

New Mexico Register

The official publication for all official notices of rulemaking
and filing of proposed, adopted and emergency rules.

Volume XXVIII - Issue 11 - June 13, 2017

COPYRIGHT © 2017
BY
THE STATE OF NEW MEXICO

ALL RIGHTS RESERVED

New Mexico Register

Volume XXVIII, Issue 11

June 13, 2017

Table of Contents

Notices of Rulemaking and Proposed Rules

Agriculture Department

Notice of Rule Hearing.....	360
Notice of Rule Hearing.....	360

Human Services Department

Income Support Division

Notice of Public Hearing.....	361
-------------------------------	-----

Medical Assistance Division

Notice of Proposed Rulemaking.....	361
Notice of Proposed Rulemaking.....	362

Secretary of State's Office

Notice of Rule Hearing.....	365
-----------------------------	-----

Adopted Rules

A = Amended, E = Emergency, N = New, R = Repealed, Rn = Renumbered

Engineer, Office of the State

19.27.4 NMAC	R	Well Driller Licensing; Construction, Repair And Plugging Of Wells.....	366
19.27.4 NMAC	N	Well Driller Licensing; Construction, Repair And Plugging Of Wells.....	366

Environment Department

Radiation Control Bureau

20.3.1 NMAC	A	Radiation Protection - General Provisions.....	377
20.3.3 NMAC	A	Licensing of Radioactive Materials.....	381
20.3.4 NMAC	A	Standards for Protection Against Radiation.....	414
20.3.5 NMAC	A	Radiation Safety Requirements for Industrial Radiographic Operations.....	418
20.3.7 NMAC	A	Medical Use of Radionuclides.....	420
20.3.12 NMAC	A	Licensing and Radiation Safety Requirements for Well Logging.....	425
20.3.15 NMAC	A	Licenses and Radiation Safety Requirements for Irradiators.....	426

to deviate from the rules contained in 19.27.4.29, 19.27.4.30, 19.27.4.31, or 19.27.4.33 NMAC. A request for a variance to a rule in this part shall be submitted in writing. The request shall contain a detailed justification that demonstrates that such a variance is necessary to preclude unreasonable hardship, or that application of a rule in this part would not be practicable. The state engineer may grant the variance if the state engineer finds the request to be reasonable and just. The state engineer shall respond in writing to the request for variance and, if the variance is granted, the state engineer may impose conditions of approval. [19.27.4.37 NMAC - Rp, 19.27.4.37 NMAC, 6/30/2017]

19.27.4.38 LIBERAL CONSTRUCTION: This part shall be liberally construed to carry out its purpose.

[19.27.4.38 NMAC - Rp, 19.27.4.38 NMAC, 6/30/2017]

19.27.4.39 SEVERABILITY: If any section, paragraph, sentence, clause, word or provision of this rule shall be held invalid, the invalidity of such section, paragraph, sentence, clause, word or provision shall not affect any of the remaining provisions of this rule.

[19.27.4.39 NMAC - Rp, 19.27.4.39 NMAC, 6/30/2017]

HISTORY OF 19.27.4 NMAC:

Pre NMAC History: The material in this part was derived from that previously filed with the State Records Center and Archives, SE-66-1, Rules and Regulations Governing Drilling of Wells and Appropriation and Use of Ground Water in New Mexico, Article 4, Well Drillers Licensing, Construction, Repair and Plugging Of Wells, originally filed with the Supreme Court Law Library 11/1/1966. Filed with the State Records Center 6/27/1991.

History of Repealed Material: SE-66-1, Rules and Regulations Governing Drilling of Wells and Appropriation and Use of Ground

Water in New Mexico, Article 4, Well Drillers Licensing, Construction, Repair and Plugging of Wells - Repealed 8/31/2005.

19.27.4 NMAC, Well Driller Licensing, Construction, Repair and Plugging of Wells filed 6/30/2017 - Repealed effective 6/30/2017.

NMAC History:

19.27.4 NMAC, Well Driller Licensing, Construction, Repair and Plugging of Wells (filed 8/16/2005) was replaced by 19.27.4 NMAC, Well Driller Licensing, Construction, Repair and Plugging of Wells, effective 6/30/2017.

ENVIRONMENT DEPARTMENT RADIATION CONTROL BUREAU

This is an amendment to 20.3.1 NMAC, Sections 7, 107, and 116, effective 06/13/2017.

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 [a unit of measurement of activity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7×10^{10} disintegrations or transformations per second (dps or tps)]. Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie is equal to 3.7×10^7 dps or tps. One microcurie is equal to 3.7×10^4 dps or tps.] 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 improvement division of the health and 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: $175 \text{ (grams contained U-235)} / 350 + 50 \text{ (grams U-233)} / 200 + 50 \text{ (grams Pu)} / 200 = 1$.

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, 04/30/2009; A, 06/13/2017]

20.3.1.107 EXEMPTIONS FROM THE REGULATORY REQUIREMENTS:

A. General Provisions. The department may, upon application of any interested

person or upon its own initiative, grant such exemptions from the requirements of this chapter as it determines are authorized by law, will not endanger public health and safety or property and are otherwise in the public interest.

B. DOE contractors and NRC contractors. Any DOE contractor or subcontractor and any NRC contractor or subcontractor of the following categories operating within this state is exempt from these regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) prime contractors performing work for the DOE at United States government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) prime contractors of the DOE performing research in, or development, manufacture, storage, testing or transportation of atomic weapons or components thereof;

(3) prime contractors of the DOE using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

(4) any other prime contractor or subcontractor of the DOE or NRC when the state and the NRC jointly determine:

(a) that the exemption of the prime contractor or subcontractor is authorized by law; and

(b) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

C. Common and contract carriers, freight forwarders, warehousemen and United States postal service are exempt from the [licensing requirements in this

chapter] regulations in 10 CFR parts 31 through 37 and 39 as well as the requirements for a license set forth in section 81 of the Atomic Energy Act to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

D. Mining, extracting, processing, storage or transportation of radioactive ores or uranium concentrates that are regulated by the mine safety and health administration (MSHA), United States department of labor (DOL), or any other federal or state agency having authority are exempt unless the authority is ceded by such agency to the board.

[20.3.1.107 NMAC - Rp, 20.3.1.107 NMAC, 04/30/2009; A, 06/13/2017]

20.3.1.116

COMMUNICATIONS: All communications and reports concerning these regulations and applications filed thereunder should be addressed to the department at its office as follows: New Mexico Environment Department, Radiation Control Bureau, P.O. Box [26110] 5469, Santa Fe, NM 87502-5469. [20.3.1.116 NMAC - Rp, 20.3.1.116 NMAC, 04/30/2009; A, 06/13/2017]

ENVIRONMENT DEPARTMENT RADIATION CONTROL BUREAU

This is an amendment to 20.3.3 NMAC Sections 7, 301, 302, 304, 305, 307, 308, 310, 311, 313, 314, 315, and 317, effective 06/13/2017.

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" means an Indian or Alaska native tribe, band, nation, pueblo, village, or community that the secretary of the interior acknowledges to exist as an Indian 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 tribal leadership, such as the chief, president, or tribal 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, 04/30/2009; A, 06/13/2017]

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 [0.05] 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 Act 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 ~~[0.25 percent]~~ 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 ~~[20]~~ twenty percent by weight source material;

(b) glassware, containing not more than ~~[10]~~ 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 ~~[10]~~ 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 ~~[2]~~ 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 ~~[4]~~ 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) ~~[the counterweights are manufactured in accordance with a specific license issued by the NRC authorizing distribution by the licensee pursuant to 10 CFR Part 40;]~~ each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "depleted uranium." (the requirements specified in Subparagraphs ~~[(b) and (c)]~~ (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 ~~[(b) and (c)]~~ (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"); and

(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 ~~[30]~~ ten percent by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, [30] thirty percent by weight of thorium; and that ~~[this] the~~ exemption contained in this paragraph does [shall] not [be deemed to] 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 thorium (thorium-dioxide); and

(b)

the thorium content in the nickel-thoria alloy does not exceed [4] four percent by weight.

D. [The exemptions in Subsection C of this section do not authorize the manufacture of any of the products described.] 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 one 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 one 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 20.3.3.301 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, 04/30/2009; A, 06/13/2017] [Editorial Note:

¹On July 25, 1983, the exemption of glass enamel or glass enamel frit was suspended. The exemption was eliminated on September 11, 1984.

²The requirements specified in Subsection C(5)(a) and (b) of this section need not be met by counterweights manufactured prior to Dec. 31, 1969, provided that such counterweights were manufactured under a specific license issued by the atomic energy commission and were impressed with the legend required by 10 CFR 40.13(c)(5)(ii) in effect on June 30, 1969.]

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) [RESERVED]
- (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;
- (d) [RESERVED];
- (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;
- (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;
- (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

(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 [~~or to transfer such products~~] 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 [~~radioactive~~] 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 [~~radioactive~~] byproduct

material, in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced or initially transferred in accordance with a specific license issued by the NRC, pursuant to 10 CFR 32.26, which license authorizes the initial transfer of the product for use under this paragraph. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by the department, agreement state or non-agreement state under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

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

(5) **[RESERVED] 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, repack 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, 04/30/2009; A, 06/30/2011; A, 06/13/2017]

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 state, federal and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, and educational, commercial or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.]

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 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;

(2) [Persons who receive, possess, use or transfer source material pursuant to the general license issued in Paragraph (1) of this subsection are exempt from the provision of 20.3.4 NMAC and 20.3.10 NMAC to the extent that such receipt, possession, use or transfer are within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this part.

(3) Persons who receive, possess, use or transfer source material pursuant to the general license in Paragraph (1) of this subsection are 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.] 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:

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

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

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

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

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

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

(b) The recipient of source material transferred under the provisions of this section is exempt from the

requirements to obtain a license under this part to the extent the source material is permanently disposed.

This provision does not apply to any person who is in possession of source material under a specific license issued under this chapter or in accordance with 20.3.4.433 NMAC.

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

(4) shall not

export such source material except in accordance with 10 CFR 110.

D. Any person who receives, possesses, uses, or transfers source material in accordance with subsection B of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the department by an appropriate method listed in 20.3.1.116 NMAC about such contamination and may consult with the department as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 20.3.4.426.B NMAC.

E. Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in Subsection B of this section is exempt from the provisions of 20.3.10 NMAC, and 20.3.4 NMAC to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 20.3.4.426.A NMAC and 20.3.4.433 NMAC to the extent necessary to meet the provisions of 20.3.3.304.B NMAC. However, this exemption

does not apply to any person who also holds a specific license issued under 20.3.3 NMAC.

F. No person may initially transfer or distribute source material to persons generally licensed under Subsection B(1) and (2) of this section, unless authorized by a specific license in accordance with 10 CFR 40.54 and equivalent 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.] G. Depleted uranium in industrial products and devices.

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

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

(3) Persons who receive, acquire, possess or use depleted uranium pursuant to

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

(a) name and address of the general licensee;

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

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

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

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

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

uranium;

(b) shall not abandon such depleted uranium;

(c) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 20.3.3.323 NMAC; in the case where the transferee receives the depleted uranium pursuant to the general license established by Paragraph (1) of this subsection, the transferor shall furnish the transferee a copy of this subsection and a copy of the registration form; in cases where the transferee receives the depleted uranium pursuant to a general license contained in the NRC or agreement state's regulation equivalent to this subsection, Subsection C of 20.3.3.304 NMAC, the transferor shall furnish the transferee a copy of this subsection and a copy of the registration form accompanied by a note explaining that use of the product or device is regulated by the NRC or agreement state under requirements substantially the same as those in this subsection;

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

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

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

[20.3.3.304 NMAC - Rp, 20.3.3.304 NMAC, 04/30/2009; A, 06/13/2017]

20.3.3.305 GENERAL LICENSES - RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL:

A. 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, ~~[radioactive]~~ 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, ~~[radioactive]~~ 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 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 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 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 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:

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 (i) 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 aircraft.

(1)

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

(a)

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

(b)

each device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions in Subsection F of 20.3.3.315 NMAC, or manufactured or assembled in accordance with a specific license

issued by the NRC or an agreement state which authorizes manufacture or assembly of the device for distribution to persons generally licensed by the NRC or an agreement state, and the device has been registered in the sealed source and device registry;

(c)

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

(d)

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

(2) Each

person licensed under 10 CFR 32.53 or equivalent agreement state regulations shall subject at least five prototypes of the device to the required tests and satisfactorily pass the required tests as follows:

(a)

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

(b)

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

(c)

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

(3) Each

person licensed under 10 CFR 32.55 or equivalent agreement state regulations shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

(4) Each person licensed under 10 CFR 32.53 or equivalent agreement state regulation 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 regulation 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 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:

(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 regulation.

(6) No person licensed under 10 CFR 32.53 or the equivalent agreement state regulation 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 regulation 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 regulation.

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

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

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

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

D. Calibration and reference sources.

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

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

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

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

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

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

(c)

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

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

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

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

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

(b) shall not receive, possess, use or transfer such source unless the source, or the storage container, bears a label which includes the

following statement or a substantially similar statement which contains the information called for in the following statement:

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

(name of manufacturer or initial transferor)

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

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

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

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

E. General license to install devices generally licensed in Subsection B of 20.3.3.305 NMAC.

Any person who holds a specific license issued by the NRC or an agreement state authorizing the holder to manufacture, install or service a device described in Subsection B of this section within such agreement state issuing the specific license or

within a location subject to NRC jurisdiction, is hereby granted a general license to install and service such device in this state; provided, that:

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

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

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

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

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

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

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

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

(e) iron-59, in units not exceeding 20

microcuries (740 kilobecquerels) each;

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

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

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

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

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

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

(ii) the location of use; and

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

(b) has a license that authorizes the medical use of radioactive material

that was issued under 20.3.7 NMAC.

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

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

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

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

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

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

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

(a) except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under Subsection H of 20.3.3.315 NMAC, or in accordance with the provisions of a specific license issued by the NRC or an agreement state, or labeled before November 30, 2007

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

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

(name of manufacturer)

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

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

and 20.3.10 NMAC with respect to radioactive material covered by that general license except that such person using a mock iodine-125 shall comply with the provisions of 20.3.4.433 NMAC, 20.3.4.451 NMAC and 20.3.4.452 NMAC.

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

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

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

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

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

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

NMAC, 20.3.4.451 NMAC and 20.3.4.452 NMAC.

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

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

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

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

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

(c) luminous items installed in air, marine or land vehicles;

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

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

static eliminators or as designated by the department or NRC.

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

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

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

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

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

(d) dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act, by transfer to a person authorized to receive radium-226 by a specific license

issued under this part, or equivalent regulations of the NRC, an agreement state or as otherwise approved by the department or NRC;

(e)

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

(4) The

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

I. General license

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

[20.3.3.305 NMAC - Rp, 20.3.3.305 NMAC, 04/30/2009; A, 06/13/2017]

20.3.3.307 FILING APPLICATION FOR SPECIFIC LICENSES:

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

incorporated by reference, provided that the reference is clear and specific.

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

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

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

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

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

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

(3) 10 CFR 37.7, 10 CFR 37.9, 10 CFR 37.11(a) and (b), 10 CFR 37.13, 10 CFR 37.105, 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.

[E.] E. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed

source must identify the source and (or) the device by manufacturer name and model number as registered with the *sealed source and device registry*.

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

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

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

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

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

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

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

quantity.

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

[F.] 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.

[G.] 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.

[H.] 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.

[I.] 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.

[J.] 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.

(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 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; and

(b) the applicant submits adequate information on, and the NRC 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 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 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 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 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 and 10 CFR 40.51 or equivalent regulations under 20.3.3.304 NMAC; and

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

(5) Each person licensed under 10 CFR 40.54 shall report transfers as follows:

(a)

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

(i)

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

(ii)

For each general licensee under 10 CFR 40.22 and 20.3.3.304.B 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 shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the NRC or to an agreement state agency.

[20.3.3.307 NMAC - Rp, 20.3.3.307 NMAC, 04/30/2009; A, 06/13/2017]

20.3.3.308 GENERAL REQUIREMENTS FOR THE ISSUANCE OF SPECIFIC LICENSES:

A. An application for a specific license shall be approved if all of the following requirements are met.

(1) The

application is for a purpose authorized by the act.

(2) The

applicant is qualified by training and experience to use the material for the purpose requested in accordance with the provisions in this chapter and in such a manner as to minimize the danger to public health and safety or property.

(3) The

applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property.

(4) The

applicant satisfies the requirements in this section, and any special requirements in 20.3.3.307 NMAC and 20.3.3.309 NMAC, 20.3.3.313

NMAC, 20.3.3.314 NMAC or 20.3.3.315 NMAC.

B. Upon a

determination that an application meets the requirements of the act and the 20.3 NMAC, the department will issue a specific license authorizing the possession and use of radioactive material.

C. The secretary may deny an application if an applicant:

(1) fails to

demonstrate that the requirements of the act and 20.3 NMAC have been addressed;

(2) fails

to meet the requirements for completeness and accuracy of information in 20.3.1.123 NMAC;

(3) has

demonstrated deliberate misconduct as described in 20.3.1.122 NMAC; and

(4) fails to

respond to a request for additional information within 30 days from the date of the request, or within such other time as may be specified in the request for information.

[20.3.3.308 NMAC - Rp, 20.3.3.308 NMAC, 04/30/2009; A, 06/13/2017]

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 [of] 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 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 [26110] 5469, Santa Fe, New Mexico 87502-[6110] 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, 04/30/2009; A, 06/13/2017]

20.3.3.311 FINANCIAL ASSURANCE AND RECORD KEEPING FOR DECOMMISSIONING:

A. Decommissioning funding plan required.

(1) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material (except source material which is subject to Paragraph (3) of this subsection) of half-life greater than 120 days in quantities exceeding 100,000 (1E+5) times the applicable quantities set forth in 20.3.3.338 NMAC, shall submit a decommissioning funding plan as described in Subsection E of this section. The decommissioning funding plan must also be submitted when a combination of radioisotopes is involved if R divided by 100,000 (1E+5) is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each radioisotope to the applicable value in 20.3.3.338 NMAC.

(2) Each applicant for a specific license authorizing the possession and use of sealed sources or plated foils of

half-life greater than 120 days and in quantities exceeding 10^{12} (1E+12) times the applicable quantities set forth in 20.3.3.338 NMAC (or when a combination of radioisotopes is involved if R, as defined in Paragraph (1) of this subsection, divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in Subsection E of this section.

(3) Each applicant for a specific license authorizing the possession and use of more than 100 (1E+2) millicuries of source material in a readily dispersible form shall submit a decommissioning funding plan as described in Subsection E of this section.

B. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in Subsection D of this section shall either:

(1) submit a decommissioning funding plan as described in Subsection E of this section; or

(2) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by Subsection D of this section using one of the methods described in Subsection F of this section; for an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material; if the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of Subsection F of this section must be submitted to the department before receipt of licensed material; if the applicant does not defer execution of the financial instrument, the applicant shall submit to the department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of Subsection F of this section.

C. **Financial assurance for holders of specific license.** Each holder of a specific license issued before the effective date of these regulations which is of a type described in Subsection A or B of this section shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(1) Each holder of a specific license issued before the effective date of these regulations, and of a type described in Subsection A of this section shall submit a decommissioning funding plan as described in Subsection E of this section.

(2) Each holder of a specific license issued before the effective date of these regulations, and of a type described in Subsection B of this section shall submit a decommissioning funding plan as described in Subsection E of this section, or a certification of financial assurance for decommissioning in accordance with the criteria set forth in Subsection D of this section.

(3) Any licensee who has submitted an application before the effective date of these regulations for renewal of license in accordance with 20.3.3.319 NMAC shall provide financial assurance for decommissioning in accordance with Subsections A and B of this section.

(4) Waste collectors and waste processors, as defined in 20.3.4.466 NMAC, must provide financial assurance in an amount based on a decommissioning funding plan as described in Subsection E of this section. The decommissioning funding plan must include the cost of disposal of the maximum amount (in curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 20.3.4.426 NMAC.

D. Required amounts of financial assurance for decommissioning by quantity of material. Licensees exceeding the upper bounds of this subsection must base financial assurance on a decommissioning funding plan as described in Subsection E of this section.

(1) Greater than 10,000 (1E+4) but less than or equal to 100,000 (1E+5) times the applicable quantities of 20.3.3.338 NMAC, in unsealed form. (For a combination of radioisotopes, if R as defined in Subsection A of this section, divided by 10,000 (1E+4) is greater than 1 but R divided by 100,000 (1E+5) is less than or equal to 1): at least equal to \$1,125,000.

(2) Greater than 1,000 (1E+3) but less than or equal to 10,000 (1E+4) times the applicable quantities of 20.3.3.338 NMAC, in unsealed form. (For a combination of radioisotopes, if R, as defined in Subsection A of this section, divided by 1,000 (1E+3) is greater than 1 but R divided by 10,000 (1E+4) is less than or equal to 1): at least equal to \$225,000.

(3) Greater than 10^{10} (1E+10) but less than or equal to 10^{12} (1E+12) times the applicable quantities of 20.3.3.338 NMAC, in sealed sources or plated foils. (For a combination of radioisotopes, if R, as defined in Subsection A of this section, divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1): at least equal to \$113,000.

(4) For source material, greater than 10 millicuries but less than or equal to 100 millicuries: at least equal to \$225,000.

E. Decommissioning funding plan. [Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from Subsection F of 20.3.3.311 NMAC including means for adjusting cost estimates and associated funding levels periodically over the life of the facility. Cost estimates must be adjusted at

intervals not to exceed 3 years. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirement of Subsection F of this section.]

(1) Each decommissioning funding plan must be submitted for review and approval and must contain a detailed cost estimate for decommissioning in an amount reflecting:

(a) the cost of an independent contractor to perform all decommissioning activities;

(b) the cost of meeting the 20.3.4.426.B NMAC criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 20.3.4.426.C NMAC, the cost estimate may be based on meeting the 20.3.4.426.C NMAC department approved criteria;

(c) the volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination;

(d) an adequate contingency factor with identification of and justification for using the key assumptions contained in the decommissioning cost estimate; [and]

(e) a description of the method of assuring funds for decommissioning from 20.3.3.311.F NMAC including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(f) a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(g) a signed original of the financial instrument obtained to satisfy the requirement of Subsection F of this

section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(a) spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(b) waste inventory increasing above the amount previously estimated;

(c) waste disposal costs increasing above the amount previously estimated;

(d) facility modifications;

(e) changes in authorized possession limits;

(f) actual remediation costs that exceed the previous cost estimate;

(g) onsite disposal; and

(h) use of a settling pond.

F. Methods of financial assurance. Financial assurance for decommissioning must be provided by one or more of the following methods.

(1) **Prepayment.** Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient

to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities.

(2) **A surety method, insurance or other guarantee method.** These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 20.3.3.334 NMAC. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 20.3.3.335 NMAC. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in 20.3.3.336 NMAC. For nonprofit entities, such as colleges, universities and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in 20.3.3.337 NMAC. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions.

(a) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the department, the beneficiary, and the

licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the department within 30 days after receipt of notification of cancellation.

(b) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the department. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(c) The surety method or insurance must remain in effect until the department has terminated the license.

(3) **An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund.** An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in Paragraph (2) of this subsection.

(4) In the case of federal, state or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on Subsection D of this section, and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

G. Record keeping requirements. Each person licensed under this part or Parts 5, 7, 12, 13 and 15 of this chapter shall keep records of information important to the decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with 20.3.3.17 NMAC, licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the department considers important to decommissioning consists of:

(1) records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment or site; these records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete; these records must include any known information on identification of involved nuclides, quantities, forms and concentrations;

(2) as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination; if required drawings are referenced, each relevant document need not be indexed individually; if drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas

and locations;

(3) except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

(a) all areas designated and formerly designated restricted areas as defined in 20.3.4.7 NMAC;

(b) all areas outside of restricted areas that require documentation under Paragraph (1) of this subsection;

(c) all areas outside of restricted areas where current and previous wastes have been buried as documented under 20.3.4.448 NMAC; and

(d) all areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 20.3.4.426 NMAC, or apply for approval for disposal under 20.3.4.434 NMAC; and

(4) records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

[20.3.3.311 NMAC - Rp, 20.3.3.311 NMAC, 04/30/2009; A, 06/13/2017]

20.3.3.313 SPECIAL REQUIREMENTS FOR ISSUANCE OF CERTAIN SPECIFIC LICENSES FOR RADIOACTIVE MATERIAL:

A. Industrial radiography operations. In addition to the requirements set forth in 20.3.3.307 NMAC and 20.3.3.308 NMAC, a specific license for use of sealed sources in industrial radiography will be issued if the applicant or licensee meets the specific requirements in 20.3.5

NMAC.

B. Medical use of radioactive materials. In addition to the requirements set forth in 20.3.3.307 NMAC and 20.3.3.308 NMAC, a specific license for use of sealed sources and unsealed radioactive materials for medical use will be issued if the applicant or licensee meets the specific requirements in 20.3.7 NMAC.

C. Well logging operations and subsurface tracer studies. In addition to the requirements set forth in 20.3.3.307 NMAC and 20.3.3.308 NMAC, a specific license for use of sealed sources in wireline service operations, including mineral-logging, radioactive markers or subsurface tracer studies will be issued if the applicant or licensee meets the specific requirements in 20.3.12 NMAC.

D. Land disposal of radioactive waste. In addition to the requirements set forth in 20.3.3.308 NMAC, a specific license for any method of land disposal of low-level radioactive waste will be issued if the applicant or licensee meets the specific requirements in 20.3.13 NMAC.

E. Naturally occurring radioactive materials in the oil and gas industry. In addition to the requirements set forth in 20.3.3.308 NMAC, a specific license for use of naturally occurring radioactive materials (NORM) in the gas and oil industry will be issued if the applicant or licensee meets the specific requirements in 20.3.14 NMAC.

F. Irradiators. In addition to the requirements set forth in 20.3.3.307 NMAC and 20.3.3.308 NMAC, a specific license for use of sealed sources in irradiators will be issued if the applicant or licensee meets the specific requirements in 20.3.15 NMAC.

[20.3.3.313 NMAC - Rp, 20.3.3.313 NMAC, 04/30/2009; A, 06/13/2017]

20.3.3.314 SPECIAL REQUIREMENTS FOR SPECIFIC LICENSES OF BROAD SCOPE: This section prescribes

requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain regulations governing holders of such licenses.

A. Types of specific licenses of broad scope.

(1) A "type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for purposes authorized by the act. The quantities specified are usually in the multicurie range.

(2) A "type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 20.3.3.332 NMAC, for purposes authorized by the act. The possession limit for a type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in column I of 20.3.3.332 NMAC. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in column I of 20.3.3.332 NMAC, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 20.3.3.332 NMAC, for any purposes authorized by the act. The possession limit for a type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in column II of 20.3.3.332 NMAC. If two or more radionuclides are possessed thereunder, the possession limit is

determined for each as follows: 1) for each radionuclide determine the ratio of the quantity possessed to the applicable quantity specified in Column II of 20.3.3.332 NMAC, for the radionuclide; 2) the sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. Requirements for the issuance of a type A specific license of broad scope.

An application for a type A specific license of broad scope will be approved if the following requirements are met.

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

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive materials.

(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, material accounting and management review that are necessary to assure safe operations, including:

(a) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(b) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiation safety matters; and

(c) the establishment of appropriate administrative procedures to assure:

(i) control of procurement and use of radioactive material;

(ii) completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of

facilities and equipment, training and experience of the user and the operating or handling procedures; and

(iii) review, approval and recording by the radiation safety committee of safety evaluation of proposed uses prepared in accordance with Item (ii) of this subparagraph prior to use of the radioactive material.

C. Requirements for the issuance of a type B specific license of broad scope.

An application for a type B specific license of broad scope will be approved if the following requirements are met.

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

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, material accounting and management review that are necessary to assure safe operations, including:

(a) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiation safety matters; and

(b) the establishment of appropriate administrative procedures to assure:

(i) control of procurement and use of radioactive material;

(ii) completion of safety evaluations of proposed uses of radioactive materials which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

(iii) review, approval and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with Item (ii) of this subparagraph.

D. Requirements

for the issuance of a type C specific license of broad scope.

An application for a type C specific license of broad scope will be approved if the following requirements are met.

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

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(a) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(b) at least 40 hours of training and experience in the safe handling of radioactive materials, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control, material accounting and management review necessary to assure safe operations.

E. Conditions of specific licenses of broad scope.

(1) Unless specifically authorized pursuant to other parts of this chapter, persons licensed under this section shall not:

(a) conduct tracer studies in the environment involving direct release of radioactive material;

(b) receive, acquire, own, possess, use, transfer or import devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of material;

(c) conduct activities for which a specific license issued by the department

under 20.3.5 NMAC, 20.3.7 NMAC or 20.3.3.315 NMAC is required; or

(d)

add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each

type A specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license shall only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each

type B specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license shall only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each

type C specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license shall only be used by, or under the direct supervision of, individuals who satisfy the requirements of Paragraph (2) of Subsection D of this section.

[20.3.3.314 NMAC - Rp, 20.3.3.314 NMAC, 04/30/2009; A, 06/13/2017]

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.

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

D. [RESERVED]

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

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

(a)

the applicant satisfies the general requirements of 20.3.3.308 NMAC;

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

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

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

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

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

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

(ii)

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

(iii)

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

The receipt, possession, use and transfer of this device model

_____, *serial number*

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

Caution-radioactive material

_____,
(name of manufacturer or distributor)

(d)

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

(e)

each device meeting the criteria of Item (i) in Subparagraph (m) of Paragraph (3) of Subsection B of 20.3.3.305 NMAC, bears a permanent (e.g., embossed, etched, stamped or engraved) label affixed to the source housing if separable, or the device if the source housing is not

separable, that includes the words, "caution-radioactive material," and, if practicable, the radiation symbol described in 20.3.4.427 NMAC.

(2) **Requests**

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

(a)

primary containment (source capsule);

(b)

protection of primary containment;

(c)

method of sealing containment;

(d)

containment construction materials;

(e)

form of contained radioactive material;

(f)

maximum temperature withstood during prototype test;

(g)

maximum pressure withstood during prototype test;

(h)

maximum quantity of contained radioactive material;

(i)

radiotoxicity of contained radioactive material; and

(j)

operating experience with identical devices or similarly designed and constructed devices.

(3)

Authorizations for general licensees to perform certain activities. In the

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

(4) **Transfer**

provisions:

(a)

If a device containing radioactive material is to be transferred for use under the general license contained in Subsection B of 20.3.3.305 NMAC, each person that is licensed under Paragraph (1) of Subsection D of 20.3.3.315 NMAC shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information shall be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information shall also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(i)

a copy of the general license contained in Paragraph (1) of Subsection D of 20.3.3.315 NMAC; if Subparagraphs (b) through (d) of Paragraph (3) of Subsection B of 20.3.3.305 NMAC or Subparagraph (m) of Paragraph (3) of Subsection B of 20.3.3.305 NMAC do not apply to

the particular device, those paragraphs may be omitted;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) The required information for transfers to general licensees includes: 1) the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an

alternate address for the general licensee shall be submitted along with information on the actual location of use; 2) the name, title and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements; 3) the date of transfer; 4) the type, model number, and serial number of the device transferred; and 5) the quantity and type of radioactive material contained in the device.

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

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

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

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

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

(vii) If no transfers have been made to or

from persons generally licensed under Subsection B of 20.3.3.305 NMAC during the reporting period, the report shall so indicate.

(b)

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

(i)

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

(ii)

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

(iii)

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

initial transferor.

(iv)

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

(v)

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

(vi)

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

(vii)

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

(c)

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

F. Special

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

(1) the

applicant satisfies the general requirements specified in 20.3.3.308 NMAC;

(2) the

applicant satisfies the requirements of 10 CFR 32.53, 10 CFR 32.54, 10

CFR 32.55 and 10 CFR 32.56 or their equivalent;

(3) each

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

(4) each

person licensed under 10 CFR 32.53 shall report annually all transfers of devices to persons for use under a general license in an agreement state's regulations that are equivalent to 10 CFR 31.7 of this paragraph to the responsible agreement 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:

<p>(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);</p>	<p>(i) ensures that the syringe, vial or other container can be correlated with the information on the transport radiation shield label.</p>	<p>at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies in non-licensing states, as defined in 20.3.1.7 NMAC, before August 8, 2009, or an earlier date as noticed by the NRC;</p>
<p>(ii) registered or licensed with a state agency as a drug manufacturer;</p>	<p>(2) A licensee described by Items (iii) or (iv) of Subparagraph (b) of Paragraph (1) of this subsection:</p>	<p>(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</p>
<p>(iii) licensed as a pharmacy by a state board of pharmacy;</p>	<p>(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;</p>	<p>(f) shall provide to the department a copy of</p>
<p>(iv) operating as a nuclear pharmacy within a federal medical institution; or</p>	<p>(b) may allow a pharmacist to work as an authorized nuclear pharmacist if:</p>	<p>(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</p>
<p>(v) a PET drug production facility registered with a state agency.</p>	<p>(i) the individual qualifies as an authorized nuclear pharmacist as defined in 20.3.7.7 NMAC;</p>	<p>(ii) the department, NRC or agreement state license, or</p>
<p>(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.</p>	<p>(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</p>	<p>(iii) the permit issued by a NRC master material licensee, or</p>
<p>(d) The applicant satisfies the following labeling requirements.</p>	<p>(iii) the individual is designated as an authorized nuclear pharmacist in accordance with Subparagraph (d) of this paragraph;</p>	<p>(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</p>
<p>(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</p>	<p>(c) may conduct the actions authorized in Subparagraphs (a) and (b) of this paragraph in spite of more restrictive language in license conditions;</p>	<p>(v) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies in non-licensing states, as defined in 20.3.1.7 NMAC, before August 8, 2009, or an earlier date as noticed by the NRC; and</p>
<p>(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</p>	<p>(d) may designate a pharmacist (as defined in 20.3.7.7 NMAC) as an authorized nuclear pharmacist if:</p> <p>(i) the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and</p> <p>(ii) the individual practiced at a pharmacy</p>	<p>(vi) the state pharmacy licensure or registration, no later than 30 days</p>

after the date that the licensee allows, under Items (i) and (iii) of Subparagraph (b) of this paragraph, the individual to work as an authorized nuclear pharmacist.

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

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

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

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

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

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

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

L. Requirements

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

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

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

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

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

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

(3) The department may deny application for a specific license under this subsection if the end use of the

industrial product or device cannot be reasonably foreseen.

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

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

(b) label or mark each unit to:

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

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

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

(d) furnish a copy of the general license contained in Subsection C of 20.3.3.304 NMAC and a copy of the department form to each person to whom they transfer depleted uranium in a product or device for use pursuant to the general license contained in Subsection C of 20.3.3.304 NMAC; or furnish a copy of the general license contained in the NRC or agreement state's regulation equivalent to Subsection C of 20.3.3.304 NMAC and a copy of the NRC or agreement state's certificate; or alternatively, furnish a copy of the general license contained in Subsection C of 20.3.3.304 NMAC and a copy of department form to each person to whom they transfer depleted uranium in a product or

device for use pursuant to the general license of the NRC or an agreement state, with a note explaining that use of the product or device is regulated by the NRC or an agreement state under requirements substantially the same as those in Subsection C of 20.3.3.304 NMAC;

(e)

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

(f)

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

(g)

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

(h)

keep records showing the name, address and point of contact for each general licensee to whom they

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

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

N. Serialization

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

[20.3.3.315 NMAC - Rp, 20.3.3.315 NMAC, 04/30/2009; A, 06/13/2017]

20.3.3.317 TERMS AND CONDITIONS OF LICENSES:

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

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

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

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

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

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

E. Filing for bankruptcy.

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

(a)

the licensee;

(b)

an entity (as that term is defined in 11 U.S.C. 101([+4] 15)) controlling the licensee or listing the license or licensee as property of the estate; or

(c)

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

(2) The

notification must indicate:

(a)

the bankruptcy court in which the petition for bankruptcy was filed; and

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

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

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

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

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

J. **PET drugs for non-commercial distribution.**

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

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

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

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

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

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

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

(4)

A pharmacy, authorized under Subsection J of 20.3.3.307 NMAC to produce PET radioactive drugs for non-commercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Subparagraph (e) of Paragraph (2) of Subsection J of 20.3.3.315 NMAC. [20.3.3.317 NMAC - Rp, 20.3.3.317 NMAC, 04/30/2009; A, 06/30/2011; A, 06/13/2017]

ENVIRONMENT DEPARTMENT RADIATION CONTROL BUREAU

This is an amendment to 20.3.4 NMAC, Section 416, 425, 426, and 442, effective 06/13/2017.

20.3.4.416 GENERAL REQUIREMENTS FOR SURVEY AND MONITORING:

A. Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

(1) may be necessary to demonstrate compliance with this part; and

(2) are necessary under the circumstances to evaluate:

(a) the magnitude and extent of radiation levels;

(b) concentrations or quantities of radioactive-material and residual radioactivity; [and]

(c) the potential radiological hazards of the radiation levels and residual radioactivity detected; and

(d) notwithstanding 10 CFR 20 or equivalent state regulations of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with the applicable

regulations in 10 CFR parts 30, 40, 50, 70, or 72.30 or equivalent state regulations.

B. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements (e.g. dose rate and effluent monitoring) are calibrated at intervals not to exceed 12 months, except when a more frequent interval is specified in another applicable part of this chapter or in a license condition.

C. All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremity) that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 20.3.4.405 NMAC, with other applicable provisions of this chapter or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(1) holding current personnel dosimetry accreditation from the national voluntary laboratory accreditation program (NVLAP) of the national institute of standards and technology (NIST); and

(2) approved in this accreditation process for the type of radiation or radiations included in the national voluntary laboratory accreditation program (NVLAP) program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

D. The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

[20.3.4.416 NMAC - Rp, 20.3.4.416 NMAC, 04/30/2009; A, 06/13/2017]

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 37.71, 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.

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, 06/13/2017]

20.3.4.426 RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION:

A. General provisions and scope.

(1) The criteria in this part apply to the decommissioning of any facility licensed under this chapter as well as other facilities subject to the

department's jurisdiction under the Act. For low-level waste disposal facilities licensed under 20.3.13 NMAC, the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities.

(2) The criteria in this section do not apply to sites which:

(a) have been decommissioned prior to the effective date of the rule; or,

(b) have previously submitted and received department approval on a license termination plan or decommissioning plan that is compatible with applicable department criteria.

(3) After a site has been decommissioned and the license terminated in accordance with the criteria in this section, the department will require additional cleanup only if, based on new information, it determines that the criteria of this section were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(4) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

B. Radiological criteria for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 millirems (0.25 millisievert) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

C. Criteria for

License Termination under Restricted Conditions. A site will be considered acceptable for license termination under restricted conditions if:

(1) the licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of Subsection B of this section would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA; determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(2) the licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirems (0.25 millisievert) per year;

(3) the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site; acceptable financial assurance mechanisms are:

(a) funds placed into ~~[an] a trust [account]~~ segregated from the licensee's assets and outside the licensee's administrative control, ~~[as described in Paragraph (1) of Subsection F of 20.3.3.311 NMAC]- and in which the adequacy of the trust funds is to be assessed based on an assumed annual one percent real rate of return on investment;~~

(b) surety method, insurance, or other guarantee method as described in Paragraph (2) of Subsection F of 20.3.3.311 NMAC;

(c) a statement of intent in the case of federal, state, or local government

licensees, as described in Paragraph (4) of Subsection F of 20.3.3.311 NMAC; or

(d) when a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity;

(4) the licensee has submitted a decommissioning plan or license termination plan to the department indicating the licensee's intent to decommission in accordance with Subsection E of 20.3.3.318 NMAC, and specifying that the licensee intends to decommission by restricting use of the site; the licensee shall document in the license termination plan or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice:

(a) licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(i) whether provisions for institutional controls proposed by the licensee: 1) will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirems (0.25 millisievert) TEDE per year; 2) will be enforceable; and 3) will not impose undue burdens on the local community or other affected parties;

(ii) whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(b) in seeking advice on the issues identified in Subparagraph (a) of this paragraph, the licensee shall provide for:

(i) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(5) residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is ALARA and would not exceed either:

(a) 100 millirems (1 millisievert) per year; or

(b) 500 millirems (5 millisieverts) per year provided the licensee:

(i) demonstrates that further reductions in residual radioactivity necessary to comply with the 100 millirems per year (1 millisievert per year) value of Subparagraph (a) of this paragraph are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) makes provisions for durable institutional controls; and

(iii) provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the criteria of Paragraph (2) of

this subsection and to assume and carry out responsibilities for any necessary control and maintenance of those controls; acceptable financial assurance mechanisms are those in Paragraph (3) of this subsection.

D. Alternate Criteria for License Termination.

(1) The department may terminate a license using alternate criteria greater than the dose criterion of Subsection B of this section, Paragraph (2) of Subsection C of this section, and Item (i) of Subparagraph (a) of Paragraph (4) of Subsection C of this section, if the licensee:

(a) provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 100 millirem per year (1 millisievert per year) limit of 20.3.4.413 NMAC, by submitting an analysis of possible sources of exposure;

(b) has employed to the extent practical restrictions on site use according to the provisions of Subsection C of this section in minimizing exposures at the site;

(c) reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal; and

(d) has submitted a decommissioning plan or license termination plan to the department indicating the licensee's intent to decommission in accordance with Subsection E of 20.3.3.318 NMAC, and specifying that the licensee proposes to decommission by use of alternate criteria; the licensee shall document in the decommissioning plan or license termination plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice; in

seeking such advice, the licensee shall provide for:

(i) participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) an opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) a publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(e) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(2) The use of alternate criteria to terminate a license requires the approval of the department after consideration of the department staff's recommendations that will address any comments provided by state and federal agencies and any public comments submitted pursuant to Subsection E of this section.

E. Public Notification and Public Participation. Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to Subsection C or D of this section, or whenever the department deems such notice to be in the public interest, the department shall:

(1) notify and solicit comments from:

(a) local governments in the vicinity of the site and any Indian nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(b) the EPA for cases where the licensee

proposes to release a site pursuant to Subsection D of this section; and

(2) publish a notice in the state register and in a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from the public and affected parties; further, that the public notice may be published in any language when appropriate.

F. Minimization of contamination. ~~[Applicants for licenses, other than renewals, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste]~~ Licensee shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 20.3.4.404 NMAC and the radiological criteria for license termination in 20.3.4.426 NMAC. [20.3.4.426 NMAC - Rp, 20.3.4.426 NMAC, 04/30/2009; A, 06/13/2017]

20.3.4.442 RECORDS OF SURVEYS:

A. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 20.3.4.416 NMAC and Subsection B of 20.3.4.432 NMAC. The licensee or registrant shall retain these records for 3 years after the record is made.

B. The licensee or registrant shall retain each of the following records until the department terminates each pertinent license or registration requiring the record:

(1) records of the results of surveys to determine the dose from external sources of radiation and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(2) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(3) records showing the results of air sampling, surveys and bioassays required pursuant to Subparagraphs (a) and (b) of Paragraph (3) of Subsection A of 20.3.4.423 NMAC; and

(4) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment; and

(5) records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with 20.3.3 NMAC as applicable.
[20.3.4.442 NMAC - Rp, 20.3.4.442 NMAC, 04/30/2009; A, 06/13/2017]

ENVIRONMENT DEPARTMENT RADIATION CONTROL BUREAU

This is an amendment to 20.3.5 NMAC, Section 10 and 21 effective 06/13/2017.

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 37.71, 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.

[B:] 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.

[C:] 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.

[D:] E. The applicant submits written operating and emergency procedures as described in 20.3.5.29 NMAC.

[E:] 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.

[F:] 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.

[G:] 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.

[H:] 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.

[I:] 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.

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

[K:] 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).
[20.3.5.10 NMAC - N, 5/19/02; A,

06/13/2017]

20.3.5.21 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT:

Equipment used in industrial radiographic operations must meet the following minimum criteria:

A. Each radiographic exposure device and all associated equipment must meet the requirements specified in American national standard N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the director of the federal register in accordance with 5 U.S.C. 552(a). This publication may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 and from the American National Standards Institute, Inc., [430 Broadway] 25 West 43rd Street, New York, New York [10018] 10036, Telephone (212) 642-4900.

B. In addition to the requirements specified in Subsection A of 20.3.5.21 NMAC, the following requirements apply to radiographic exposure devices and associated equipment;

(1) Each radiographic exposure device utilizing radioactive material must have attached to it by the user, a durable, legible, clearly visible label bearing the:

(a) chemical symbol and mass number of the radionuclide in the device;

(b) activity and the date on which this activity was last measured;

(c) model number and serial number of the sealed source;

(d) manufacturer of the sealed sources; and

(e) licensee's name, address, and telephone number.

(2)

Radiographic exposure devices intended for use as type B transport containers must meet the applicable requirements of 10 CFR part 71; and

(3)

Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

C. In addition to the requirements specified in Subsections A and B of 20.3.5.21 NMAC, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation.

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words "DANGER--RADIOACTIVE." The label must not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

(9) Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

D. All radiographic exposure devices and associated equipment in use must comply with the requirements of this section.

E. Notwithstanding Subsection A of 20.3.5.21 NMAC, equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the endurance test in American national standards institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism. [20.3.5.21 NMAC - Rp, 20 NMAC 3.1.5.506, 5/19/02; A, 06/13/2017]

**ENVIRONMENT
DEPARTMENT
RADIATION CONTROL
BUREAU**

This is an amendment to 20.3.7 NMAC, Section 700 and 703, effective 06/13/2017.

**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 37.71, 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.

~~(3)~~ (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.

~~(4)~~ (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.

~~(5)~~ (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.

~~(6)~~ (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: 1) 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 2) 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, 04/30/2009; A, 06/13/2017]

20.3.7.703 GENERAL TECHNICAL REQUIREMENTS:

A. Possession, use and calibration of instruments used to measure the activity of unsealed radioactive material. Other than unit dosages of beta-emitting

unsealed radioactive material obtained from the manufacturer or preparer, licensed pursuant to Subsection J of 20.3.3.315 NMAC, a medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator, and use it to measure the activity of unsealed radioactive material prior to the administration to each patient or human research subject for diagnostic applications. For therapeutic applications, a medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator, and use it to measure the activity of unsealed radioactive material prior to and after the administration to each patient or human research subject.

(1) A licensee

shall:

(a)

check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use; to satisfy the requirements of this section, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (370 kilobecquerels) of radium-226 or 50 microcuries (1.85 megabecquerels) of any other photon-emitting radionuclide;

(b)

test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within five percent of the stated activity, with minimum activity of 10 microcuries (370 kilobecquerels) for radium-226 and 50 microcuries (1.85 megabecquerels) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 kiloelectron volts and 500 kiloelectron volts;

(c)

test each dose calibrator for linearity upon installation and at intervals not to exceed [3] three months thereafter over the range of use between 30 microcuries (1.11 megabecquerels), and the highest dosage that will be administered to a patient or human

research subject; and

(d)

test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used; the licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(2)

A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds [10] ten percent if the dosage is greater than 10 microcuries (370 kilobecquerels), and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds ten percent.

(3)

A licensee shall also perform checks and tests required under this subsection, following adjustment or repair of the dose calibrator.

(4)

Beta-emitting radionuclides.

A licensee shall develop quality control procedures and use appropriate instrumentation to measure the radioactivity for beta-emitting radiopharmaceuticals. A licensee may use checks, tests or calibration techniques other than those described in this section for instruments measuring the dosages of beta-emitting unsealed radioactive material if checks, tests or calibration techniques are in accordance with nationally recognized standards or the equipment manufacturer's instructions and have been approved by the department.

(5)

A licensee shall retain a record of each instrument check, test and calibration required by this subsection in accordance with Subsection E of 20.3.7.715 NMAC.

B. Determination of dosages of unsealed radioactive material for medical use.

(1)

A licensee shall determine and record the activity of each dosage before medical use for diagnostic applications and before and after medical use for therapeutic applications.

(2)

This determination must be made by:

(a)

direct measurement of radioactivity pursuant to Subsection A of this section;

(b)

combination of direct measurement of radioactivity pursuant to Subsection A of this section and mathematical calculations;

(c)

combination of volumetric measurements and mathematical calculations, based on the measurement made by:

(i)

a manufacturer or preparer licensed under Subsection J of 20.3.3.315 NMAC or equivalent requirement of NRC or agreement state; or

(ii)

a PET radioactive drug producer licensed under Subsection J of 20.3.3.307 NMAC or equivalent NRC or agreement state requirements; or

(d)

decay correction, for unit dosages of beta-emitting unsealed radioactive material, based on the activity or activity concentration determined by:

(i)

a manufacturer or preparer licensed under Subsection J of 20.3.3.315 NMAC or equivalent NRC or agreement state requirement;

(ii)

a department, NRC or agreement state licensee for use in research in accordance with a radioactive drug research committee-approved protocol or an investigational new drug (IND) protocol accepted by FDA; or

(iii)

a PET radioactive drug producer licensed under Subsection J of 20.3.3.307 NMAC or equivalent NRC or agreement state requirements.

(3)

Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than [20] twenty percent.

(4)

A licensee shall retain a record of the dosage determination required by this subsection in accordance with

Subsection G of 20.3.7.715 NMAC.

C. Calibration

and check of radiation survey instruments.

(1)

A licensee shall calibrate the radiation survey instruments used to show compliance with this part and 20.3.4 NMAC before first use, annually and following a repair that affects the calibration.

(2)

A licensee shall:

(a)

calibrate all scales with readings up to 1000 millirems (10 millisieverts) per hour with a radiation source;

(b)

calibrate two separate readings on each scale or decade that will be used to show compliance; and

(c)

conspicuously note on the instrument the date of calibration.

(3)

A licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by no more than twenty percent.

(4)

A licensee shall check each radiation survey instrument for proper operation with a dedicated check source at the beginning of each day of use.

(5)

A licensee shall retain a record of each radiation survey instrument calibration in accordance with Subsection F of 20.3.7.715 NMAC.

D. Quality control

for other equipment. Each licensee shall establish written quality control procedures (checks, tests, calibrations, efficiency measurements, etc.) for equipment used to obtain quantitative radiation measurements for radionuclide studies, described in this part, or radiation safety surveys, necessary to demonstrate compliance with this part and 20.3.4 NMAC. At a minimum, quality control procedures and their frequencies shall be those recommended by the equipment manufacturer.

E. Authorization

for calibration, transmission and reference sources. Any person authorized by Subsection D of

20.3.7.700 NMAC for medical use of radioactive material may receive, possess and use any of the following radioactive material for check, calibration, transmission and reference use:

(1) sealed sources, not exceeding 30 millicuries (1.11 gigabecquerels) each, manufactured and distributed by a person specifically licensed under Subsection K of 20.3.3.315 NMAC or equivalent NRC or an agreement state requirements;

(2) sealed sources, not exceeding 30 millicuries (1.11 gigabecquerels) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Subsection K of 20.3.3.315 NMAC, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

(3) any radioactive material with a half-life no longer than 120 days in individual amounts not to exceed 15 millicuries (0.56 gigabecquerel);

(4) any radioactive material with a half-life longer than 120 days in individual amounts not to exceed 200 microcuries (7.4 megabecquerels) or 1000 times the quantities in 20.3.3.338 NMAC; and

(5) technetium-99m in amounts as needed but not to exceed 100 millicuries.

F. Requirements for possession of sealed sources and brachytherapy sources.

(1) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer and shall maintain the instructions for the duration of source use in a legible form convenient for users.

(2) A licensee in possession of a sealed source shall:

(a) test the source for leakage before its first use unless the licensee has a

certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(b) test the source for leakage at intervals not to exceed [6] six months or at other intervals approved by the department, NRC or an agreement state.

(3) To satisfy the leak test requirements of this subsection, the licensee shall measure the sample so that the leak test can detect the presence of 0.005 microcurie (185 becquerels) of radioactive material in the sample.

(4) A licensee shall retain leak test records in accordance with Paragraph (1) of Subsection H of 20.3.7.715 NMAC.

(5) If the leak test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, the licensee shall:

(a) immediately withdraw the sealed source from use and store, cause it to be repaired or disposed of in accordance with the requirements in 20.3.3 NMAC and 20.3.4 NMAC; and

(b) file a report within [5] five days of the leak test result in accordance with Subsection C of 20.3.7.716 NMAC.

(6) A licensee need not perform a leak test on the following sources:

(a) sources containing only radioactive material with a half-life of less than 30 days;

(b) sources containing only radioactive material as a gas;

(c) sources containing 100 microcuries (3.7 megabecquerels) or less of beta or gamma-emitting material or 10 microcuries (0.37 megabecquerel) or less of alpha-emitting material;

(d) seeds of iridium-192 encased in nylon ribbon; and

(e) sources stored and not being used; however, the licensee shall test each

such source for leakage before any use or transfer unless it has been leak tested within [6] six months, or other frequency approved by the department, NRC or an agreement state, before the date of use or transfer.

(7) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with Paragraph (2) of Subsection H of 20.3.7.715 NMAC.

G. Labeling of vials and syringes. Each syringe and vial that contains unsealed radioactive material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

H. Surveys for contamination and ambient radiation exposure rate.

(1) In addition to the surveys required by 20.3.4 NMAC:

(a) a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared or administered; and

(b) a licensee shall survey for removable contamination at the end of each day of use all areas where radiopharmaceuticals requiring written directive are routinely prepared for use or administered.

(2) A licensee does not need to perform the surveys required by Paragraph (1) of this subsection in areas where patients or human research subjects are confined when they cannot be released under Subsection I of 20.3.7.703 NMAC.

(3) A licensee shall retain a record of each survey in accordance with Subsection I of 20.3.7.715 NMAC.

I. Release of individuals containing radiopharmaceuticals or permanent

implants.

(1) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem ([5] five millisieverts) (the current revision of the NRC guidance NUREG-1556, volume 9, "*consolidated guidance about materials licenses: program-specific guidance about medical licenses*", describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem ([5] five millisieverts)).

(2) A licensee shall provide the released individual or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (one millisievert). If the total effective dose equivalent to a nursing infant or child could exceed 0.1 rem (one millisievert), assuming there was no interruption of breast-feeding, the instructions must also include:

(a) guidance on the interruption or discontinuation of breast-feeding; and

(b) information on the potential consequences, if any, of failure to follow the guidance.

(3) A licensee shall maintain a record of the basis for authorizing the release of an individual, in accordance with Paragraph (1) of Subsection J of 20.3.7.715 NMAC.

(4) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with Paragraph (2) of Subsection J of 20.3.7.715 NMAC.

J. Provision of mobile medical service.

(1) A licensee providing mobile medical service shall:

(a) obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;

(b) check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent; at a minimum, the check for proper function required by this paragraph must include a constancy check;

(c) check radiation survey instruments for proper operation with a dedicated check source before use at each client's address or on each day of use, whichever is more frequent; and

(d) before leaving a client's address, survey all areas of use to ensure compliance with the requirements in 20.3.4 NMAC and 20.3.7 NMAC.

(2) A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client must be received and handled in conformance with the client's license.

(3) A licensee providing mobile medical services shall retain the letter required in Subparagraph (a) of Paragraph (1) of this subsection and the record of each survey required in Subparagraph (d) of Paragraph (1) of this subsection in accordance with Paragraphs (1) and (2) of Subsection K of 20.3.7.715 NMAC, respectively.

K. Storage of volatiles and gases.

(1) A license shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield

and container.

(2) A license shall store and use a multi-dosage container in a properly functioning fume hood.

L. Decay-in-storage.

(1) A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard of its radioactivity if the licensee:

(a) holds radioactive material for decay a minimum of 10 half-lives;

(b) monitors radioactive material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(c) removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

(d) separates and monitors each generator column individually with all radiation shielding removed to ensure that its content have decayed to background radiation level before disposal.

(2) A licensee shall retain a record of each disposal permitted under Paragraph (1) of this subsection in accordance with Subsection L of 20.3.7.715 NMAC. [20.3.7.703 NMAC - Rp, 20 NMAC 3.1.7.703, 04/30/2009; A, 06/13/2017]

**ENVIRONMENT
DEPARTMENT
RADIATION CONTROL
BUREAU**

This is an amendment 20.3.12 NMAC, Section 9, effective 06/13/2017.

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 37.71, 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.

[B:] 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.

[E:] 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.

[D:] 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.

[E:] E. 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.

[F:] 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, 06/13/2017]

ENVIRONMENT DEPARTMENT RADIATION CONTROL BUREAU

This is an amendment to 20.3.15 NMAC, Sections 1502, 1506, 1515, 1518 and 1524, effective 06/13/2017.

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 37.71, 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 New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.

[B:] 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.

[G:] 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.

[D:] 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.

[E:] E. 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.

[F:] 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.

[G:] 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.

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

[05/03/95; 20.3.15.1502 NMAC - Rn, 20 NMAC 3.1.15.1502, 04/15/2004; A, 06/13/2017]

20.3.15.1506 PERFORMANCE CRITERIA FOR SEALED SOURCES:

A. Requirements.

Sealed sources installed after July 1, 1993:

- (1) must be doubly encapsulated;
- (2) must use radioactive material that is as non-dispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;
- (3) must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and
- (4) in prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in Subsections B [and] through G of 20.3.15.1506 NMAC.

B. Temperature. The test source must be held at -40 degrees C for 20 minutes, 600 degrees C for one hour, and then be subject to a thermal shock test with a temperature drop from 600 degrees C to 20 degrees C within 15 seconds.

C. Pressure. The test source must be twice subjected for

at least five minutes to an external pressure (absolute) of 2 million newtons per square meter.

D. Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

E. Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz, with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

F. Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

G. Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

[05/03/95; 20.3.15.1506 NMAC - Rn, 20 NMAC 3.1.15.1506, 04/15/2004; A, 06/13/2017]

20.3.15.1515 DESIGN REQUIREMENTS: Irradiators whose construction begins after July 1, 1993, must meet the design requirements of this section.

A. Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete, and design the walls, wall penetrations and entrance ways to meet the radiation shielding requirements of 20.3.15.1508 NMAC. If the irradiator will use more than 2×10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

B. Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil

characteristics, to ensure it is adequate to support the weight of the facility shield walls.

C. Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of Subsection B of 20.3.15.1512 NMAC, and that metal components are metallurgically compatible with other components in the pool.

D. Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of ~~[Subsection B]~~ Subsection E of 20.3.15.1512 NMAC. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

E. Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by Subsection A of 20.3.15.1510 NMAC. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under Subsection B of 20.3.15.1521 NMAC, the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

F. Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that

source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

G. Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of 20.3.15.1507 NMAC.

H. Fire protection. For panoramic irradiators, the licensee shall verify that the number, location and spacing of the smoke and heat detectors are appropriate to detect fires, and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities and flow characteristics for complete coverage of the radiation room, and that the system is protected from mechanical and radiation damage.

I. Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if off-site power is lost for more than 10 seconds.

J. Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American concrete institute standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

K. Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to

radiation.

[05/03/95; 20.3.15.1515 NMAC - Rn, 20 NMAC 3.1.15.1515, 04/15/2004; A, 06/13/2017]

20.3.15.1518 OPERATING AND EMERGENCY PROCEDURES:

A. The licensee shall have and follow written operating procedures for:

- (1) operation of the irradiator, including entering and leaving the radiation room;
- (2) use of personnel dosimeters;
- (3) surveying the shielding of panoramic irradiators;
- (4) monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
- (5) leak testing of sources;
- (6) inspection and maintenance checks required by 20.3.15.1522 NMAC;
- (7) loading, unloading and repositioning sources, if the operations will be performed by the licensee; and
- (8) inspection of movable shielding required by Subsection H of ~~[20.3.15.1517 NMAC]~~ 20.3.15.1507 NMAC; if applicable.

B. The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

- (1) sources stuck in the unshielded position;
- (2) personnel overexposures;
- (3) a radiation alarm from the product exit portal monitor or pool monitor;
- (4) detection of leaking sources, pool contamination or alarm caused by contamination of pool water;
- (5) a low or high water level indicator, an abnormal water loss or leakage from the source storage pool;
- (6) a prolonged loss of electrical power;

(7) a fire alarm or explosion in the radiation room;

(8) an alarm indicating unauthorized entry into the radiation room, area around pool or another alarmed area;

(9) natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(10) the jamming of automatic conveyor systems.

C. The licensee may revise operating and emergency procedures without department approval only if all of the following conditions are met:

(1) the revisions do not reduce the safety of the facility;

(2) the revisions are consistent with the outline or summary of procedures submitted with the license application;

(3) the revisions have been reviewed and approved by the radiation safety officer; and

(4) the users or operators are instructed and tested on the revised procedures before they are put into use.

[05/03/95; 20.3.15.1518 NMAC - Rn, 20 NMAC 3.1.15.1518, 04/15/2004; A, 06/13/2017]

20.3.15.1524 ATTENDANCE DURING OPERATION:

A. Both an irradiator operator, and at least one other individual who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present on-site:

(1) whenever the irradiator is operated using an automatic product conveyor system; and

(2) whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

B. At a panoramic irradiator at which static irradiations

(no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in Subsection G of 20.3.15.1517 NMAC must be onsite.

C. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in Subsections F and G of 20.3.15.1517 NMAC. Static irradiations may be performed without a person present at the facility.

[05/03/95; 20.3.15.1524 NMAC - Rn, 20 NMAC 3.1.15.1524, 04/15/2004; A, 06/13/2017]

End of Adopted Rules.