with applicable FDA, other federal and state requirements governing radioactive drugs or devices.

C. Implementation.

(1) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

(2) A licensee shall continue to comply with any license condition that requires it to implement procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC until there is a license amendment or renewal that modifies the license condition.

D. License required.

(1) A person may manufacture, produce, acquire, receive, possess, prepare, use or transfer radioactive material for medical use only in accordance with a specific license issued by the department or as allowed in Paragraph (2) of this subsection.

(2) A specific license is not needed for an individual who:

(a) receives, possesses, uses or transfers radioactive material in accordance with the requirements in this chapter under the supervision of an authorized user as provided in Subsection F of 20.3.7.702 NMAC unless prohibited by license condition; or

(b) prepares unsealed radioactive material for medical use in accordance with the requirements in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in Subsection F of 20.3.7.702 NMAC unless prohibited by license condition.

E. Application for license, amendment or renewal.

(1) An application must be signed by the applicant or licensee, or a person duly authorized to act for or on their behalf.

(2) An application for a license for medical use of radioactive material as described in 20.3.7.704 NMAC, 20.3.7.705 NMAC, 20.3.7.708 NMAC, 20.3.7.710 NMAC, 20.3.7.711 NMAC, 20.3.7.712 NMAC and 20.3.7.713 NMAC must be made by:

(a) filing in duplicate of a department form, *application for radioactive material license*, completed according to the instructions in the form; and

(b) submitting written procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable.

(3) 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:

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

(b) 10 CFR 37.5 Definitions of: agreement state, byproduct material, commission and person shall not be applicable,

(c) 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 37.71, 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable;

(d) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81, the licensee shall use the following address: New Mexico environment department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.

(4) A request for a license amendment or renewal must be made by:

(a) filing in duplicate of a department form, *application for radioactive material license*, as described in Paragraph (2) of this subsection; and

(b) submitting procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable.

(5) In addition to the requirements in Paragraphs (2) and (3) of this subsection, an application for a license or amendment for medical use of radioactive material described in 20.3.7.713 NMAC must also include information regarding any radiation safety aspects of the medical use of the material that are not addressed in sections 20.3.7.702 NMAC and 20.3.7.703 NMAC. The applicant shall also provide specific information on:

(a) radiation safety precautions and instructions;

(b) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c) calibration, maintenance and repair of instruments and equipment necessary for radiation safety.

(6) The applicant or licensee shall also provide any other additional information requested by the department in its review of the application, license renewal or amendment, within 30 days of the request or other time as may be specified in the request.

(7) An applicant that satisfies the requirements specified in Subsection B of 20.3.3.314 NMAC may apply for a type "A" specific license of broad scope.

F. License amendments. A licensee shall apply for and must receive a license amendment:

(1) before it receives, prepares or uses radioactive material for a type of use that is permitted under 20.3.7 NMAC but that is not authorized on the licensee's current license issued under this part;

(2) before it permits anyone to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist under the license, except:

(a) for an authorized user, an individual who meets the definition of an *authorized user* as defined in 20.3.7.7 NMAC;

(b) for an authorized nuclear pharmacist, an individual who meets the definition of an *authorized nuclear pharmacist* as defined in 20.3.7.7 NMAC;

(c) for an authorized medical physicist, an individual who meets the definition of an *authorized medical physicist* as defined in 20.3.7.7 NMAC; or

(d) a physician, podiatrist or dentist who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or a nuclear pharmacist who used only accelerator-produced radioactive materials in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007 or at all other locations of use in non-licensing state (as defined in 20.3.1.7 NMAC) before August 8, 2009, or an earlier date as noticed by the NRC, and for only those materials and uses performed before these dates;

(3) before it changes radiation safety officers, except as provided in Paragraph (4) of Subsection A of 20.3.7.702 NMAC;

(4) before it receives radioactive material in excess of the amount or in a different form, or receives a different radioactive material than is authorized on the license;

(5) before it adds to or changes the areas of use identified in the application or on the license, including areas used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC if the change includes the addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; other areas of use where radioactive material is used only in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC are exempt;

(6) before it changes the address(es) of use identified in the application or on the license; and

(7) before it revises procedures required by Subsections D, J, K and L of 20.3.7.711 NMAC, as applicable, where such revision reduces radiation safety.

G. Notifications.

(1) For each individual, no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under Paragraph (2) of Subsection F of this section:

(a) the licensee shall verify the training and experience and provide the department with a copy the documentation demonstrating the training and experience as listed in the definitions of authorized user, authorized nuclear pharmacist or authorized medical physicist in 20.3.7.7 NMAC; or

(b) the licensee shall verify the training and experience and provide the department of a copy of the documentation demonstrating that only accelerator-produced radioactive materials, discrete sources, or both, were used for medical use or in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007 or at all other locations of use 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.

(2) A licensee shall notify the department by letter no later than 30 days after:

(a) an authorized user, an authorized nuclear pharmacist, radiation safety officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(b) the licensee permits an authorized user or an individual qualified to be a radiation safety officer, under Subsection A of 20.3.7.714 NMAC, incorporating 10 CFR 35.50 and Subsection E of 20.3.7.714 NMAC, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with Paragraph (4) of Subsection A of 20.3.7.702 NMAC.

(c) the licensee's mailing address changes;

(d) the licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Subsection B of 20.3.3.317 NMAC; or

(e) the licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide or PET radioactive drug production area.

(3) A licensee shall notify the department by letter no later than 30 days after a calibration, transmission or reference source under Subsection E of 20.3.7.703 NMAC is acquired. The notification shall contain a description of the source, manufacturer name, model and serial number of the source, and the license number of the manufacturer of the specific license issued by the department, NRC or an agreement state under Subsection K of 20.3.3.315 NMAC or equivalent NRC or agreement state requirements.

(4) The licensee shall send the documents required in this subsection to the appropriate address identified in 20.3.1.116 NMAC.

H. Exemptions regarding type A specific licenses of broad scope. A licensee possessing a type "A" specific license of broad scope for medical use, issued under 20.3.3.314 NMAC, is exempt from:

(1) the provisions of Paragraph 4 of Subsection E of 20.3.7.700 NMAC regarding the need to file an amendment to the license for medical use of radioactive materials, for use described in 20.3.7.713 NMAC;

(2) the provisions of Paragraph (2) of Subsection F of 20.3.7.700 NMAC;

(3) the provisions of Paragraph (5) of Subsection F of 20.3.7.700 NMAC regarding additions to or changes in the areas of use at the addresses specified in the application or on the license;

(4) the provisions of Paragraph (1) of Subsection G of 20.3.7.700 NMAC;

(5) the provisions of Subparagraph (a) of Paragraph (2) of Subsection G of 20.3.7.700 NMAC for an authorized user, an authorized nuclear pharmacist or an authorized medical physicist;

(6) the provisions of Subparagraph (e) of Paragraph (2) of Subsection G of 20.3.7.700 NMAC regarding additions to or changes in the areas of use identified in the application or on the license where radioactive material is used in accordance with either 20.3.7.704 NMAC or 20.3.7.705 NMAC;

(7) the provisions in Paragraph (3) of Subsection G of 20.3.7.700 NMAC; and

(8) the provisions of Paragraph (1) of Subsection I of 20.3.7.702 NMAC.

[20.3.7.700 NMAC - Rp, 20 NMAC 3.1.7.700, 4/30/2009; A, 8/10/2021]

This is an amendment to 20.3.12 NMAC, Section 9, effective 8/10/2021.

20.3.12.9 SPECIFIC LICENSES FOR WELL LOGGING: The department will approve an application for a specific license for the use of licensed material in well logging if the applicant meets the following requirements.

A. The applicant shall satisfy the general requirements specified in 10 CFR 30.33 for byproduct material, 10 CFR 40.32 for source material and in 10 CFR 70.23 for special nuclear material and in 20.3.3.308 NMAC and any special requirements contained in this part.

B. 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, 37.11(a) and (b), 10 CFR 37.13, 10 CFR 37.27(c), 10 CFR 37.71, 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable;

(4) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81, the licensee shall use the following address: New Mexico environment department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.

C. The applicant shall develop a program for training logging supervisors and logging assistants and submit to the department a description of this program which specifies the:

(1) initial training;

(2) on-the-job training;

(3) annual safety reviews provided by the licensee;

(4) means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the department's regulations and licensing requirements and the applicant's operating and emergency procedures; and

(5) means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

D. The applicant shall submit to the department written operating and emergency procedures as described in 20.3.12.12 NMAC or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

E. The applicant shall establish and submit to the department its program for annual inspections of the job performance of each logging supervisor to ensure that the department's regulations, license requirements and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three years after each internal inspection.

F. The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

G. If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and the model numbers of the leak test kits to be used. If the applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the department. The description must include the:

(1) instruments to be used;

(2) methods of performing the analysis; and

(3) pertinent experience of the person who will analyze the wipe samples.

[20.3.12.9 NMAC - N, 6/30/2011; A, 8/10/2021]

This is an amendment to 20.3.15 NMAC, Section 1502 effective 8/10/2021.

20.3.15.1502 SPECIFIC LICENSES FOR IRRADIATORS: The department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

A. The applicant shall satisfy the general requirements specified in 20.3.3 NMAC and the requirements contained in this part (20.3.15 NMAC).

B. 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 37.71, 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable;

(4) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), 10 CFR 37.81, the licensee shall use, when applicable, New Mexico environment department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.

C. The application must describe the training provided to irradiator operators including:

(1) classroom training;

(2) on-the-job or simulator training;

(3) safety reviews;

(4) means employed by the applicant to test each operator's understanding of these regulations and licensing requirements, and the irradiator operating and emergency procedures; and

(5) minimum training and experience of personnel who may provide training.

D. The application must include an outline of the written operating and emergency procedures listed in 20.3.15.1518 NMAC that describes the radiation safety aspects of the procedures.

E. The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer, and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who within the management structure has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

F. The application must include a description of the access control system required by 20.3.15.1507 NMAC, the radiation monitors required by 20.3.15.1510 NMAC, the method of detecting leaking sources required by 20.3.15.1521 NMAC including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

G. If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the department. The description must include the:

(1) instruments to be used;

(2) methods of performing the analysis; and

(3) pertinent experience of the individual who analyzes the samples.

H. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the department to load or unload irradiator sources.

I. The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by 20.3.15.1522 NMAC.

[5/3/1995; 20.3.15.1502 NMAC - Rn, 20 NMAC 3.1.15.1502, 4/15/2004; A, 6/13/2017; A, 8/10/2021]