STATEMENT OF REASONS

1. Pursuant to NMSA 1978, Section 74-3-15 (1977), the State of New Mexico ("State") administers the Radiation Protection Program through an agreement between the United States Nuclear Regulatory Commission ("NRC") and the State titled "Agreement Between the United States Atomic Energy Commission and the State of New Mexico for Discontinuance of Certain Commission Regulatory Authority and Responsibility within the State Pursuant to Section 274 of the Atomic Energy Act of 1954, As Amended" executed on April 3, 1974 ("Agreement"). The Agreement provides for discontinuance of the regulatory authority of the NRC and acceptance of that authority by the Environmental Improvement Board ("EIB") and Environmental Protection Division of the New Mexico Environment Department ("Department"). §74-3-15. For the duration of the Agreement, the EIB shall have the authority to regulate the radioactive materials covered by the Agreement for the protection of the public health and safety and the environment from radiation hazards. *Id*.

2. As an agreement state under 42 U.S.C. § 2021 and Section 74-3-15, New Mexico's state regulations must be compatible to the NRC's regulations. 42 U.S.C. § 2021(d)(2).

3. The compatibility requirement is met through the promulgation of state regulations when necessary.

4. New Mexico must maintain a compatible and adequately staffed radiation control program to keep its agreement status.

5. The NRC provides review summary sheets for the regulation amendments called the

Regulation Amendment Tracking System Identification Numbers ("RATS IDs") the RATS IDs are divided into several columns, such as the "NRC Regulation Section", "State Section", and "Compatibility Category."

6. Failure to maintain compatibility with NRC regulations jeopardizes the Agreement between the State and the NRC and potentially endangers the authority of the State to regulate certain uses of radioactive materials within the State and to collect radioactive materials license fees.

7. The Department is authorized by NMSA 1978, Section 74-1-7(A)(5) (2000) to revise New Mexico's radiation regulations to align with their federal counterparts as required by the Agreement between the State and the NRC.

8. The EIB has the authority to adopt the proposed amendments pursuant to NMSA 1978, Section 74-1-8(A)(5) (2020), NMSA 1978, Section 74-1-9 (1985), and NMSA 1978, Section 74-3-5(A) (2000).

9. The amendments currently being proposed to 20.3.3 NMAC, 20.3.5 NMAC, 20.3.7 NMAC, 20.3.12 NMAC, and 20.3.15 NMAC are federally required in order to meet the compatibility and health and safety categories established by the NRC. The required changes are found in the following RATS ID #'s:

- RATS ID# 2018-1; and
- RATS ID# 2018-2;

10. Additional amendments being proposed to 20.3.3 NMAC, 20.3.5 NMAC, 20.3.7 NMAC, 20.3.12 NMAC, and 20.3.15 NMAC are to clarify existing requirements, fix minor and

typographical errors, and update citations based on the federally required changes discussed in paragraph 9 above.

11. Adoption of the amendments to 20.3.3 NMAC, 20.3.5 NMAC, 20.3.7 NMAC, 20.3.12 NMAC, and 20.3.15 NMAC will allow New Mexico to become compatible with the current federal regulations required by the NRC's RATS IDs and will provide consistency between the federal and state regulations.

12. Adoption of the additional amendments to 20.3.3 NMAC, 20.3.5 NMAC, 20.3.7 NMAC, 20.3.12 NMAC, and 20.3.15 NMAC will help clarify the existing requirements, resolve minor and typographical errors, and update citations.

13. Under 20.1.1.300(A) NMAC and Section 74-1-9(A), any person may petition the EIB for an amendment of regulations within the jurisdiction of the EIB. The EIB shall determine whether or not to hold a hearing for the proposed regulations. 20.1.1.300(C) NMAC; Section 74-1-9(A).

14. The EIB shall, pursuant to the advice and recommendations of the RTAC, adopt and promulgate such rules, regulations, and licensure standards as may be necessary to effectuate the provisions of the Radiation Protection Act, NMSA 1978, Sections 74-3-1 to -16 (1953, amended 2003). §74-3-5(A).

TITLE 20 ENVIRONMENTAL PROTECTION
CHAPTER 3 RADIATION PROTECTION
PART 3 LICENSING OF RADIOACTIVE MATERIAL

20.3.3.1 ISSUING AGENCY: Environmental Improvement Board.
[20.3.3.1 NMAC - Rp, 20.3.3.1 NMAC, 4/30/2009]

20.3.3.2 SCOPE:

A. This part provides for the licensing of radioactive material. Except for persons exempt as provided in this part, no person shall manufacture, produce, receive, possess, use, own, transfer or acquire radioactive material except as authorized in a specific or general license issued pursuant to the requirements in this part.

B. In addition to the requirements of this part, all licensees are subject to the requirements of 20.3.1 NMAC, 20.3.4 NMAC, 20.3.10 NMAC and 20.3.16 NMAC.

C. The requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between a requirement in this part and a specific requirement in another part of this chapter, the specific requirement governs.

[20.3.3.2 NMAC - Rp, 20.3.3.2 NMAC, 4/30/2009]

20.3.3.3 STATUTORY AUTHORITY: Sections 74-1-9, 74-3-5 and 74-3-9 NMSA 1978.
[20.3.3.3 NMAC - Rp, 20.3.3.3 NMAC, 4/30/2009]

20.3.3.4 DURATION: Permanent.
[20.3.3.4 NMAC - Rp, 20.3.3.4 NMAC, 4/30/2009]

20.3.3.5 EFFECTIVE DATE: April 30, 2009, unless a later date is cited at the end of a section.
[20.3.3.5 NMAC - Rp, 20.3.3.5 NMAC, 4/30/2009]

20.3.3.6 OBJECTIVE: This part sets forth rules applicable to all persons in the state of New Mexico governing licensing of radioactive material under the act, and exemptions from the licensing requirements.
[20.3.3.6 NMAC - Rp, 20.3.3.6 NMAC, 4/30/2009]

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 Tribe 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; A, 8/10/2021]

20.3.3.8 to 20.3.3.300 [RESERVED]

20.3.3.301 EXEMPTIONS - UNIMPORTANT QUANTITIES OF SOURCE MATERIAL:

A. Any person is exempt from the requirements in this part to the extent that such person receives,

possesses, uses, transfers or delivers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than one twentieth of one percent of the mixture, compound, solution or alloy. The exemption contained in this subsection does not include *byproduct material* as defined in Paragraph (2) of Subsection F of 20.3.1.7 NMAC.

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

C. Any person is exempt from the requirements for a license set forth in the Radiation Protection Act, NMSA 1978, Sections 74-3-1 through 16 and from the regulations in this part and in 10 CFR Parts 19, 20, and 21 to the extent that such person receives, possesses, uses or transfers:

(1) any quantities of thorium contained in:

(a) incandescent gas mantles;

(b) vacuum tubes;

(c) welding rods;

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

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

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

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

(2) source material contained in the following products:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[20.3.3.301 NMAC - Rp, 20.3.3.301 NMAC, 4/30/2009; A, 8/10/2021]

[Editorial Note:

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

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

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

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

(e) [**RESERVED**];

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Any person who desires to manufacture, process or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85 or promethium-147 for use pursuant to

Subparagraph (a) of this paragraph, shall apply to NRC for a license pursuant to 10 CFR 32.22, and for a certificate of registration in accordance with 10 CFR 32.210.

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

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

(4) Gas and aerosol detectors containing radioactive material.

(a) Except for persons who manufacture, process, produce or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the licensing requirements in this part to the extent that such person receives, possesses, uses, transfers, owns or acquires byproduct material, in gas and aerosol detectors designed to protect life or property, 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 and for a certificate of registration in accordance with 10 CFR 32.210.

(5) Certain industrial devices.

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

(b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under subparagraph (a) of this paragraph, should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210.

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

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

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

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

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

[20.3.3.302 NMAC - Rp, 20.3.3.302 NMAC, 4/30/2009; A, 6/30/2011; A, 8/10/2021]

20.3.3.303 TYPES OF LICENSES: Licenses for radioactive materials are of two types: general and specific.

A. General License. A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the department or the issuance of a licensing document to a particular person. However, registration with the department may be required by the particular general license.

B. Specific License. A specific license is issued by the department to a named person who has filed an application for the license under the specific licensing provisions of 20.3.3 NMAC, 20.3.5 NMAC, 20.3.7 NMAC, 20.3.12 NMAC, 20.3.13 NMAC, 20.3.14 NMAC and 20.3.15 NMAC.

[20.3.3.303 NMAC - Rp, 20.3.3.303 NMAC, 4/30/2009]

20.3.3.304 GENERAL LICENSES - SOURCE MATERIAL:

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

B. Small quantities of source material.

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

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

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

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

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

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

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

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

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

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

(3) is subject to the provisions in accordance with 10 CFR 40.1 through 40.10, 10 CFR

40.41(a) through (e), 10 CFR 40.46, 10 CFR 40.51, 10 CFR 40.56, 10 CFR 40.60 through 40.63, 10 CFR 40.71, 10 CFR 40.81, and the equivalent regulations in 20.3.3 NMAC; and

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

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

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

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

G. Depleted uranium in industrial products and devices.

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

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

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

(a) name and address of the general licensee;

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

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

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

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

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

covering of the depleted uranium;

(b) shall not abandon such depleted uranium;

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

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

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

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

[20.3.3.304 NMAC - Rp, 20.3.3.304 NMAC, 4/30/2009; A, 8/10/2021]

20.3.3.305 GENERAL LICENSES - RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL:

A. [**Reserved**]

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

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

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

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

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

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

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

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

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

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

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

(c) The general licensee shall assure that the test required by Subparagraph (b) of

Paragraph (3) of this subsection and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment are performed:

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

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

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

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

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

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

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

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

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

(h) Device transfer requirements.

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

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

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

would be applicable under the specific license (such as leak testing procedures); and reports the transfer under Item (ii) of this subparagraph.

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

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

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

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

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

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

(m) Registration requirements.

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

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

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

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

(n) The general licensee shall report changes to the mailing address for the location

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

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

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

C. Luminous safety devices for use in aircraft.

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

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

(b) each device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions 10 CFR 32.53 or manufactured or assembled in accordance with a specific license issued by the NRC];

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

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

(2) The applicant shall subject at least five prototypes of the device to 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 Subsection C of 20.3.3.305 NMAC shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

(4) Each person licensed under 10 CFR 32.53 or Subsection C of 20.3.3.305 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 Subsection C of 20.3.3.305 NMAC to provide at least ninety-five percent confidence that the lot tolerance percent defective of five percent will not be exceeded.

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

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

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

(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 Subsection C of 20.3.3.305 NMAC.

(6) No person licensed under 10 CFR 32.53 or Subsection C of 20.3.3.305 NMAC shall transfer 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 Subsection C of 20.3.3.305 NMAC and each individual sub-lot is sampled, tested, and accepted in accordance with Subsection C(2) of this section and any other criteria that may be required as a condition of the license issued under 10 CFR 32.53 or Subsection C of 20.3.3.305 NMAC.

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

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

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

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

D. Calibration and reference sources.

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

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

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

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

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

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

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

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

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

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

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

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

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

_____

(name of manufacturer or initial transferor)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

form:

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

(ii) the location of use; and

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

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

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

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

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

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

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

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

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

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

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

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

_____

(name of manufacturer)

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

(6) Any person using radioactive material pursuant to the general license of Paragraph (1) of this subsection is exempt from the requirements of 20.3.4 NMAC and 20.3.10 NMAC with respect to radioactive material covered by that general license except that such person using a mock iodine-125 shall comply with the provisions of 20.3.4.433 NMAC, 20.3.4.451 NMAC and 20.3.4.452 NMAC.

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

(1) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85

megabecquerels) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the department, the NRC or an agreement state, which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the department, NRC or an agreement state.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) respond to written requests from the department to provide information relating

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

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

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

[20.3.3.305 NMAC - Rp, 20.3.3.305 NMAC, 04/30/2009; A, 8/10/2021]

20.3.3.306 TRANSPORTATION OF RADIOACTIVE MATERIAL:

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

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

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

(1) **"commission"** means the NRC except a specified in subsection (4) below;

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

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

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

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

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

[20.3.3.306 NMAC - Rp, 20.3.3.306 NMAC & 20.3.3.325 NMAC, 04/30/2009; A, 6/30/2011; A, 8/10/2021]

20.3.3.307 FILING APPLICATION FOR SPECIFIC LICENSES:

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

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

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

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

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

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

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

(3) 10 CFR 37.7, 10 CFR 37.9, 10 CFR 37.11(a) and (b), 10 CFR 37.13, 10 CFR 37.27(c),

10 CFR 37.105, and 10 CFR 37.107 shall not be applicable; and

(4) the license required report of events or notification in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 71, 10 CFR 37.77(a) through (d), and 10 CFR 37.81 shall use the following address when applicable: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469.

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

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

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

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

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

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

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

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

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

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

H. An application for a license to receive and possess radioactive material for the conduct of any activity which the department has determined pursuant to Subpart A of 10 CFR 51 will significantly affect the quality of the environment shall be filed at least nine months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by an environmental impact report required pursuant to Subpart A of 10 CFR 51.

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

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

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

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

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

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

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

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

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

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

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

L. An application for a specific license to transfer source material under this section.

(1) An application for a specific license to initially transfer source material for use under 20.3.3.307 NMAC, will be approved if:

(a) the applicant satisfies the general requirements specified in this section; and

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

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

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

(4) Each person licensed under this section shall provide the information specified in this paragraph to each person to whom source material is transferred for use under this section. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

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

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

(5) Each person licensed under this section shall report transfers as follows:

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

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

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

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

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

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

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

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

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

information shall be reported to the responsible agreement state agency upon request of the agency.

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

[20.3.3.307 NMAC - Rp, 20.3.3.307 NMAC, 04/30/2009; A, 8/10/2021]

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, 4/30/2009; A, 6/13/2017]

20.3.3.309 REQUIREMENTS FOR EMERGENCY RESPONSE PLANS FOR CERTAIN LICENSEES:

A. Each application to possess radioactive materials in unsealed forms, on foils or plated sources, or sealed in glass in excess of the quantities in 20.3.3.333 NMAC (Schedule E - Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release), must contain either:

(1) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems (50 millisieverts) to the thyroid; or

(2) an emergency plan for responding to a release of radioactive material.

B. One or more of the following factors may be used to support an evaluation submitted under Paragraph (1) of Subsection A of this section:

(1) the radioactive material is physically separated so that only a portion could be involved in an accident;

(2) all or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(3) the release fraction in the respirable size range would be lower than the release fraction shown in 20.3.3.333 NMAC of this part due to the chemical or physical form of the material;

(4) the solubility of the radioactive material would reduce the dose received;

(5) facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in 20.3.3.333 NMAC;

(6) other factors appropriate for the specific facility; or

(7) operating restrictions or procedures would prevent a release fraction as large as that shown in 20.3.3.333 NMAC.

C. An emergency plan for responding to a release of radioactive material submitted under Paragraph (2) of Subsection A of this section must include the following information.

(1) **Facility description:** a brief description of the licensee's facility and area near the site.

(2) **Types of accidents:** an identification of each type of radioactive materials accident for which protective actions may be needed.

(3) **Classification of accidents:** a system for classifying each accident as “alert” or “site area emergencies”.

(4) Detection of accidents: identification of the means of detecting each type of accident in a timely manner.

(5) Mitigation of consequences: a brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(6) Assessment of releases: a brief description of the methods and equipment to assess releases of radioactive materials.

(7) Responsibilities: a brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the secretary; also responsibilities for developing, maintaining, and updating the plan.

(8) Notification and coordination: a commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the secretary immediately and ensure notification of other appropriate offsite response organizations "and not later than one hour after the licensee declares an emergency".

(9) Information to be communicated: a brief description of the types of information regarding facility status, radioactive releases and, if necessary, recommended protective actions.

(10) Training: a brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(11) Safe shutdown: a brief description of the means of restoring the facility to a safe condition after an accident.

(12) Exercises: provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment and training of personnel and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(13) Hazardous chemicals: a certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act (title III, pub. l. 99-499), if applicable to the applicant's activities at the proposed place of use of the radioactive material.

D. The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it in final form to the department. The licensee shall provide any comments received within the 60 days to the department with the emergency plan.

[20.3.3.309 NMAC - Rp, 20.3.3.309 NMAC, 4/30/2009]

20.3.3.310 PUBLIC NOTICE, PARTICIPATION AND HEARING:

A. Within 60 days following:

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

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

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

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

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

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

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

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

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

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

(1) the name and address of the applicant;

(2) the location of the proposed activity;

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

(4) a brief description of the proposed activity;

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

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

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

PUBLIC NOTICE

The New Mexico Environment Department (the Department) has received an application for a Radioactive Material License from_____(company name and address) for _____(proposed activity) to be located at _____(location). During the early part of the evaluation period, the Department will review and comment upon the application. The NMED may, at its discretion, retain consultants to assist it in its evaluation of the application. Relevant comments and questions received by the NMED from various agencies and interested parties will be forwarded to the applicant for its response. Correspondence associated with the application will be on file with the Radiation Control Bureau and will be available for inspection by the applicant and any other interested parties.

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

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

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

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

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

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

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

E. Public comment period.

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

(2) Following the notice of acceptance of the license application pursuant to Subsections A through C of this section and prior to ruling on any application required to be accompanied by an environmental

report pursuant to Subsection H of 20.3.3.307 NMAC, the secretary shall allow a period of at least 60 days during which written comments or questions may be submitted by any interested person. If the secretary determines that the questions are relevant to the considerations enumerated in Subsection H of 20.3.3.307 NMAC or 20.3.3.308 NMAC, the secretary shall require the applicant to answer them.

The secretary may allow an additional written comment period upon submission of additional information to the license application, amendment request or renewal license application described by Subsection A of this section by the applicant, or upon request by members of the public. A written request for a hearing may be made by the members of the public within the time period specified in the public notice described in Subsection C of this section.

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

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

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.

(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;

(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 20.3.3.317 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, 4/30/2009; A, 6/13/2017]

20.3.3.312 [RESERVED]

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

A. Industrial radiographic 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, 4/30/2009; A, 6/13/2017]

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:

(a) 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; and

(b) 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, 4/30/2009; A, 6/13/2017]

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 and for distribution submit to the NRC pursuant to 10 CFR 32.53.

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

D. [RESERVED]

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

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

(a) the applicant satisfies the general requirements of 20.3.3.308 NMAC;

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

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

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

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

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

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

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

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

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

Caution-radioactive material

_____;

(name of manufacturer or distributor)

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

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

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

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

(a) primary containment (source capsule);

(b) protection of primary containment;

(c) method of sealing containment;

(d) containment construction materials;

(e) form of contained radioactive material;

(f) maximum temperature withstood during prototype test;

(g) maximum pressure withstood during prototype test;

(h) maximum quantity of contained radioactive material;

(i) radiotoxicity of contained radioactive material; and

(j) operating experience with identical devices or similarly designed and constructed devices.

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

(4) Transfer provisions:

(a) [Reserved]

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

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

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

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

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

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

(d) Each device shall meet the labeling requirements in Subparagraphs (c) through

(e) of Paragraph (1) of this Subsection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) If the licensee makes changes to a device possessed by a general

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

_____

(name of manufacturer); and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) A label is affixed to each transport radiation shield, whether it is

constructed of lead, glass, plastic or other material, of a radioactive drug to be transferred for commercial distribution; the label must include the radiation symbol and the words "*caution, radioactive material*" or "*danger, radioactive material*"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

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

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

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

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

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

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

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

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

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

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

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

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

(f) shall provide to the commission a copy of

(i) each individual's certification by a specialty board whose certification process has been recognized by the [~~department, NRC~~] Commission 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)~~] 10 CFR 35.55(a); or

(ii) the [~~department, NRC~~] Commission or agreement state license, or

(iii) [~~the permit issued by a NRC~~] Commission master material licensee permit, or

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

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

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

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of

alpha, beta or photon emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) label or mark each unit to:

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

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

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

(d) furnish a copy of the general license contained in Subsection C of 20.3.3.304

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

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

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

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

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

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

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

[20.3.3.315 NMAC - Rp, 20.3.3.315 NMAC, 04/30/2009; A, 8/10/2021]

20.3.3.316 ISSUANCE OF SPECIFIC LICENSES:

A. Upon a determination that an application meets the requirements of the act and 20.3 NMAC, the department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary to effectuate the purposes of the act.

B. The department may incorporate in any license at the time of issuance, or thereafter by license amendment, rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property; or

(2) require reports and the keeping of records, or to provide for inspections of activities under the license as may be appropriate or necessary; or

(3) prevent loss or theft of material subject to this chapter.

C. The department may request, and the licensee shall provide, additional information after the license has been issued to enable the department to determine whether the license shall be modified in accordance with 20.3.3.322 NMAC.

[20.3.3.316 NMAC - Rp, 20.3.3.316 NMAC, 4/30/2009]

20.3.3.317 TERMS AND CONDITIONS OF LICENSES:

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

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

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

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

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

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

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

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

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

E. Filing for bankruptcy.

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

(a) the licensee;

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

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

(2) The notification must indicate:

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

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

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

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

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

I. Generators. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 20.3.7.706 NMAC of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 10 CFR 35.204(a) at the time of generator elution, in accordance with 10 CFR 35.3204.

J. PET drugs for non-commercial distribution.

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

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

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

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

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

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

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

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

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

20.3.3.318 EXPIRATION AND TERMINATION OF LICENSES AND DECOMMISSIONING OF SITES AND SEPARATE BUILDINGS OR OUTDOOR AREAS:

A. The term of a specific license is five years unless the department granted a different term. Except as provided in Subsection B of this section, each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 20.3.3.319 NMAC not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the department makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

B. If the licensee failed to pay outstanding annual fees to the department as required by 20.3.16 NMAC, the specific license expires at the end of the day on the expiration date stated in the license. The licensee shall follow the requirements in Subsection F through [~~M~~] L of this section for termination of the specific license, or apply for a license pursuant to 20.3.3.307 NMAC after the outstanding annual fee(s) has been paid.

C. Each specific license revoked by the department expires at the end of the day on the date of the department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by department order.

D. Expiration of the specific license does not relieve the licensee from the requirements in 20.3 NMAC. All license provisions continue in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the department notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) limit actions involving radioactive material to those related to decommissioning; and

(2) continue to control entry to restricted areas until they are suitable for release in accordance with department requirements.

E. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the department in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with department requirements, or submit within 12 months of notification a decommissioning plan, if required by Subsection H of this section, and begin decommissioning upon approval of that plan if:

(1) the license has expired or has been revoked pursuant to Subsections A, B or C of this

section; or

(2) the licensee has decided to permanently cease principal activities, as defined in 20.3.3.7 NMAC, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with department requirements; or

(3) no principal activities under the license have been conducted for a period of 24 months; or

(4) no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with department requirements.

F. Coincident with the notification required by Subsection E of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to 20.3.3.311 NMAC in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to Subparagraph (e) of Paragraph (4) of Subsection H of this section.

G. The department may grant a request to extend the time periods established in Subsection E of this section, if the department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to Subsection E of this section. The schedule for decommissioning set forth in Subsection E of this section may not commence until the department has made a determination on the request.

H. Decommissioning Plan.

(1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(a) procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(b) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(c) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(d) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The department may approve an alternate schedule for submittal of a decommissioning plan required pursuant to Subsection E of this section if the department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures, such as those listed in Paragraph (1) of this subsection, with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(a) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(b) a description of planned decommissioning activities;

(c) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(d) a description of the planned final radiation survey;

(e) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning; and

(f) for decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in Subsection J of this section.

(5) The proposed decommissioning plan will be approved by the department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

I. Deadline for Decommissioning.

(1) Except as provided in Subsection J of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in Subsection J of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

J. The department may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the department determines that the alternative is warranted by consideration of the following:

(1) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) other site-specific factors which the department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

K. As the final step in decommissioning, the licensee shall:

(1) certify the disposition of all licensed material, including accumulated wastes, by submitting a completed c*ertificate - disposition of radioactive material* form or equivalent information; and

(2) conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 20.3.4.426 NMAC; the licensee shall, as appropriate:

(a) report levels of gamma radiation in units of millisievert (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters, removable and fixed, for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(b) specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

L. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the department determines that:

(1) radioactive material has been properly disposed;

(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 20.3.4.426 NMAC; or other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 20.3.4.426 NMAC; and

(4) records required by Subsections D and F of 20.3.3.326 NMAC, have been received by the department.

[20.3.3.318 NMAC - Rp, 20.3.3.318 NMAC, 4/30/2009]

20.3.3.319 RENEWAL OF LICENSES:

A. Applications for renewal of specific licenses shall be filed in accordance with 20.3.3.307 NMAC not less than 30 days before the expiration date stated in the existing license.

B. In any case in which a licensee, not less than 30 days prior to expiration of their existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the department.

C. An application for renewal of a license shall be approved if the department determines that the requirements of this part have been satisfied, and the licensee has paid any outstanding annual fee(s) pursuant to

20.3.16 NMAC.
[20.3.3.319 NMAC - Rp, 20.3.3.319 NMAC and 20.3.3.321 NMAC, 4/30/2009]

20.3.3.320 AMENDMENT OF LICENSES AT REQUEST OF LICENSEE:

A. An license amendment may be requested by filing a form prescribed by the department pursuant to 20.3.3.307 NMAC which shall specify the proposed amendment and the grounds for the amendment.

B. Supporting documentation (e.g. training records, certificates, procedures, etc.) shall be submitted with the amendment, or provided upon request by the department within 30 days from the date of the request or other time as may be specified in the request. Failure to provide the appropriate supporting documentation within the prescribed time frame will be grounds for denial of the amendment.

C. A request for a license amendment shall be approved if the department determines that the requirements of this part have been satisfied, and the licensee has paid any outstanding annual fee(s) pursuant to 20.3.16 NMAC.

[20.3.3.320 NMAC - Rp, 20.3.3.320 NMAC and 20.3.3.321 NMAC, 4/30/2009]

20.3.3.321 [RESERVED]

20.3.3.322 MODIFICATION, SUSPENSION AND REVOCATION OF LICENSES:

A. The terms and conditions of all licenses shall be subject to amendment or modification by the department by reason of amendments to the act, or by reason of rules, regulations and orders issued by the board or department.

B. Any license may be modified, suspended or revoked, in whole or in part by the department, for any material false statement in the application or any statement of fact required under provisions of the act; or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the department to refuse to grant a license on an original application; or for violation of, or failure to observe any of the terms and conditions of the act, conditions of the license, or of any rule, regulation, or order of the board or department; or the department determines that existing conditions constitute a substantial threat to the public health and safety or the environment.

C. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such actions shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

[20.3.3.322 NMAC - Rp, 20.3.3.322 NMAC, 4/30/2009]

20.3.3.323 TRANSFER OF MATERIAL:

A. No licensee shall transfer radioactive material except as authorized by this section.

B. Except as otherwise provided in their license and subject to the provisions of Sections C and D this section any licensee may transfer radioactive material:

(1) to the department after receiving prior approval from the department;

(2) to the agency in any agreement state which regulates radioactive material pursuant to an agreement under Section 274 of the Atomic Energy Act;

(3) to the United States department of energy;

(4) to any person exempt from the Radiation Protection Act to the extent permitted under such exemptions; or to any person in the NRC jurisdiction or an agreement state, subject to the jurisdiction of that state, who has been exempted from the licensing requirements and regulations of the NRC or the agreement state, to the extent permitted under such exemption;

(5) to any person authorized to receive such material under terms of a general license or a specific license or equivalent licensing document issued by the department, the NRC or an agreement state; or

(6) as otherwise authorized by the department in writing.

C. Before transferring radioactive material to a specific licensee of the department, the NRC or an agreement state, or to a general licensee who is required to register with the department, the NRC or an agreement state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.

D. The following methods for the verification required by Subsection C of this section are acceptable:

(1) the transferor may have in their possession, and read, a current copy of the transferee's

specific license or registration certificate;

(2) the transferor may have in their possession a written certification by the transferee that they are authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(3) for emergency shipments, the transferor may accept oral certification by the transferee that they are authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying registration certificate number, issuing agency and expiration date; provided that the oral certification is confirmed in writing within 10 days;

(4) the transferor may obtain other sources of information compiled by a reporting service from official records of the department, the NRC or an agreement state as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) when none of the methods of verification described in Paragraphs (1) to (4) of this subsection are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the department, the NRC or an agreement state that the transferee is licensed to receive the radioactive material.

[20.3.3.323 NMAC - Rp, 20.3.3.323 NMAC, 4/30/2009]

20.3.3.324 RECIPROCAL RECOGNITION OF LICENSES:

A. Provided that the requirements of this section have been met, any person who holds a specific license from the NRC or an agreement state, and issued by the regulatory authority having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within the state of New Mexico for a period not in excess of 180 days in any calendar year provided that:

(1) the licensing document does not limit the activity authorized by such document to specified installations or locations;

(2) the out-of-state licensee notifies the department in writing at least three business days prior to engaging in such activity, filing a form, *reciprocity application - proposed activities*; such notification shall indicate the location of work, period of work, and type, manufacturer name and model number of radioactive material to be brought within the state, the client's name and address, and shall be accompanied by a copy of the pertinent licensing document and application fee as determined by 20.3.16 NMAC charged once for each calendar year; if, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, they may, upon application to the department, obtain permission to proceed sooner; the department may waive the requirements for filing additional written notifications during the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this section;

(3) the out-of-state licensee complies with all applicable provisions of 20.3 NMAC, all provisions of the act, now or hereafter in effect, and orders of the board or department and with all the terms and conditions of their licensing document, except any such terms and conditions which may be inconsistent with requirements in this chapter;

(4) the out-of-state licensee supplies such other information as the department may request; and

(5) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person specifically licensed by the department, an agreement state or by the NRC to receive such material.

B. Notwithstanding the provisions of Subsection A of this section, any person who holds a specific license issued by the NRC or an agreement state authorizing the holder to manufacture, transfer, install or service a device described in Paragraph (1) of Subsection B of 20.3.3.305 NMAC within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate or service such a device in this state provided that:

(1) such person shall file a report with the department within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state; each such report shall identify each general license to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(2) 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;

(3) such person shall assure that any labels required to be affixed in the device under regulations of the authority which licensed manufacture of the device bear a statement that *"removal of this label is*

prohibited"; and

(4) the holder of the specific license shall furnish to each general licensee to whom they transfer such device or on whose premises they install such device a copy of the general license contained in Subsection B of 20.3.3.305 NMAC.

C. The department may withdraw, limit or qualify its acceptance of any specific license or equivalent licensing document issued by another department, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

D. Reciprocity in Areas of Exclusive Federal Jurisdiction:

(1) Before radioactive material can be used at temporary jobsites at any federal facility, the jurisdictional status of the jobsites shall be determined. If a temporary jobsite is under exclusive federal jurisdiction, the general license authorized under Subsection A of this section is subject to all the rules, regulations, orders and fees of the NRC.

(2) Authorizations for use of radioactive materials in areas of exclusive federal jurisdiction shall be obtained from the NRC by:

(a) filing an NRC form 241 in accordance with 10 CFR 150.20(b); or

(b) applying for a specific NRC license.

E. Reciprocity in Other States:

(1) Before radioactive material can be used at a temporary jobsite in another state, authorization shall be obtained from the state if it is an agreement state or from NRC for any non-agreement state, either by filing for reciprocity or applying for a specific license.

(2) The general license authorized under Subsection A of this section is subject to all the rules, regulations, orders and fees of the agreement state, or those of the NRC for any non-agreement state.

[20.3.3.324 NMAC - Rp, 20.3.3.324 NMAC, 4/30/2009]

20.3.3.325 REPORTING REQUIREMENTS:

A. Immediate Report. Each licensee shall notify the department as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

B. Twenty-Four Hour Report. Each licensee shall notify the department within 24 hours after the discovery of any of the following events involving licensed material.

(1) An unplanned contamination event that:

(a) requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

(b) involves a quantity of material greater than five times the lowest annual limit on intake specified in 20.3.4.461 NMAC for the material; and

(c) has access to the area restricted for a reason other than to allow radioactive material with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(a) the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(b) the equipment is required to be available and operable when it is disabled or fails to function; and

(c) no redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container or equipment containing licensed material when:

(a) the quantity of material involved is greater than five times the lowest annual limit on intake specified in 20.3.4.461 NMAC for the material; and

(b) the damage affects the integrity of the licensed material or its container.

C. Preparation and Submission of Reports. Reports made by licensees in response to the requirements of this section must be made as follows.

(1) Licensees shall make reports required by Subsections A and B of this section by telephone to the department. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(a) the caller's name and call back telephone number;

(b) a description of the event, including date and time;

(c) the exact location of the event;

(d) the radioactive material, quantities and chemical and physical form of the licensed material involved; and

(e) any personnel radiation exposure data available;

(2) Written report. Each licensee who makes a report required by Subsections A and B of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the department at the address in 20.3.1.116 NMAC. The reports must include the following:

(a) a description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(b) the exact location of the event;

(c) the radioactive material, quantities and chemical and physical form of the licensed material involved;

(d) date and time of the event;

(e) corrective actions taken or planned and the results of any evaluations or assessments; and

(f) the extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

[20.3.3.325 NMAC - Rp, 20.3.3.312 NMAC, 4/30/2009]

20.3.3.326 RECORDS: Each person who receives radioactive material pursuant to a license and the regulations in this part and parts 20.3.5 NMAC, 20.3.7 NMAC, 20.3.12 NMAC, 20.3.13 NMAC, 20.3.14 NMAC and 20.3.15 NMAC is subject to the requirements of this section.

A. The licensee shall keep records showing the receipt, transfer and disposal of the radioactive material as follows.

(1) The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three years following transfer or disposal of the material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this chapter dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of radioactive material until the department terminates each license that authorizes disposal of the material.

B. The licensee shall retain each record required by applicable parts of 20.3 NMAC or by license condition for the period specified by the applicable regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record shall be retained until the department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

C. Records Format and Retention Period.

(1) Records which must be maintained pursuant to 20.3 NMAC may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by 20.3 NMAC. The record may also be stored in electronic media with the capability for producing legible, accurate and complete records during the required retention period. Records such as letters, drawings, specifications, shall include all pertinent information such as stamps, initials and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the retention period in 20.3 NMAC, license condition or other written department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in 20.3 NMAC for such records shall apply unless the department, pursuant to Subsection A of 20.3.1.107 NMAC, has granted a specific exemption from the record retention requirements specified in 20.3 NMAC.

D. Prior to license termination, each licensee authorized to possess radioactive material with a half-

life greater than 120 days, in an unsealed form, shall forward the following records to the department:

(1) records of disposal of licensed material made under Sections 434 (including burials authorized before January 28, 1981), 435, 436 and 437 of 20.3.4 NMAC; and

(2) records required by Paragraph (4) of Subsection B of 20.3.4.442 NMAC.

E. If licensed activities are transferred or assigned in accordance with Subsection B of 20.3.3.317 NMAC, each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) records of disposal of licensed material made under Sections 434 (including burials authorized before January 28, 1981), 435, 436 and 437 of 20.3.4 NMAC;

(2) records required by Paragraph (4) of Subsection B of 20.3.4.442 NMAC; and

(3) the records required under Subsection G of 20.3.3.311 NMAC.

F. Prior to license termination, each licensee shall forward the records required by Subsection G of 20.3.3.311 NMAC to the department.

[20.3.3.326 NMAC - Rp, 20.3.3.300 NMAC, 4/30/2009]

20.3.3.327 [RESERVED]

20.3.3.328 [RESERVED]

20.3.3.329 SCHEDULE A - EXEMPT CONCENTRATIONS:

A. Table 339.1.

TABLE 329.1

Element (Atomic Number)	**Isotope**	**Column I Gas Concentration microcurie/milliliter[1]**	**Column II Liquid and Solid Concentration microcurie/milliliter[2]**
Antimony (51)	Sb-122 Sb-124 Sb-125		$3x10^{-4}$ $2x10^{-4}$ $1x10^{-3}$
Argon (18)	Ar-37 Ar-41	$1x10^{-3}$ $4x10^{-7}$	
Arsenic (33)	As-73 As-74 As-76 As-77		$5x10^{-3}$ $5x10^{-4}$ $2x10^{-4}$ $8x10^{-4}$
Barium (56)	Ba-131 Ba-140		$2x10^{-3}$ $3x10^{-4}$
Beryllium (4)	Be-7		$2x10^{-2}$
Bismuth (83)	Bi-206		$4x10^{-4}$
Bromine (35)	Br-82	$4x10^{-7}$	$3x10^{-3}$
Cadmium (48)	Cd-109 Cd-115m Cd-115		$2x10^{-3}$ $3x10^{-4}$ $3x10^{-4}$
Calcium (20)	Ca-45 Ca-47		$9x10^{-5}$ $5x10^{-4}$
Carbon (6)	C-14	$1x10^{-6}$	$8x10^{-3}$
Cerium (58)	Ce-141 Ce-143 Ce-144		$9x10^{-4}$ $4x10^{-4}$ $1x10^{-4}$
Cesium (55)	Cs-131 Cs-134m Cs-134		$2x10^{-2}$ $6x10^{-2}$ $9x10^{-5}$
Chlorine (17)	Cl-38	$9x10^{-7}$	$4x10^{-3}$

TABLE 329.1			
Element (Atomic Number)	**Isotope**	**Column I Gas Concentration microcurie/milliliter[1]**	**Column II Liquid and Solid Concentration microcurie/milliliter[2]**
Chromium (24)	Cr-51		$2x10^{-2}$
Cobalt (27)	Co-57 Co-58 Co-60		$5x10^{-3}$ $1x10^{-3}$ $5x10^{-4}$
Copper (29)	Cu-64		$3x10^{-3}$
Dysprosium (66)	Dy-165 Dy-166		$4x10^{-3}$ $4x10^{-4}$
Erbium (68)	Er-169 Er-171		$9x10^{-4}$ $1x10^{-3}$
Europium (63)	Eu-152 (T ½ = 9.2 h) Eu-155		$6x10^{-4}$ $2x10^{-3}$
Fluorine (9)	F-18	$2x10^{-6}$	$8x10^{-3}$
Gadolinium (64)	Gd-153 Gd-159		$2x10^{-3}$ $8x10^{-4}$
Gallium (31)	Ga-72		$4x10^{-4}$
Germanium (32)	Ge-71		$2x10^{-2}$
Gold (79)	Au-196 Au-198 Au-199		$2x10^{-3}$ $5x10^{-4}$ $2x10^{-3}$
Hafnium (72)	Hf-181		$7x10^{-4}$
Hydrogen (1)	H-3	$5x10^{-6}$	$3x10^{-2}$
Indium (49)	In-113m In-114m		$1x10^{-2}$ $2x10^{-4}$
Iodine (53)	I-126 I-131 I-132 I-133 I-134	$3x10^{-9}$ $3x10^{-9}$ $8x10^{-8}$ $1x10^{-8}$ $2x10^{-7}$	$2x10^{-5}$ $2x10^{-5}$ $6x10^{-4}$ $7x10^{-5}$ $1x10^{-3}$
Iridium (77)	Ir-190 Ir-192 Ir-194		$2x10^{-3}$ $4x10^{-4}$ $3x10^{-4}$
Iron (26)	Fe-55 Fe-59		$8x10^{-3}$ $6x10^{-4}$
Krypton (36)	Kr-85m Kr-85	$1x10^{-6}$ $3x10^{-6}$	
Lanthanum (57)	La-140		$2x10^{-4}$
Lead (82)	Pb-203		$4x10^{-3}$
Lutetium (71)	Lu-177		$1x10^{-3}$
Manganese (25)	Mn-52 Mn-54 Mn-56		$3x10^{-4}$ $1x10^{-3}$ $1x10^{-3}$
Mercury (80)	Hg-197m Hg-197 Hg-203		$2x10^{-3}$ $3x10^{-3}$ $2x10^{-4}$
Molybdenum (42)	Mo-99		$2x10^{-3}$
Neodymium (60)	Nd-147		$6x10^{-4}$

TABLE 329.1			
Element (Atomic Number)	**Isotope**	**Column I Gas Concentration microcurie/milliliter[1]**	**Column II Liquid and Solid Concentration microcurie/milliliter[2]**
	Nd-149		$3x10^{-3}$
Nickel (28)	Ni-65		$1x10^{-3}$
Niobium (Columbium) (41)	Nb-95 Nb-97		$1x10^{-3}$ $9x10^{-3}$
Osmium (76)	Os-185 Os-191m Os-191 Os-193		$7x10^{-4}$ $3x10^{-2}$ $2x10^{-3}$ $6x10^{-4}$
Palladium (46)	Pd-103 Pd-109		$3x10^{-3}$ $9x10^{-4}$
Phosphorous (15)	P-32		$2x10^{-4}$
Platinum (78)	Pt-191 Pt-193m Pt-197m Pt-197		$1x10^{-3}$ $1x10^{-2}$ $1x10^{-2}$ $1x10^{-3}$
Potassium (19)	K-42		$3x10^{-3}$
Praseodymium (59)	Pr-142 Pr-143		$3x10^{-4}$ $5x10^{-4}$
Promethium (61)	Pm-147 Pm-149		$2x10^{-3}$ $4x10^{-4}$
Rhenium (75)	Re-183 Re-186 Re-188		$6x10^{-3}$ $9x10^{-4}$ $6x10^{-4}$
Rhodium (45)	Rh-103m Rh-105		$1x10^{-1}$ $1x10^{-3}$
Rubidium (37)	Rb-86		$7x10^{-4}$
Ruthenium (44)	Ru-97 Ru-103 Ru-105 Ru-106		$4x10^{-3}$ $8x10^{-4}$ $1x10^{-3}$ $1x10^{-4}$
Samarium (62)	Sm-153		$8x10^{-4}$
Scandium (21)	Sc-46 Sc-47 Sc-48		$4x10^{-4}$ $9x10^{-4}$ $3x10^{-4}$
Selenium (34)	Se-75		$3x10^{-3}$
Silicon (14)	Si-31		$9x10^{-3}$
Silver (47)	Ag-102 Ag-110m Ag-111		$1x10^{-3}$ $3x10^{-4}$ $4x10^{-4}$
Sodium (11)	Na-24		$2x10^{-3}$
Strontium (38)	Sr-85 Sr-89 Sr-91 Sr-92		$1x10^{-3}$ $1x10^{-4}$ $7x10^{-4}$ $7x10^{-4}$
Sulfur (16)	S-35	$9x10^{-8}$	$6x10^{-4}$
Tantalum (73)	Ta-182		$4x10^{-4}$
Technetium (43)	Tc-96m		$1x10^{-1}$

TABLE 329.1			
Element (Atomic Number)	**Isotope**	**Column I Gas Concentration microcurie/milliliter[1]**	**Column II Liquid and Solid Concentration microcurie/milliliter[2]**
	Tc-96		$1x10^{-3}$
Tellurium (52)	Te-125m Te-127m Te-127 Te-129m Te-131m Te-132		$2x10^{-3}$ $6x10^{-4}$ $3x10^{-3}$ $3x10^{-4}$ $6x10^{-4}$ $3x10^{-4}$
Terbium (65)	Tb-160		$4x10^{-4}$
Thallium (81)	Tl-200 Tl-201 Tl-202 Tl-204		$4x10^{-3}$ $3x10^{-3}$ $1x10^{-3}$ $1x10^{-3}$
Thulium (69)	Tm-170 Tm-171		$5x10^{-4}$ $5x10^{-3}$
Tin (50)	Sn-113 Sn-125		$9x10^{-4}$ $2x10^{-4}$
Tungsten (Wolfram) (74)	W-181 W-187		$4x10^{-3}$ $7x10^{-4}$
Vanadium (23)	V-48		$3x10^{-4}$
Xenon (54)	Xe-131m Xe-133 Xe-135	$4x10^{-6}$ $3x10^{-6}$ $1x10^{-6}$	
Ytterbium (70)	Yb-175		$1x10^{-3}$
Yttrium (39)	Y-90 Y-91m Y-91 Y-92 Y-93		$2x10^{-4}$ $3x10^{-2}$ $3x10^{-4}$ $6x10^{-4}$ $3x10^{-4}$
Zinc (30)	Zn-65 Zn-69m Zn-69		$1x10^{-3}$ $7x10^{-4}$ $2x10^{-2}$
Zirconium (40)	Zr-95 Zr-97		$6x10^{-4}$ $2x10^{-4}$
Beta or gamma emitting radioactive material not listed above with half-life less than 3 years.		$1x10^{-10}$	$1x10^{-6}$

Table 329.1 notes:

[1] values are given in column I only for those materials normally used as gases;

[2] microcuries per gram for solids.

B. Notes.

(1) Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Subsection A the activity stated is that of the parent isotope and takes into account the daughters.

(2) For purposes of 20.3.3.302 NMAC where there is involved a combination of isotopes, the limit for the combination shall be derived as follows: determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Subsection A of this section for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity). Example: (concentration of isotope A in product) / (exempt concentration of isotope A) + (concentration of isotope B in

product) / (exempt concentration of isotope B) <1.

(3) The values in this table are presented in scientific notation. In this notation, a value of 3 x 10^{-4} represents a value of 3E-4 or 0.0003.

(4) To convert microcuries to SI units of kilobecquerels multiply the above values by 37. For example: Zirconium-97 of 2x10^{-4} microcurie multiplied by 37 is equivalent to 0.0074 kilobecquerel or 7.4 becquerels.

[20.3.3.329 NMAC - Rp, 20.3.3.329 NMAC, 4/30/2009]

20.3.3.330 SCHEDULE B - EXEMPT QUANTITIES:

TABLE 330.1

Radioactive Material	Acronym	Microcuries
Antimony-122	(Sb-122)	100
Antimony-124	(Sb-124)	10
Antimony-125	(Sb-125)	10
Arsenic-73	(As-73)	100
Arsenic-74	(As-74)	10
Arsenic-76	(As-76)	10
Arsenic-77	(As-77)	100
Barium-131	(Ba-131)	10
Barium-133	(Ba-133)	10
Barium-140	(Ba-140)	10
Bismuth-210	(Bi-210)	1
Bromine-82	(Br-82)	10
Cadmium-109	(Cd-109)	10
Cadmium-115m	(Cd-115m)	10
Cadmium-115	(Cd-115)	100
Calcium-45	(Ca-45)	10
Calcium-47	(Ca-47)	10
Carbon-14	(C-14)	100
Cerium-141	(Ce-141)	100
Cerium-143	(Ce-143)	100
Cerium-144	(Ce-144)	1
Cesium-129	(Cs-129)	100
Cesium-131	(Cs-131)	1,000
Cesium-134m	(Cs-134m)	100
Cesium-134	(Cs-134)	1
Cesium-135	(Cs-135)	10
Cesium-136	(Cs-136)	10
Cesium-137	(Cs-137)	10
Chlorine-36	(Cl-36)	10
Chlorine-38	(Cl-38)	10
Chromium-51	(Cr-51)	1,000
Cobalt-57	(Co-57)	100
Cobalt-58m	(Co-58m)	10
Cobalt-58	(Co-58)	10
Cobalt-60	(Co-60)	1
Copper-64	(Cu-64)	100
Dysprosium-165	(Dy-165)	10
Dysporsium-166	(Dy-166)	100
Erbium-169	(Er-169)	100
Erbium-17	(Er-171)	100
Europium-152(9.2h)	(Eu-152)	100

TABLE 330.1		
Radioactive Material	**Acronym**	**Microcuries**
Europium-152(13y)	(Eu-152)	1
Europium-154	(Eu-154)	1
Europium-155	(Eu-155)	10
Fluorine-18	(F-18)	1,000
Gadolinium-153	(Gd-153)	10
Gadolinium-159	(Gd-159)	100
Gallium-67	(Ga-67)	100
Gallium-72	(Ga-72)	10
Germanium-68	(Ge-68)	10
Germanium-71	(Ge-71)	100
Gold-195	(Au-195)	10
Gold-198	(Au-198)	100
Gold-199	(Au-199)	100
Hafnium-181	(Hf-181)	10
Holmium-166	(Ho-166)	100
Hydrogen-3	(H-3)	1,000
Indium-111	(In-111)	100
Indium-113m	(In-113m)	100
Indium-114m	(In-114m)	10
Indium-115m	(In-115m)	100
Indium-115	(In-115)	10
Iodine-123	(I-123)	100
Iodine-125	(I-125)	1
Iodine-126	(I-126)	1
Iodine-129	(I-129)	0.1
Iodine-131	(I-131)	1
Iodine-132	(I-132)	10
Iodine-133	(I-133)	1
Iodine-134	(I-134)	10
Iodine-135	(I-135)	10
Iridium-192	(Ir-192)	10
Iridum-194	(Ir-194)	100
Iron-52	(Fe-52)	10
Iron-55	(Fe-55)	100
Iron-59	(Fe-59)	10
Krypton-85	(Kr-85)	100
Krypton-87	(Kr-87)	10
Lanthanum-140	(La-140)	10
Lutetium-177	(Lu-177)	100
Manganese-52	(Mn-52)	10
Manganese-54	(Mn-54)	10
Manganese-56	(Mn-56)	10
Mercury-197m	(Hg-197m)	100
Mercury-197	(Hg-197)	100
Mercury-203	(Hg-203)	10
Molybdenum-99	(Mo-99)	100
Neodymium-147	(Nd-147)	100
Neodymium-149	(Nd-149)	100
Nickel-59	(Ni-59)	100
Nickel-63	(Ni-63)	10

TABLE 330.1		
Radioactive Material	**Acronym**	**Microcuries**
Nickel-65	(Ni-65)	100
Niobium-93m	(Nb-93m)	10
Niobium-95	(Nb-95)	10
Niobium-97	(Nb-97)	10
Osmium-185	(Os-185)	10
Osmium-191m	(Os-191m)	100
Osmium-191	(Os-191)	100
Osmium-193	(Os-193)	100
Palladium-103	(Pd-103)	100
Palladium-109	(Pd-109)	100
Phosphorus-32	(P-32)	10
Platinum-191	(Pt-191)	100
Platinum-193m	(Pt-193m)	100
Platinum-193	(Pt-193)	100
Platinum-197m	(Pt-197m)	100
Platinum-197	(Pt-197)	100
Polonium-210	(Po-210)	0.1
Potassium-42	(K-42)	10
Potassium-43	(K-43)	10
Praseodymium-142	(Pr-142)	100
Praseodymium-143	(Pr-143)	100
Promethium-147	(Pm-147)	10
Promethium-149	(Pm-149)	10
Rhenium-186	(Re-186)	100
Rhenium-188	(Re-188)	100
Rhodium-103m	(Rh-103m)	100
Rhodium-105	(Rh-105)	100
Rubidium-81	(Rb-81)	10
Rubidium-86	(Rb-86)	10
Rubidium-87	(Rb-87)	10
Ruthenium-97	(Ru-97)	100
Ruthenium-103	(Ru-103)	10
Ruthenium-105	(Ru-105)	10
Ruthenium-106	(Ru-106)	1
Samarium-151	(Sm-151)	10
Samarium-153	(Sm-153)	100
Scandium-46	(Sc-46)	10
Scandium-47	(Sc-47)	100
Scandium-48	(Sc-48)	10
Selenium-75	(Se-75)	10
Silicon-31	(Si-31)	100
Silver-105	(Ag-105)	10
Silver-110m	(Ag-110m)	1
Silver-111	(Ag-111)	100
Sodium-22	(Na-22)	10
Sodium-24	(Na-24)	10
Strontium-85	(Sr-85)	10
Strontium-89	(Sr-89)	1
Strontium-90	(Sr-90)	0.1
Strontium-91	(Sr-91)	10

TABLE 330.1		
Radioactive Material	**Acronym**	**Microcuries**
Strontium-92	(Sr-92)	10
Sulphur-35	(S-35)	100
Tantalum-182	(Ta-182)	10
Technetium-96	(Tc-96)	10
Technetium-97m	(Tc-97m)	100
Technetium-97	(Tc-97)	100
Technetium-99m	(Tc-99m)	100
Technetium-99	(Tc-99)	10
Tellurium-125m	(Te-125m)	10
Tellurium-127m	(Te-127m)	10
Tellurium-127	(Te-127)	100
Tellurium-129m	(Te-129m)	10
Tellurium-129	(Te-129)	100
Tellurium-131m	(Te-131m)	10
Tellurium-132	(Te-132)	10
Terbium-160	(Tb-160)	10
Thallium-200	(T1-200)	100
Thallium-201	(T1-201)	100
Thallium-202	(T1-202)	100
Thallium-204	(T1-204)	10
Thulium-170	(Tm-170)	10
Thulium-171	(Tm-171)	10
Tin-113	(Sn-113)	10
Tin-125	(Sn-125)	10
Tungsten-181	(W-181)	10
Tungsten-185	(W-185)	10
Tungsten-187	(W-187)	100
Vanadium-48	(V-48)	10
Xenon-131m	(Xe-131m)	1,000
Xenon-133	(Xe-133)	100
Xenon-135	(Xe-135)	100
Ytterbium-175	(Yb-175)	100
Yttrium-87	(Y-87)	10
Yttrium-88	(Y-88)	10
Yttrium-90	(Y-90)	10
Yttrium-91	(Y-91)	10
Yttrium-92	(Y-92)	100
Yttrium-93	(Y-93)	100
Zinc-65	(Zn-65)	10
Zinc-69m	(Zn-69m)	100
Zinc-69	(Zn-69)	1,000
Zirconium-93	(Zr-93)	10
Zirconium-95	(Zr-95)	10
Zirconium-97	(Zr-97)	10
Any radioactive material not listed above other than alpha emitting radioactive material		0.1

Table 330.1 note: to convert microcuries to SI units of kilobecquerels multiply the above values by 37. For example: Zirconium-97 of 10 microcuries multiplied by 37 is equivalent to 370 kilobecquerels.
[20.3.3.330 NMAC - Rp, 20.3.3.330 NMAC, 4/30/2009]

20.3.3.331 [RESERVED]

[20.3.3.331 NMAC - Rp, 20.3.3.331 NMAC, 4/30/2009; Repealed, 6/30/2011]

20.3.3.332 SCHEDULE D - RADIOACTIVE MATERIAL QUANTITIES FOR BROAD SCOPE LICENSES:

A. Table 332.1

TABLE 332.1		
Radioactive Material	**Column I curies**	**Column II curies**
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.0
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.0
Cesium-134m	100	1.0
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.0
Chromium-51	100	1.0
Cobalt-57	10	0.1
Cobalt-58m	100	1.0
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.0
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.0
Gadolinium-153	1	0.01

TABLE 332.1		
Radioactive Material	**Column I curies**	**Column II curies**
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.0
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.0
Indium-113m	100	1.0
Indium-114m	1	0.01
Indium-115m	100	1.0
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.01
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.0
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.0
Osmium-185	1	0.01
Osmium-191m	100	1.0
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1

TABLE 332.1		
Radioactive Material	**Column I curies**	**Column II curies**
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.0
Platinum-193	10	0.1
Platinum-197m	100	1.0
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.0
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.0
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.0
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.0
Technetium-99	1	0.01
Tellurium-125m	1	0.01

TABLE 332.1		
Radioactive Material	**Column I curies**	**Column II curies**
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.0
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.0
Xenon-133	100	1.0
Xenon-135	100	1.0
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.0
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above	0.1	0.001

B. Note. To convert curies to SI units of gigabecquerels, multiply the above values by 37. For example: Zirconium-97 (Column II) of 0.01 curie multiplied by 37 is equivalent to 0.37 gigabecquerel.

[20.3.3.332 NMAC - Rp, 20.3.3.332 NMAC, 4/30/2009]

20.3.3.333 SCHEDULE E - QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE:

A. Table 333.1

TABLE 333.1		
Radioactive Material	**Release Fraction**	**Quantity (Curies)**
Actinium-228	0.001	4,000
Americium-241	0.001	2
Americium-242	0.001	2

TABLE 333.1		
Radioactive Material	**Release Fraction**	**Quantity (Curies)**
Americium-243	0.001	2
Antimony-124	0.01	4,000
Antimony-126	0.01	6,000
Barium-133	0.01	10,000
Barium-140	0.01	30,000
Bismuth-207	0.01	5,000
Bismuth-210	0.01	600
Cadmium-109	0.01	1,000
Cadmium-113	0.01	80
Calcium-45	0.01	20,000
Californium-252	0.001	9 (20 mg)
Carbon-14 (Non CO_2)	0.01	50,000
Cerium-141	0.01	10,000
Cerium-144	0.01	300
Cesium-134	0.01	2,000
Cesium-137	0.01	3,000
Chlorine-36	0.5	100
Chromium-51	0.01	300,000
Cobalt-60	0.001	5,000
Copper-64	0.01	200,000
Curium-242	0.001	60
Curium-243	0.001	3
Curium-244	0.001	4
Curium-245	0.001	2
Europium-152	0.01	500
Europium-154	0.01	400
Europium-155	0.01	3,000
Gadolinium-153	0.01	5,000
Germanium-68	0.01	2,000
Gold-198	0.01	30,000
Hafnium-172	0.01	400
Hafnium-181	0.01	7,000
Holmium-166m	0.01	100
Hydrogen-3	0.5	20,000
Iodine-125	0.5	10
Iodine-131	0.5	10
Indium-114m	0.01	1,000
Iridium-192	0.001	40,000
Iron-55	0.01	40,000
Iron-59	0.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	0.01	8
Manganese-56	0.01	60,000
Mercury-203	0.01	10,000
Molybdenum-99	0.01	30,000
Neptunium-237	0.001	2
Nickel-63	0.01	20,000
Niobium-94	0.01	300
Phosphorus-32	0.5	100

TABLE 333.1		
Radioactive Material	**Release Fraction**	**Quantity (Curies)**
Phosphorus-33	0.5	1,000
Polonium-210	0.01	10
Potassium-42	0.01	9,000
Promethium-145	0.01	4,000
Promethium-147	0.01	4,000
Radium-226	0.001	100
Ruthenium-106	0.01	200
Samarium-151	0.01	4,000
Scandium-46	0.01	3,000
Selenium-75	0.01	10,000
Silver-110m	0.01	1,000
Sodium-22	0.01	9,000
Sodium-24	0.01	10,000
Strontium-89	0.01	3,000
Strontium-90	0.01	90
Sulfur-35	0.5	900
Technetium-99	0.01	10,000
Technetium-99m	0.01	400,000
Tellurium-127m	0.01	5,000
Tellurium-129m	0.01	5,000
Terbium-160	0.01	4,000
Thulium-170	0.01	4,000
Tin-113	0.01	10,000
Tin-123	0.01	3,000
Tin-126	0.01	1,000
Titanium-44	0.01	100
Vanadium-48	0.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	0.01	2,000
Zinc-65	0.01	5,000
Zirconium-93	0.01	400
Zirconium-95	0.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid. noncombustible	.01	1,000
Irradiated material solid, noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment alpha	.0001	20
Packaged waste, alpha[1]	.0001	20

Table 333.1 note:

[1] waste packaged in Type B containers does not require an emergency plan.

B. Notes.

(1) To convert curies to SI units of gigabecquerels, multiply the above values by 37. Example: Zirconium-95 of 5000 curies multiplied by 37 is equivalent to 185,000 gigabecquerels or 185 terabecquerels.

(2) For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in table 333.1 exceeds one.

[20.3.3.333 NMAC - Rp, 20.3.3.333 NMAC, 4/30/2009]

20.3.3.334 CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING:

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This section establishes criteria for passing the financial test and for obtaining the parent company guarantee.

B. Financial Test.

(1) To pass the financial test, the parent company must meet the criteria of either Subparagraphs (a) or (b) of this paragraph.

(a) The parent company must have:

(i) two of the following three ratios: a ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5;

(ii) net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used);

(iii) tangible net worth of at least $10 million; and

(iv) assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used);

(b) The parent company must have:

(i) a current rating for its most recent bond issuance of AAA, AA, A or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's;

(ii) tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used);

(iii) tangible net worth of at least $10 million; and

(iv) assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

(2) The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the department within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test shall be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(4) If the parent company no longer meets the requirements of Subsection A of this section, the licensee must send notice to the department of intent to establish alternate financial assurance as specified in this section. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

C. Parent Company Guarantee. The terms of a parent company guarantee which an applicant or licensee obtains must provide the following.

(1) The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the department; cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the department, as evidenced by the return receipts.

(2) If the licensee fails to provide alternate financial assurance as specified in the department’s regulations within 90 days after receipt by the licensee and department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in

the name of the licensee.

(3) The parent company guarantee and financial test provisions must remain in effect until the department has terminated the license.

(4) If a trust is 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.

[20.3.3.334 NMAC - Rp, 20.3.3.334 NMAC, 4/30/2009]

20.3.3.335 CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING:

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Subsection B of this section. The terms of the self-guarantee are in Subsection C of this section. This section establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

B. Financial Test.

(1) To pass the financial test, a company must meet all of the following criteria:

(a) tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor;

(b) assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities of parts thereof (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(c) a current rating for its most recent bond issuance of AAA, AA or A as issued by Standard and Poors, or Aaa, Aa or A as issued by Moodys.

(2) To pass the financial test, a company must meet all of the following additional requirements:

(a) the company must have at least one class of equity securities registered under the Securities Exchange Act;

(b) the company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement; in connection with that procedure, the licensee shall inform the department within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test shall be adjusted and that the company no longer passes the test; and

(c) after the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of Paragraph (1) of Subsection B of this section, the licensee must send immediate notice to the department of its intent to establish alternate financial assurance as specified in the department's regulations within 120 days of such notice.

C. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide the following.

(1) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the department; cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the department, as evidenced by the return receipt.

(2) The licensee shall provide alternative financial assurance as specified in 20.3.3.311 NMAC within 90 days following receipt by the department of a notice of cancellation of the guarantee.

(3) The guarantee and financial test provisions must remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in effect by the licensee.

(4) The licensee will promptly forward to the department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the securities and exchange commission pursuant to the requirements of Section 13 of the Securities and Exchange Act.

(5) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the department within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Paragraph (1) of Subsection B of this section.

(6) The applicant or licensee must provide to the department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

[20.3.3.335 NMAC - Rp, 20.3.3.335 NMAC, 4/30/2009]

20.3.3.336 CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEES FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED BONDS:

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Subsection B of this section. The terms of the self-guarantee are in Subsection C of this section. This section establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

B. Financial Test.

(1) To pass the financial test, a company must meet the following criteria:

(a) tangible net worth greater than $10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor;

(b) assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor; and

(c) a ratio of cash flow divided by total liabilities greater than 0.12 and a ratio of total liabilities divided by net worth less than 1.5.

(2) In addition, to pass the financial test, a company must meet all of the following requirements:

(a) the company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement; in connection with that procedure, the licensee shall inform the department within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test shall be adjusted and that the company no longer passes the test;

(b) after the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year; and

(c) if the licensee no longer meets the requirements of Paragraph (1) of Subsection B of this section, the licensee must send immediate notice to the department of its intent to establish alternate financial assurance as specified in 20.3.3.311 NMAC; the notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements; the licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

C. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide the following.

(1) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the department; cancellation may not occur until alternative financial assurance mechanism is in place.

(2) The licensee shall provide alternative financial assurance as specified in 20.3.3.311 NMAC within 90 days following receipt by the department of a notice of cancellation of the guarantee.

(3) The guarantee and financial test provisions must remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in

effect by the licensee.

(4) The applicant or licensee must provide to the department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

[20.3.3.336 NMAC - N, 4/30/2009]

20.3.3.337 CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF-GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY NONPROFIT COLLEGES, UNIVERSITIES AND HOSPITALS:

A. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Subsection B of this section. The terms of the self-guarantee are in Subsection C of this section. This section establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

B. Financial Test.

(1) For colleges and universities, to pass the financial test a college or university must meet either the criteria in Subparagraph (a) or the criteria in Subparagraph (b) of this paragraph.

(a) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized and unencumbered bond issuance of AAA, AA or A as issued by Standard and Poors or Aaa, Aa or A as issued by Moodys.

(b) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(2) For hospitals, to pass the financial test a hospital must meet either the criteria in Subparagraph (a) or the criteria in Subparagraph (b) of this paragraph.

(a) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA or A as issued by Standard and Poors or Aaa, Aa or A as issued by Moodys.

(b) For applicants or licensees that do not issue bonds, all the following tests must be met:

(i) total revenues less total expenditures divided by total revenues must be equal to or greater than 0.04;

(ii) long term debt divided by net fixed assets must be less than or equal to 0.67;

(iii) current assets and depreciation fund divided by current liabilities must be greater than or equal to 2.55; and

(iv) operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

(3) In addition, to pass the financial test, a licensee must meet all the following requirements:

(a) the licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement; in connection with that procedure, the licensee shall inform the department within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test shall be adjusted and that the licensee no longer passes the test;

(b) after the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year; and

(c) if the licensee no longer meets the requirements of Subsection B of this section, the licensee must send notice to the department of its intent to establish alternative financial assurance as specified in 20.3.3.311 NMAC; the notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements; the licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

C. Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide the following.

(1) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail and return receipt requested, to the department. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(2) The licensee shall provide alternative financial assurance as specified in the 20.3.3.311 NMAC within 90 days following receipt by the department of a notice of cancellation of the guarantee.

(3) The guarantee and financial test provisions must remain in effect until the department has terminated the license or until another financial assurance method acceptable to the department has been put in effect by the licensee.

(4) The applicant or licensee must provide to the department a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(5) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee shall provide notice in writing of such fact to the department within 20 days after publication of the change by the rating service.

[20.3.3.337 NMAC - N, 4/30/2009]

20.3.3.338 QUANTITIES FOR USE WITH DECOMMISSIONING AND QUANTITIES OF LICENSED MATERIAL REQUIRING LABELING:

A. Table 338.1

TABLE 338.1	
Radioactive Material	**Microcuries[1]**
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000
Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10

TABLE 338.1	
Radioactive Material	**Microcuries[1]**
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1
Europium-154	1
Europium-155	10
Florine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100

TABLE 338.1	
Radioactive Material	**Microcuries[1]**
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-22	1
Sodium-24	10

TABLE 338.1	
Radioactive Material	**Microcuries[1]**
Strontium-89	1
Strontium-90	0.1
Strontium-91	10
Strontium-92	10
Sulfur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[2]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[3]	100
Uranium-233	0.01
Uranium-234	0.01
Uranium-235	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10

TABLE 338.1	
Radioactive Material	**Microcuries[1]**
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

Table 338.1 notes:

[1] to convert microcurie to kilobecquerels, multiply the microcurie value by 37;

[2] based on alpha disintegration rate of Th-232, Th-230 and their daughter products;

[3] based on alpha disintegration rate of U-238, U-234 and U-235.

B. Note. Where a combination of isotopes in known amounts is involved, the limit for the combination shall be derived as follows: determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e. “unity”).

[20.3.3.338 NMAC - Rp, 20.3.4.465 NMAC, 4/30/2009]

HISTORY OF 20.3.3 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed as follows:
EIB 73-2, Regulations for Governing the Health and Environmental Aspects of Radiation filed on 7/9/1973;
EIB 73-2, Amendment 1, Regulations for Governing the Health and Environmental Aspects of Radiation filed on 4/17/1978;
EIB RPR-1, Radiation Protection Regulations filed on 4/21/1980;
EIB RPR-1, Amendment 1, Radiation Protection Regulations filed on 10/13/1981;
EIB RPR-1, Amendment 2, Radiation Protection Regulations filed on 12/15/1982; and
EIB RPR-1, Radiation Protection Regulations filed on 3/10/1989.

History of Repealed Material:
20.3.3 NMAC, Licensing of Radioactive Material (filed 03/15/2004) repealed 4/30/2009.

Other History: EIB RPR 1, Radiation Protection Regulations (filed 3/10/1989) renumbered and reformatted to 20 NMAC 3.1; Radioactive Materials and Radiation Machines, effective 5/3/1995;
20 NMAC 3.1; Radioactive Materials and Radiation Machines (filed 4/3/1995) internally renumbered, reformatted and replaced by 20 NMAC 3.1, Radioactive Materials and Radiation Machines, effective 7/30/1999.
20 NMAC 3.1.Subpart 3, Licensing of Radioactive Material (filed 6/17/1999), reformatted, amended and replaced by 20.3.3 NMAC, Licensing of Radioactive Material, effective 4/15/2004.
20.3.3 NMAC, Licensing of Radioactive Material (filed 3/15/2004) replaced by 20.3.3 NMAC, Licensing of Radioactive Material, effective 4/30/2009.

TITLE 20 ENVIRONMENTAL PROTECTION
CHAPTER 3 RADIATION PROTECTION
PART 5 RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

20.3.5.1 ISSUING AGENCY: Environmental Improvement Board.
[20.3.5.1 NMAC - N, 5/19/2002]

20.3.5.2 SCOPE: The regulations in this part apply to all licensees or registrants who use sources of radiation for industrial radiography. Except for those regulations of this Part clearly applicable only to sealed radioactive sources, both radiation machine and sealed radioactive sources are covered by this part. The requirements of this part are in addition to, and not in substitution for, other applicable requirements of 20.3 NMAC.
[20.3.5.2 NMAC - Rp, 20 NMAC 3.1.5.501, 5/19/2002]

20.3.5.3 STATUTORY AUTHORITY: Sections 74-1-8, 74-1-9, 74-3-5, and 74-3-9 NMSA 1978.
[20.3.5.3 NMAC - N, 5/19/2002]

20.3.5.4 DURATION: Permanent.
[20.3.5.4 NMAC - N, 5/19/2002]

20.3.5.5 EFFECTIVE DATE: May 19, 2002, unless a later date is cited at the end of a section.
[20.3.5.5 NMAC - N, 5/19/2002]

20.3.5.6 OBJECTIVE: To establish radiation safety requirements for both radiation machines and sealed radioactive sources used for industrial radiography.
[20.3.5.6 NMAC - Rp, 20 NMAC 3.1.5.500, 5/19/2002]

20.3.5.7 DEFINITIONS: As used in this Part, the following apply:

A. "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits specified in Part 4 of 20.3 NMAC as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of radiation and licensed materials in the public interest;

B. "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions;

C. "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head;

D. "Becquerel" (Bq) means one disintegration per second;

E. "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in 20.3.4.406 NMAC;

F. "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "Cabinet") which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material thing irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system;

G. "Certified cabinet x-ray system" means an x-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40;

H. "Certifying Entity" means an independent certifying organization meeting the requirements in 20.3.5.12 NMAC or an Agreement State meeting the requirements in 20.3.5.12 NMAC;

I. "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure;

J. "Control (drive) cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location;

K. "Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device;

L. "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device;

M. "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (an exposure head is also known as a source stop);

N. "Field station" means a facility where licensed material or registered machines may be stored or used, and from which equipment is dispatched;

O. "Gray" means the SI unit of absorbed dose; one gray is equal to an absorbed dose of 1 Joule/kilogram. It is also equal to 100 rads;

P. "Guide tube" (Projection sheath) means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head; the guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head;

Q. "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process;

R. "Independent certifying organization" means an independent organization that meets all of the criteria of 20.3.5.12 NMAC;

S. "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images;

T. "Lixiscope" means a portable light-intensified imaging device using a sealed source;

U. "Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed;

V. "Personal supervision" means guidance and instruction to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required;

W. "Practical examination" means a documented demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures;

X. "Radiation safety officer" (RSO) for industrial radiography means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements as specified in Subsection C of 20.3.5.11 NMAC;

Y. "Radiographer" means any individual who performs, or in attendance personally supervises, industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these regulations and all license and/or certificate of registration conditions; this individual must meet the training requirements as specified in Subsection B of 20.3.5.11 NMAC;

Z. "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria;

AA. "Radiographer instructor" means any radiographer who provides on-the-job training to radiographer trainees in accordance with Subsection D of 20.3.5.11 NMAC;

AB. "Radiographer trainee" means any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction;

AC. "Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in industrial radiography;

AD. "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure;

AE. "Radiographic operations" means all activities performed with a radiographic device, or with a radiation machine; these include however are not limited to activities associated with the use of the device or machine, or transport (except when being transported by a common or contract transport), including surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries;

AF. "Radiographic personnel" means any radiographer, radiographer's assistant, radiographer instructor, or radiographer trainee;

AG. "Residential location" means any area where structures in which people lodge or live are located, and the grounds on which structures are located including, but not limited to, houses, apartments, condominiums, and garages;

AH. "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device;

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

AJ. "Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement;

AK. "Shielded-room radiography" means industrial radiography conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is shielded so that radiation levels at every location on the exterior meet the limitations specified in 20.3.4.406 NMAC;

AL. "sievert" (Sv) means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems);

AM. "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable; the source assembly may also include a stop ball used to secure the source in the shielded position;

AN. "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources;

AO. "Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source;

AP. "Storage container" means a shielded device in which sealed sources are secured and stored;

AQ. "Temporary job site" means any location where industrial radiography is performed and where licensed material or X-ray machines may be stored other than the location(s) listed in a specific license or certificate of registration; and

AR. "Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. department of transportation;

AS. "Underwater radiography" means industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.

[20.3.5.7 NMAC - Rp, 20 NMAC 3.1.5.502, 5/19/2002]

20.3.5.8 EXEMPTIONS:

A. Except for the requirements of Subsections B and C of 20.3.5.25 NMAC, certified x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this part.

B. Industrial uses of lixiscopes are exempt from the requirements of this part.

[20.3.5.8 NMAC - Rp, 20 NMAC 3.1.5.503, 5/19/2002]

20.3.5.9 PROHIBITIONS: Industrial radiography performed with a sealed source that is not fastened to or contained in a radiographic exposure device, known as fish pole radiography, is prohibited unless specifically authorized in a license issued by the department.

[20.3.5.9 NMAC - Rp, 20 NMAC 3.1.5.526, 5/19/2002]

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

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

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

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

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

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

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

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

(1) instruments to be used;

(2) methods of performing the analysis; and

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

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

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

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

[20.3.5.12 NMAC - N, 5/19/02; A, XX/XX/2022]

20.3.5.11 TRAINING AND QUALIFICATION REQUIREMENTS:

A. Radiographer’s assistant. Licensees and registrants may not permit any individual to act as a radiographer's assistant until the requirements of this subsection have been completed. Until completion of these requirements the individual is considered to be a radiographer trainee. Licensees and registrants will have 120 days from the effective date of these regulations to comply with these requirements:

(1) Training shall be provided regarding the fundamentals of radiation safety including:

(a) Characteristics of gamma and X-ray radiation;

(b) Units of radiation dose and quantity of radioactivity;

(c) Hazards of exposure to radiation during radiographic operations, including case histories of accidents in radiography;

(d) Levels of radiation experienced during radiographic operations; and

(e) Methods of controlling radiation dose (time, distance, and shielding).

(f) Proper techniques for use and operation, and limitations of, the specific radiation survey instruments and personnel monitoring equipment used by the licensee or registrant.

(2) The individual has been provided copies of and instruction in the requirements contained in this part, applicable sections of Parts 3, 4, and 10 of 20.3 NMAC, 10 CFR 71 of federal regulations, and conditions of the radioactive materials license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

(3) The individual has developed competence to use, under the personal supervision of the radiographer or radiographer instructor, the radiographic exposure devices, sealed sources, radiation machines, associated equipment, and radiation survey instruments that the assistant will use; and

(4) The individual has demonstrated understanding of the instructions provided under Paragraph (2) of Subsection A of 20.3.5.11 NMAC by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in Paragraph (3) of Subsection A of 20.3.5.11 NMAC by successful completion of a practical examination on the use of such hardware.

B. Radiographer. Licensees may not permit any individual to act as a radiographer until the individual has completed the requirements of this subsection. With the exception of Paragraph (3) of Section B of 20.3.5.11 NMAC, licensees and registrants will have 120 days from the effective date of these regulations to comply with these requirements:

(1) The requirements of Subsection A of 20.3.5.11 NMAC; and,

(2) Two months minimum on-the-job training in addition to paragraph (1) of Subsection B of 20.3.5.11 NMAC; and,

(3) Certification through a radiographer certification program by a certifying entity in accordance with the criteria specified in 20.3.5.12 NMAC. Licensees or registrants will have one calendar year from the effective date of these regulations to comply with this requirement. Records of radiographer certification maintained in accordance with Subsection F of 20.3.5.11 NMAC provide appropriate affirmation of meeting this certification requirement; and,

(4) Has demonstrated understanding of the license or registration and the operating and emergency procedures by successful completion of a written or oral examination covering this material; and,

(5) Has received adequate training and has demonstrated understanding in the use of the licensee's or registrant's radiation survey instruments and associated equipment by successful completion of a practical examination covering the following material:

(a) Use, operation, calibration, and limitations of radiation survey instruments; and

(b) Survey techniques; and

(c) Use of personnel monitoring equipment; and

(6) Has received adequate training and has demonstrated understanding in the use of the licensee's or registrant's radiographic exposure devices, sources, radiation machines, and associated equipment by successful completion of a practical examination covering the following material:

(a) Operation and control of radiographic exposure equipment, radiation machines, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails); and

(b) Storage, control, and disposal of licensed material; and

(c) Inspection and maintenance of equipment.

C. Radiation safety officer (RSO). The licensee may not permit any individual to act as an RSO until the requirements of this subsection have been satisfied. Licensees and registrants will have one year from the effective date of these regulations to comply with these requirements:

(1) The minimum qualifications, training, and experience for RSOs are as follows:

(a) Completion of the training and qualification requirements of Subsection B of 20.3.5.11 NMAC; and

(b) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(c) Formal training in the establishment and maintenance of a radiation protection program.

(2) The department will consider alternatives to these requirements when the RSO has appropriate training and/or experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

D. Radiographer instructor. No individual shall act as a radiographer instructor unless such individual:

(1) Has met the requirements of Subsection B of 20.3.5.11 NMAC; and

(2) Has 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(3) Has been named as a radiographer instructor on the license or a registration certificate issued by the Department.

E. Annual refresher training. The licensee or registrant shall provide annual refresher training in radiation safety for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

F. Records of training and certification. Each licensee or registrant shall maintain the following records (of training and certification) for three years after the record is made:

(1) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

(2) Records of annual refresher safety training for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance required by Subsection B of 20.3.5.13 NMAC, the records must also include a list showing the items checked and any non-compliances observed by the RSO.

[20.3.5.11 NMAC - Rp, 20 NMAC 3.1.5.515, 5/19/2002]

20.3.5.12 Requirements For An Independent Certifying Organization:

A. An independent certifying organization shall:

(1) be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography; and

(2) make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability; and

(3) have a certification program open to nonmembers, as well as members; and

(4) be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise; and

(5) have an adequate staff, a viable system for financing its operations, and a policy-and decision-making review board; and

(6) have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies; and

(7) have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program; and

(8) have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions; and

(9) have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program; and

(10) have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals; and

(11) have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees; and

(12) exchange information about certified individuals with other independent certifying organizations, the Department, the U.S. nuclear regulatory commission, and/or Agreement States and allow periodic review of its certification program and related records; and

(13) provide a description to the department of its procedures for choosing examination sites and for providing an appropriate examination environment.

B. Requirements for certification programs. All certification programs must:

(1) require applicants for certification to:

(a) receive training in the topics set forth in Subsection D of 20.3.5.12 NMAC or equivalent Agreement State regulations; and

(b) satisfactorily complete a written examination covering these topics.

(2) require applicants for certification to provide documentation that demonstrates that the applicant has:

(a) received training in the topics set forth in Subsection D of 20.3.5.12 NMAC or equivalent Agreement State regulations;

(b) satisfactorily completed a minimum period of on-the-job training; and

(c) has received verification by an Agreement State or a NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer; and

(3) include procedures to ensure that all examination questions are protected from disclosure; and

(4) include procedures for denying an application, revoking, suspending, and reinstating a certificate; and

(5) provide a certification period of not less than three years nor more than five years; and

(6) include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training.

(7) Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

C. Requirements for written examinations. All examinations must be:

(1) designed to test an individual's knowledge and understanding of the topics listed in Subsection D of 20.3.5.12 NMAC or equivalent Agreement State requirements; and

(2) written in a multiple-choice format; and

(3) have test items drawn from a question bank containing psychometrically valid questions based on the material in Subsection D of 20.3.5.12 NMAC.

D. Required Training Topics. All certification programs shall include training in the following topics:

(1) fundamentals of radiation safety including:

(a) characteristics of gamma radiation; and

(b) units of radiation dose and quantity of radioactivity; and

(c) hazards of exposure to radiation; and

(d) levels of radiation from licensed material; and

(e) methods of controlling radiation dose (time, distance, and shielding); and

(2) radiation detection instruments including:

(a) use, operation, calibration, and limitations of radiation survey instruments; and

(b) survey techniques; and

(c) use of personnel monitoring equipment; and

(3) equipment to be used including:

(a) operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails); and

(b) storage, control, and disposal of licensed material; and

(c) inspection and maintenance of equipment; and

(4) the requirements of pertinent State and Federal regulations; and

(5) case histories of accidents in radiography.

[20.3.5.12 NMAC - N, 5/19/2002]

20.3.5.13 Requirements Of The Radiation Safety Officer (Rso):

A. The specific duties and authorities of the RSO include, but are not limited to:

(1) Ensuring that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant’s program; and

(2) Establish, document, and oversee all operating, emergency, and ALARA procedures required by Part 4 of 20.3 NMAC. The procedures shall be revised by the RSO whenever necessary to ensure procedural accuracy. The procedures shall be reviewed regularly by the RSO at intervals not to exceed one calendar year to ensure that they conform to Part 4, other pertinent regulations, and to the conditions of the license or registration; and

(3) Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught; and

(4) Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits; and

(5) Ensuring that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 20.3.4.453 NMAC; and

(6) Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

B. Inspections of Job Performance. Except as provided in paragraph (4) of Subsection B of 20.3.5.13 NMAC, the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Department's regulations, license or registration requirements, and the applicant's operating and emergency procedures are followed. The inspection program must:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than six months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of paragraph (5) of Subsection B of 20.3.5.11 NMAC and the radiographer's assistant must re-demonstrate knowledge of the training requirements of paragraph (3) of Subsection A of 20.3.5.11 NMAC by a practical examination before these individuals can next participate in a radiographic operation.

(3) The Department may consider alternatives requested in writing in those situations where the individual serves as both radiographer and RSO.

(4) Records of semi-annual inspections of job performance for each radiographer and each radiographer's assistant shall include a list showing the items checked and any non-compliances observed by the RSO.

[20.3.5.13 NMAC - N, 5/19/2002]

20.3.5.14 SUPERVISION OF RADIOGRAPHER'S ASSISTANTS: Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment, sealed sources, radiation machines, or conducts radiation surveys required by Subsection B of 20.3.5.17 NMAC to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision must include:

A. The radiographer's physical presence at the site where the sealed sources or radiation machines are being used;

B. The availability of the radiographer to give immediate assistance if required; and

C. The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

[20.3.5.14 NMAC - Rp, 20 NMAC 3.1.5.518, 5/19/2002]

20.3.5.15 PERSONNEL MONITORING:

A. The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an operating alarm ratemeter, and a NVLAP certified dosimeter. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

(1) Pocket dosimeters must have a range from zero to two millisieverts (200 millirems) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(2) Each NVLAP certified dosimeter must be assigned to and worn by only one individual.

(3) Film badges must be replaced at periods not to exceed one month. All other NVLAP certified dosimeters must be replaced at periods not to exceed three months.

(4) After replacement, each NVLAP certified dosimeter must be processed as soon as possible.

B. Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters must be read and the exposures recorded at the beginning and end of each shift. Records shall be maintained in accordance with paragraph (2) of Subsection H of 20.3.5.15 NMAC.

C. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure. Records shall be maintained in accordance with paragraph (1) of Subsection H of 20.3.5.15 NMAC.

D. If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personal dosimeter reads greater than two millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's NVLAP certified dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with radiation use until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination shall be documented. The documents shall be maintained in accordance with paragraph (4) of Subsection H of 20.3.5.15 NMAC.

E. If a NVLAP certified dosimeter is lost or damaged, the worker shall cease work immediately until a replacement dosimeter is provided and the exposure is calculated for the time period from issuance to loss or damage of the dosimeter. The results of the calculated exposure and the time period for which the dosimeter was lost or damaged shall be documented. The documents shall be maintained in accordance with paragraph (4) of Subsection H of 20.3.5.15 NMAC.

F. Reports received from dosimetry processors shall be maintained in accordance with paragraph (3) of Subsection H of 20.3.5.15 NMAC.

G. Each alarm ratemeter must--

(1) Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of five mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee or registrant shall maintain records of alarm ratemeter calibrations in accordance with paragraph (2) of Subsection H of 20.3.5.15 NMAC.

H. Personnel Monitoring Records. Each licensee and registrant shall maintain the following exposure records pursuant to 20.3.5.15 NMAC:

(1) Direct reading dosimeter readings and yearly operability checks required by Subsections B and C of 20.3.5.15 NMAC for three years after the record is made.

(2) Records of alarm ratemeter calibrations for three years after the record is made.

(3) Reports received from dosimetry processors shall be maintained until the Department terminates the license or registration.

(4) Records of estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged external dosimetric device, until the Department terminates the license or registration.

[20.3.5.15 NMAC - Rp, 20 NMAC 3.1.5.517, 5/19/2002]

20.3.5.16 RADIATION SURVEY INSTRUMENTS:

A. Licensees and registrants shall keep sufficient calibrated and operable radiation survey instruments at each location to make the radiation surveys required by this Part and by 20.3.4.416 NMAC. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 millirems) per hour through 0.01 sievert (one rem) per hour.

B. Each radiation survey instrument shall be calibrated:

(1) At energies appropriate for use and at intervals not to exceed 6 months and after each instrument servicing (except battery changes);

(2) Such that accuracy within plus or minus 20 percent can be demonstrated; and

(3) At two points located approximately one-third and two-third of full-scale on each scale for linear scale instruments; at mid-range of each decade, and at two points of at least one decade for logarithmic scale instruments; and at appropriate points for digital instruments.

C. Records of these calibrations shall be maintained for three years after the calibration date for inspection by the Department.

D. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

[20.3.5.16 NMAC - Rp, 20 NMAC 3.1.5.509, 5/19/2002]

20.3.5.17 RADIATION SURVEYS AND SURVEY RECORDS:

A. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 20.3.5.16 NMAC is available and used at each site where radiographic exposures are made.

B. Survey Requirements for Devices Containing Radioactive Materials.

(1) Using a survey instrument meeting the requirements of Subsection A of 20.3.5.17 NMAC, conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

(2) Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in Subsection AO of 20.3.5.7 NMAC), to ensure that the sealed source is in its shielded position.

C. Survey Requirements for Radiation Machines. A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off".

D. Records shall be kept of the surveys required by Subsection B of 20.3.5.17 NMAC. Such records shall be maintained for inspection by the Department for three years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the Department authorizes their disposition.

[20.3.5.17 NMAC - Rp, 20 NMAC 3.1.5.521, 5/19/2002]

20.3.5.18 SPECIFIC REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS:

A. Licensees and registrants shall supply the following items at each job site:

(1) At least one operable, calibrated survey instrument;

(2) A current whole body NVLAP certified dosimeter for each individual;

(3) An operable, calibrated pocket dosimeter with a range of 0 to 200 milliroentgens (two milligrays) for each worker; and

(4) The appropriate barrier ropes and signs.

B. Industrial radiographic operations shall not be performed if any of the items in Subsection A of 20.3.5.18 NMAC are not available at the job site or are inoperable.

C. No individual other than a qualified radiographer, radiographer's assistant, radiographer instructor, or radiographer trainee (under the personal supervision of a radiographer instructor) shall manipulate controls or operate equipment used in industrial radiographer operations.

D. No individual shall act as radiographer instructor unless such individual possesses the qualifications required for radiographer instructors as listed in Subsection D of 20.3.5.11 NMAC.

E. During an inspection by the Department, the Department inspector may terminate an operation if any of the items in Subsection A of 20.3.5.18 NMAC are not available and operable or if the required number of radiographic personnel is not present. Operations shall not be resumed until such conditions are met.

F. All radiographic operations conducted at locations of use authorized on the license or registration must be conducted in a permanent radiographic installation, unless specifically authorized by the Department.

G. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or a radiographer's assistant who has at a minimum met the requirements specified within Subsections B or A of 20.3.5.11 NMAC as appropriate. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present. Licensees will have one calendar year from the effective date of these regulations to meet the requirements for having two qualified individuals present at locations other than a permanent radiographic installation.

H. During each radiographic operation the radiographer, or the other individual present as required by Subsection G of 20.3.5.18 NMAC, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Part 1 of 20.3 NMAC, except:

(1) Where the high radiation area is equipped with a control device or alarm system as described in Part 4 of 20.3 NMAC; or

(2) Where the high radiation area is locked to protect against unauthorized or accidental entry.

I. All areas in which industrial radiography is being performed must be conspicuously posted as required by Part 4 of 20.3 NMAC. Exceptions to posting requirements listed in Part 4 do not apply to industrial radiographic operations.

J. Utilization Logs. Each licensee or registrant shall maintain current logs which shall be kept available for inspection by the Department for three years from the date of the recorded event, showing for each source of radiation the following information:

(1) A description, including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source is located;

(2) The identity and signature of the radiographer to whom assigned;

(3) Locations where used and dates of use; and

(4) The date(s) each source of radiation is removed from storage and returned to storage.

K. Locking of Sources of Radiation.

(1) Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in Subsection G of 20.3.5.18 NMAC. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

(2) Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

L. A licensee may conduct underwater radiography only if procedures have been approved by the Department.

[20.3.5.18 NMAC - Rp, 20 NMAC 3.1.5.523, 5/19/2002]

20.3.5.19 PERMANENT RADIOGRAPHIC INSTALLATIONS:

A. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

(1) An entrance control of the type described in Part 4 of 20.3 NMAC that reduces the radiation level upon entry into the area, or

(2) Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed.

B. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry (designated in Subsection A of 20.3.5.19 NMAC) must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven calendar days. The facility may continue to be used during this seven-day period, provided the licensee implements the continuous surveillance requirements of Subsection H of 20.3.5.18 NMAC and uses an alarming ratemeter.

C. Test records for entrance controls and audible and visual alarms must be maintained for three years after they are made.

[20.3.5.19 NMAC - Rp, 20 NMAC 3.1.5.514, 5/19/2002]

20.3.5.20 LABELING, STORAGE, AND TRANSPORTATION:

A. The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION (or "DANGER")
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY")

B. The licensee may not transport licensed radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in 10 CFR part 71.

C. Locked radiographic exposure devices, storage containers, and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

D. The licensee shall lock and physically secure the transport package containing licensed material or radiation machine(s) in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

[20.3.5.20 NMAC - N, 5/19/2002]

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., 25 West 43rd Street, New York, New York 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, 5/19/2002; A, 6/13/2017]

20.3.5.22 LIMITS ON EXTERNAL RADIATION LEVELS FROM STORAGE CONTAINERS AND SOURCE CHANGERS: The maximum exposure rate limits for storage containers and source changers are two millisieverts (200 millirem) per hour at any exterior surface, and 0.1 millisieverts (10 millirem) per hour at one meter from any exterior surface with the sealed source in the shielded position.

[20.3.5.22 NMAC - Rp, 20 NMAC 3.1.5.504, 5/19/2002]

20.3.5.23 INSPECTION AND MAINTENANCE:

A. The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before use on each day the equipment is to be used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.

B. Each licensee or registrant shall perform, and have written procedures for, inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

C. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

D. If any inspection conducted pursuant to Subsections A, B, or C of 20.3.5.23 NMAC reveals damage to components critical to radiation safety, the device shall be removed from service and labeled as defective until repairs have been made.

E. Records of equipment problems and of any maintenance performed pursuant to the requirements of this section shall be made in accordance with the following:

(1) Each licensee or registrant shall maintain records of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for three years after it is made.

(2) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.

[20.3.5.23 NMAC - Rp, 20 NMAC 3.1.5.513, 5/19/2002]

20.3.5.24 LEAK TESTING, REPAIR, TAGGING, OPENING, MODIFICATION, AND REPLACEMENT OF SEALED SOURCES:

A. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the Department.

B. Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within the six-month period prior to the transfer, the sealed source shall not be put into use until tested.

C. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to Part 3 of 20.3 NMAC. Records of leak test results shall be kept in units of becquerels or microcuries and maintained for inspection by the Department for three years.

D. Any test conducted pursuant to Subsections B and C of 20.3.5.24 NMAC that reveals the presence of 185 becquerels (0.005 microcuries) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with 20.3 NMAC. Within five days after obtaining results of the test, the licensee shall file a report with the Department describing the equipment involved, the test results, and the corrective action taken.

E. A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a square durable tag at least 2.5 cm on each side bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger - Radioactive Material - Do Not Handle - Notify Civil Authorities if Found."

F. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department to perform the analysis. Should such testing reveal the presence of 185 Bq (0.005 microcuries) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeded 12 months. Records of DU leak tests results shall be kept in units of microcuries (becquerels) and maintained for inspection by the department for 3 years.

[20.3.5.24 NMAC - Rp, 20 NMAC 3.1.5.510, 5/19/2002]

20.3.5.25 SPECIAL REQUIREMENTS AND EXEMPTIONS FOR CABINET RADIOGRAPHY:

A. Systems for cabinet radiography designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this Part, and Sections 405 to 412 of 20.3.4 NMAC. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this Part and 21 CFR 1020.40; and

(2) Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in paragraph (1) of Subsection A of 20.3.5.25 NMAC. Records of these evaluations shall be maintained for inspection by the Department for a period of three years after the evaluation.

B. Certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this Part except that:

(1) Operating personnel must be provided with a NVLAP certified dosimeter, and reports of the results shall be maintained for inspection by the Department;

(2) No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this section shall be maintained for inspection by the Department until disposition is authorized by the Department;

(3) Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with Subsection B of 20.3.5.19 NMAC; and

(4) The registrant shall perform an evaluation at intervals not to exceed one year, to determine conformance with Sections 405 to 412 of 20.3.4 NMAC. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Department for a period of three years after the evaluation.

C. Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.49 unless prior approval has been granted by the Department pursuant to Subsection A of 20.3.1.107 NMAC.

[20.3.5.25 NMAC - Rp, 20 NMAC 3.1.5.524, 5/19/2002]

20.3.5.26 SPECIAL REQUIREMENTS FOR RADIOGRAPHY EMPLOYING RADIATION MACHINES:

A. Shielded room radiography. Shielded room radiography (as defined in Subsection AK of 20.3.5.7 NMAC) using radiation machines shall be exempt from other requirements of this Part; however:

(1) no registrant shall permit any individual to operate a radiation machine for shielded room radiography until such individual has received a copy of, and instruction in, and demonstrated an understanding of operating procedures of the unit, and has demonstrated competence in its use;

(2) each registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by, every individual who operates, makes "set-ups", or performs maintenance on a radiation machine for shielded room radiography; and

(3) a physical radiation survey shall be conducted to determine that the radiation machine is "off" prior to each entry into the shielded room. Such surveys shall be made with a radiation measuring instrument which is capable of measuring radiation of the energies and at the exposure rates to be encountered, which is in good working order, and which has been properly calibrated within the preceding three months or following the last instrument servicing, whichever is later.

B. Other radiography using radiation machines. Other radiography using machines shall be exempt from 20.3.5.17 NMAC, 20.3.5.21 NMAC, 20.3.5.22 NMAC, and 20.3.5.24 NMAC; however:

(1) A physical radiation survey shall be conducted to determine that the radiation machine is "off" prior to each entry into the radiographic exposure area. Such surveys shall be made with a radiation measuring instrument capable of measuring radiation of the energies and at the exposure rates to be encountered, which is in good working order, and which has been properly calibrated within the preceding three months or following the last instrument servicing, whichever is later. Survey results and records of boundary locations shall be maintained and kept available for inspection; and

(2) Mobile or portable radiation machines shall be physically secured to prevent removal by unauthorized personnel.

[20.3.5.26 NMAC - Rp, 20 NMAC 3.1.5.525, 5/19/2002]

20.3.5.27 REPORTING REQUIREMENTS:

A. In addition to the reporting requirements specified in Part 3 and under other sections of 20.3 NMAC, each licensee or registrant (as appropriate) shall provide a written report to the department within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the control cable;

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position; or

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function.

B. The licensee or registrant shall include the following information in each report submitted under Subsection A of 20.3.5.27 NMAC:

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Manufacturer and model number of equipment involved in the incident;

(4) Place, time and date of the incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence; and

(7) Qualifications of personnel involved in the incident.

C. Any licensee or registrant conducting radiographic operations, or storing radioactive material or radiation machine(s), at any location not listed on the license for a period in excess of 180 days in a calendar year, shall notify the Department in writing prior to exceeding the 180 days.

[20.3.5.27 NMAC - Rp, 20 NMAC 3.1.5.507, 5/19/2002]

20.3.5.28 INVENTORY ACCOUNTING REQUIREMENTS:

A. Receipt and Transfer of Sealed Sources.

(1) Each licensee shall maintain records showing the receipts and transfers of sealed sources, radiation machines, and devices using DU for shielding and retain each record for three years after it is made.

(2) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each sealed source, radiation machine, or device, as appropriate.

B. Quarterly Inventories.

(1) Quarterly physical inventories shall be conducted by licensees and registrants to account for all sealed sources, radiography exposure devices, radiation machines, and devices containing depleted uranium received or in their possession. Inventory records shall be maintained for three years from the date of the inventory for inspection by the Department.

(2) Each record must include the date of the inventory, name of the individual conducting the inventory, quantities of radiation machines, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sealed source and/or devices, and manufacturer, model, and serial number of each sealed source, radiation machines, and/or device, as appropriate.

[20.3.5.28 NMAC - Rp, 20 NMAC 3.1.5.511, 5/19/2002]

20.3.5.29 OPERATING AND EMERGENCY PROCEDURES:

A. Operating and emergency procedures must include, as a minimum, instructions in the following:

(1) Appropriate handling and use of licensed sealed sources and radiographic exposure devices so that no person is likely to be exposed to radiation doses in excess of the limits established in Part 4 of 20.3 NMAC;

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for controlling access to radiographic areas;

(4) Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

(5) Personnel monitoring and the use of personnel monitoring equipment;

(6) Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the sealed sources during transportation (refer to 49 CFR parts 171-173);

(7) The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, transport containers, and storage containers;

(8) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly;

(9) The procedure for notifying proper persons in the event of an accident;

(10) Minimizing exposure of persons in the event of an accident;

(11) Source recovery procedure if licensee will perform source recovery;

(12) Maintenance of records.

B. Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Department terminates the license or registration. Superseded material must be retained for three years after the change is made.

[20.3.5.29 NMAC - Rp, 20 NMAC 3.1.5.516, 5/19/2002]

20.3.5.30 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOB SITES: Each licensee or registrant shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:

A. Appropriate license or certificate of registration or equivalent document;

B. Operating and emergency procedures;

C. A copy of Parts 4, 5, and 10 of 20.3 NMAC;

D. Survey records required pursuant to 20.3.5.17 NMAC and area survey records required pursuant to Part 4 of 20.3 NMAC for the period of operation at the site;

E. Daily pocket dosimeter records for the period of operation at the site;

F. The latest instrument calibration and leak test records for specific devices and sealed sources in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter;

G. Utilization records for each radiographic exposure device dispatched from that location as required by Subsection J of 20.3.5.18 NMAC;

H. Records of equipment problems identified in daily checks of equipment as required by Subsection A of 20.3.5.23 NMAC;

I. Records of alarm system and entrance control checks required by Subsection B of 20.3.5.19 NMAC, if applicable;

J. Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by Subsection H of 20.3.5.15 NMAC; and,

K. The shipping papers for the transportation of radioactive materials required by 10 CFR 71.5.

L. When operating under reciprocity pursuant to Part 3 of 20.3 NMAC, a copy of the Agreement State license authorizing the use of licensed materials.

[20.3.5.30 NMAC - Rp, 20 NMAC 3.1.5.522, 5/19/2002]

HISTORY OF 20.3.5 NMAC:

Pre-NMAC History:

Material in this part was derived from that previously filed with the commission of public records - state records center and archives:

EIB 73-2, Regulations For Governing The Health And Environment Aspects Of Radiation, filed 7/9/1973;

EIB RP,R-1, Radiation Protection Regulations, filed 4/21/1980;

EIB RP,R 1, Radiation Protection Regulations, filed 3/10/1989.

History of Repealed Material: 20 NMAC 3.1, Subpart 5, Radiation Safety Requirements For Industrial Radiographic Operations, repealed effective 5/19/2002.

Other History:

EIB RP,R 1, Radiation Protection Regulations, filed 3/10/1989 was **renumbered** into first version of the New Mexico Administrative Code as 20 NMAC 3.1, Radioactive Materials And Radiation Machines, filed 7/3/1995;

20 NMAC 3.1, Radioactive Materials And Radiation Machines, filed 7-3-95 was **replaced** by 20 NMAC 3.1, Radioactive Materials And Radiation Machines, filed 6/17/1999;

20 NMAC 3.1, Subpart 5, Radiation Safety Requirements For Industrial Radiographic Operations, filed 6/17/1999 **replaced by** 20.3.5 NMAC, Radiation Safety Requirements For Industrial Radiographic Operations, effective 5/19/2002.

TITLE 20 ENVIRONMENTAL PROTECTION
CHAPTER 3 RADIATION PROTECTION
PART 7 MEDICAL USE OF RADIONUCLIDES

20.3.7.1 ISSUING AGENCY: Environmental Improvement Board.
[20.3.7.1 NMAC - Rp, 20 NMAC 3.1.1.100, 4/30/2009]

20.3.7.2 SCOPE: This part contains the requirements and provisions for the medical use of radioactive materials and for issuance of specific licenses authorizing the medical use of radioactive material. These requirements and provisions provide for the radiation safety of workers, the general public, patients and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, other parts in this chapter. The requirements and provisions of 20.3.3 NMAC, 20.3.4 NMAC, 20.3.10 NMAC and 20.3.16 NMAC apply to applicants and licensees subject to this part unless specifically exempted. Other federal, state or local regulations may apply.
[20.3.7.2 NMAC - Rp, 20 NMAC 3.1.7.700, 4/30/2009]

20.3.7.3 STATUTORY AUTHORITY: Sections 74-1-9, 74-3-5 and 74-3-9 NMSA 1978.
[20.3.7.3 NMAC - Rp, 20 NMAC 3.1.1.102, 4/30/2009]

20.3.7.4 DURATION: Permanent.
[20.3.7.4 NMAC - Rp, 20 NMAC 3.1.1.103, 4/30/2009]

20.3.7.5 EFFECTIVE DATE: April 30, 2009, unless a later date is cited at the end of a section.
[20.3.7.5 NMAC - Rp, 20 NMAC 3.1.1.104, 4/30/2009]

20.3.7.6 OBJECTIVE: This part provides for the medical use and licensing of radioactive materials.
[20.3.7.6 NMAC - Rp, 20 NMAC 3.1.1.105, 4/30/2009]

20.3.7.7 DEFINITIONS:

A. "Address of use" means the building or buildings that are identified on the license and where radioactive material may be prepared, received, used or stored.

B. "Area of use" means a portion of an address of use that has been set aside for the purpose of preparing, receiving, using or storing radioactive material.

C. "Associate Radiation Safety Officer (ARSO)" means an individual who:

(1) Meets the requirements in 10 CFR § 35.50 and 10 CFR §35.59; and

(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(a) A specific medical use license issued by the Commission or an Agreement State; or

(b) A medical use permit issued by a Commission master material licensee.

[C] D. "Authorized medical physicist" means an individual who:

(1) meets the requirements in Subsection B of 20.3.7.714 NMAC, incorporating 10 CFR 35.51(a), and Subsection E of 20.3.7.714 NMAC; or

(2) is identified as an authorized medical physicist or teletherapy physicist on:

(a) a specific medical use license issued by the department, NRC or agreement state;

(b) a medical use permit issued by a NRC master material licensee;

(c) a permit issued by the department, NRC or agreement state broad scope medical use licensee; or

(d) a permit issued by a NRC master material license broad scope medical use permittee.

[D] E. "Authorized nuclear pharmacist" means a pharmacist who:

(1) meets the requirements in Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(a), and Subsection E of 20.3.7.714 NMAC; or

(2) is identified as an authorized nuclear pharmacist on:

(a) a specific license issued by the department, NRC or agreement state that authorizes medical use or the practice of nuclear pharmacy;

(b) a permit issued by a NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

(c) a permit issued by a department, NRC or agreement state broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

(d) a permit issued by a NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

(3) is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

(4) is designated as an authorized nuclear pharmacist in accordance with Subparagraph (e) of Paragraph (2) of Subsection J of 20.3.3.315 NMAC.

[~~E~~] F. "Authorized user" means a physician, dentist or podiatrist who:

(1) meets the requirements in Subsection E of 20.3.7.714 NMAC and any of the following subsections of 20.3.7.714 NMAC: Subsection F, incorporating 10 CFR 35.190(a); Subsection G, incorporating 10 CFR 35.290(a); Subsection H, incorporating 10 CFR 35.390(a); Subsection I, incorporating 10 CFR 35.392(a); Subsection J, incorporating 10 CFR 35.394(a); Subsection L, incorporating 10 CFR 35.490(a); Subsection N, incorporating 10 CFR 35.590(a); or Subsection O, incorporating 10 CFR 35.690(a); or

(2) is identified as an authorized user on:

(a) a department, NRC or agreement state license that authorizes the medical use of radioactive material;

(b) a permit issued by a NRC master material licensee that is authorized to permit the medical use of radioactive material;

(c) a permit issued by a department, NRC or agreement state specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

(d) a permit issued by a NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

[~~F~~] G. "Brachytherapy" means a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal or interstitial application.

[~~G~~] H. "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

[~~H~~] I. "Client's address" means the area of use or a temporary job site for the purpose of providing mobile medical service in accordance with Subsection J of 20.3.7.703 NMAC.

[~~I~~] J. "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

[~~J~~] K. "Dentist" means an individual licensed by a state or territory of the United States, the District of Columbia or the commonwealth of Puerto Rico to practice dentistry.

[~~K~~] L. "High dose-rate remote afterloader", as used in this part, means a brachytherapy device that remotely delivers a dose rate in excess of 12 grays (1200 rads) per hour at the point or surface where the dose is prescribed.

[~~L~~] M. "Low dose-rate remote afterloader", as used in this part, means a brachytherapy device that remotely delivers a dose rate of less than or equal to two grays (200 rads) per hour at the point or surface where the dose is prescribed.

[~~M~~] N. "Management" means the chief executive officer or other individual having the authority to manage, direct or administer the licensee's activities or those persons' delegate or delegates.

[~~N~~] O. "Manual brachytherapy", as used in this part, means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

[~~O~~] P. "Medical event" means an event that meets the criteria in Paragraph (1) or (2) of Subsection A of 20.3.7.716 NMAC.

[~~P~~] Q. "Medical institution" means an organization in which more than one medical discipline is practiced.

[~~Q~~] R. "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

[R] S. "Medium dose-rate remote afterloader", as used in this part, means a brachytherapy device that remotely delivers a dose rate of greater than two grays (200 rads) per hour, but less than or equal to12 grays (1200 rads) per hour at the point or surface where the dose is prescribed.

[S] T. "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

[T] U. "NIST" means the national institute of standards and technology which is the standards-defining agency of the United States government, formerly the national bureau of standards. It is one of three agencies that fall under the technology administration (www.technology.gov), a branch of the United States commerce department that is devoted to advancing American economic growth through the use of technology.

V. "Ophthalmic physicist" means an individual who

(1) Meets the requirements in 10 CFR § 35.433(a)(2) and 10 CFR § 35.59; and

(2) Is identified as an ophthalmic physicist on a:

(a) Specific medical use license issued by the Commission or an Agreement State;

(b) Permit issued by a Commission or Agreement State broad scope medical use licensee;

(c) Medical use permit issued by a Commission master material licensee; or

(d) Permit issued by a Commission master material licensee broad scope medical use permittee.

[U] W. "Output" means the exposure rate, dose rate or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

[V] X. "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

[W] Y. "Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia or the commonwealth of Puerto Rico to practice pharmacy.

[X] Z. "Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia or the commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

[Y] AA. "Podiatrist" means an individual licensed by a state or territory of the United States, the District of Columbia or the commonwealth of Puerto Rico to practice podiatry.

[**Z] BB.** "**Positron emission tomography (PET) radionuclide production facility"** is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

[AA] CC. "Preceptor" means an individual who provides, directs or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, [or a] R[r]adiation S[s]afety O[o]fficer, or a Associate Radiation Officer.

[BB] DD. "Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

(1) in a written directive; or

(2) in accordance with the directions of the authorized user for procedures performed pursuant to 20.3.7.704 NMAC and 20.3.7.705 NMAC.

[CC] EE. "Prescribed dose" means:

(1) for gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) for teletherapy, the total dose and dose per fraction as documented in the written directive;

(3) for manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) for remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

[DD] FF. "Pulsed dose-rate remote afterloader", as used in this part, means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

(1) is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

(2) is used to simulate the radiobiology of a low dose-rate treatment by inserting the source for a given fraction of each hour.

[~~EE~~] GG. "Radiation safety officer" means an individual who:

(1) meets the requirements in Subsection E of 20.3.7.714 NMAC and either Subsection A of 20.3.7.714 NMAC, incorporating 10 CFR 35.50(a), or Subsection A of 20.3.3.714 NMAC, incorporating 10 CFR 35.50(c)(1); or

(2) is identified as a radiation safety officer on:

(a) a specific medical use license issued by the department, NRC or agreement state; or

(b) a medical use permit issued by a NRC master material licensee.

[~~FF~~] HH. "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

[~~GG~~] II. "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

[~~HH~~] JJ. "Teletherapy", as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

[~~II~~] KK. "Temporary job site" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

[~~JJ~~] LL. "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

[~~KK~~] MM. "Therapeutic dose" means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

[~~LL~~] NN. "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

[~~MM~~] OO. "Type of use" means use of radioactive material under the following sections: 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.

[~~NN~~] PP. "Unit dosage" means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

[~~OO~~] QQ. "Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research object, as specified in Subsection G of 20.3.7.702 NMAC.

[20.3.7.7 NMAC - Rp, 20 NMAC 3.1.7.701, 04/30/2009; A, XX/XX/2022]

20.3.7.8 - 20.3.7.699 [RESERVED]

20.3.7.700 GENERAL REGULATORY REQUIREMENTS:

A. Provisions for research involving human subjects.

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

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

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

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

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

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

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

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

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

C. Implementation.

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

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

D. License required.

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

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

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

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

E. Application for license, amendment or renewal.

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

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

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

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

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

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

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

(c) 10 CFR 37.7, 10 CFR 37.9, 10 CFR 37.11(a) and (b), 10 CFR 37.13, 10 CFR 37.27(c),10 CFR 37.71, 10 CFR 37.105, and 10 CFR 37.107 shall not be applicable;

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

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

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

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

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

(a) radiation safety precautions and instructions;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

G. Notifications.

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

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

(b) the licensee shall verify the training and experience and provide the department of a copy of the documentation demonstrating that only accelerator-produced radioactive materials, discrete sources, or both, were used for medical use or in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007 or at all other locations of use in non-licensing states (as defined in 20.3.1.7 NMAC) before August 8, 2009, or an earlier date as noticed by the NRC.

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

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

(b) the licensee permits an authorized user or an individual qualified to be a radiation safety officer, under Subsection A of 20.3.7.714 NMAC, incorporating 10 CFR 35.50 and Subsection E of

20.3.7.714 NMAC, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with Paragraph (4) of Subsection A of 20.3.7.702 NMAC.

(c) the licensee's mailing address changes;

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

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

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

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

H. Exemptions Regarding Type A Specific Licenses of Broad Scope. A licensee possessing a type "A" specific license of broad scope for medical use, issued under 20.3.3.314 NMAC, is exempt from:

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

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

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

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

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

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

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

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

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

20.3.7.701 [RESERVED]

20.3.7.702 GENERAL ADMINISTRATIVE REQUIREMENTS:

A. Radiation safety officer.

(1) A licensee or licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing a radiation protection program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(2) A licensee shall establish the authority, duties and responsibilities of the radiation safety officer in writing.

(3) A licensee shall provide the radiation safety officer sufficient authority, organizational freedom, time, resources and management prerogative to:

(a) identify radiation safety problems;

(b) initiate, recommend or provide corrective actions;

(c) prevent or order the cessation of unsafe operations; and

(d) verify implementation of corrective actions.

(4) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer, under Subsections A and 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, as provided in Paragraph (3) of this subsection, if the licensee takes the actions required in Paragraphs (1), (2), (3) and (5) of this subsection and notifies the department in accordance with Paragraph (2) of Subsection G of 20.3.7.700 NMAC.

(5) A licensee may simultaneously appoint more than one temporary radiation safety officer in accordance with Paragraph (4) of this subsection, if needed to ensure that the licensee has a temporary radiation safety officer that satisfies the requirements to be a radiation safety officer for each of the different types of uses of radioactive material permitted by the license.

B. Authority and responsibilities for the radiation protection program. In addition to the radiation protection program requirements of 20.3.4.404 NMAC, a licensee or licensee's management shall approve in writing:

(1) requests for a license application, renewal or amendment before submittal to the department;

(2) any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and

(3) radiation protection program changes that do not require a license amendment and are permitted under Subsection E of this section.

C. Record keeping. A licensee shall retain a record of actions taken under Subsections A and B of this section in accordance with Subsection A of 20.3.7.715 NMAC.

D. Radiation safety committee. Licensees that are authorized for two or more different types of use of radioactive material under 20.3.7.708, 20.3.7.710 and 20.3.7.711 NMAC or two or more types of units under 20.3.7.711 NMAC shall establish a radiation safety committee to oversee all uses of radioactive material permitted by the license. The radiation safety committee shall meet the following administrative requirements.

(1) The radiation safety committee must include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service and a representative of management who is neither an authorized user, nor a radiation safety officer. The radiation safety committee may include other members who the licensee considers appropriate.

(2) The radiation safety committee shall meet at least once each calendar quarter. To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the radiation safety officer and the management's representative.

(3) The licensee shall maintain minutes of each radiation safety committee meeting, promptly provide each member with a copy of the meeting minutes and retain one copy for the duration of the license.

(4) To oversee the use of licensed material, the radiation safety committee shall:

(a) review and verify the training and experience documentation (such as the board certification, preceptor statement(s), or any additional required training) and approve or disapprove any individual who is to be listed on a license as an authorized user, an authorized nuclear pharmacist, a radiation safety officer or an authorized medical physicist before submitting a license application or request for amendment or renewal;

(b) review and verify the training and experience documentation (such as the board certification, preceptor statement(s), the license or the permit identifying an individual as an authorized user, authorized nuclear pharmacist, authorized medical physicist or a radiation safety officer) and approve or disapprove any individual prior to allowing that individual to work as an authorized user, authorized nuclear pharmacist, a radiation safety officer or an authorized medical physicist;

(c) review, on the basis of safety, and approve or disapprove each proposed method of use of radioactive material;

(d) review, on the basis of safety, and approve or disapprove with the advice and consent of the radiation safety officer and the management representative, licensee’s procedures and radiation protection program changes prior to submittal to the department for licensing action;

(e) review quarterly records of the radiation protection program indicating non-ALARA occurrences and all incidents and medical events involving radioactive material with respect to cause and subsequent actions taken; and

(f) review, annually, with the assistance of the radiation safety officer, the radiation protection program.

E. Radiation protection program changes.

(1) A licensee may revise its radiation protection program without department approval if:

(a) the revision does not require a license amendment under Subsection F of 20.3.7.700 NMAC;

(b) the revision is in compliance with the requirements in 20.3 NMAC and the license;

(c) the revision has been reviewed and approved by the radiation safety officer and licensee's management; and

(d) the affected individuals are instructed on the revised program before the changes are implemented.

(2) A licensee shall retain a record of each change in accordance with Subsection B of 20.3.7.715 NMAC.

F. Supervision.

(1) A licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by Subparagraph (a) of Paragraph (2) of Subsection D of 20.3.7.700 NMAC, shall:

(a) in addition to the requirements in 20.3.10.1002 NMAC, instruct the supervised individual in the licensee's written radiation protection program and quality assurance procedures, written directive procedures, requirements of this chapter and license conditions with respect to the use of radioactive material;

(b) require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection program and quality assurance procedures established by the licensee, written directive procedures, the requirements in 20.3 NMAC and license conditions with respect to the medical use of radioactive material;

(c) require the supervising authorized user to periodically review the supervised individual's use of radioactive material and the records kept to reflect this use; and

(d) document the performance of the supervised individual with respect to the medical use of radioactive material.

(2) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by Subparagraph (b) of Paragraph (2) of Subsection D of 20.3.7.700 NMAC shall:

(a) in addition to the requirements in 20.3.10.1002 NMAC, instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material;

(b) require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the licensee's written radiation protection program and quality assurance procedures, the requirements of 20.3 NMAC and license conditions;

(c) require the supervising authorized nuclear pharmacist or authorized user to periodically review the work of the supervised individual as it pertains to radiation safety and quality assurance in preparing radioactive material for medical use and the records kept to reflect that work; and

(d) document the performance of the supervised individual with respect to the medical use of radioactive material.

(3) A licensee who permits supervised activities under Paragraphs (1) and (2) of this subsection is responsible for the acts and omissions of the supervised individual.

G. Written directive. Each applicant or licensee under this part, as applicable, shall establish and maintain written directive procedures to provide high confidence that [~~radioactive~~] byproduct material or radiation from radioactive material will be administered as directed by the authorized user. The written directive procedures must include written policies and procedures that meet the following specific requirements.

(1) A written directive must be prepared, dated and signed by an authorized user before the administration of I-131 sodium iodide of quantities greater than 30 microcuries (1.11 megabecquerels), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive documenting the oral directive must be prepared, dated and signed by the authorized user within 48 hours of the oral directive.

(2) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed [~~radioactive~~] byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next

fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's record. A revised written directive documenting the oral revision must be prepared, dated and signed by the authorized user within 48 hours of the oral revision.

(3) The written directive must contain the patient's or human research subject's name and the following information:

(a) for any administration of quantities greater than 30 microcuries (1.11 megabecquerels) of I-131 sodium iodide: the dosage;

(b) for an administration of a therapeutic dosage of unsealed radioactive material other than I-131 sodium iodide: the radioactive drug, dosage and route of administration;

(c) for gamma stereotactic radiosurgery: the total dose, treatment site and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(d) for teletherapy: the total dose, dose per fraction, number of fractions and treatment site;

(e) for high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions and total dose; or

(f) For permanent implant brachytherapy:

(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or [~~for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders, before implantation: treatment site, the radionuclide and dose; and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose).~~]

(g) for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders: before implantation: the treatment site, [~~the~~] radionuclide and dose; and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose); and date.

(4) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

[~~**(4)**~~] **(5)** The licensee shall retain a copy of the written directive in accordance with Subsection C of 20.3.7.715 NMAC.

H. Procedures for administrations requiring a written directive.

(1) For any administration requiring a written directive, the licensee shall develop, implement and maintain written procedures to provide high confidence that:

(a) the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive before each administration; and

(b) each administration is in accordance with the written directive.

(2) At a minimum, the procedures required by Paragraph (1) of this subsection must address the following items that are applicable to the licensee's use of radioactive material:

(a) verifying the identity of the patient or human research subject;

(b) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(c) checking both manual and computer-generated dose calculations; and

(d) verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 20.3.7.711 NMAC or 20.3.7.713 NMAC.

(e) Determining if a medical event, as defined in 20.3.7.716 NMAC and 10 CFR 35.3045, has occurred; and

(f) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(3) A licensee shall retain a copy of the procedures required under Paragraph (1) of this subsection in accordance with Subsection D of 20.3.7.715 NMAC.

I. Suppliers of sealed sources or devices for medical use. For medical use, a licensee may only use:

(1) sealed sources or devices manufactured, labeled, packaged and distributed in accordance with a license issued under Subsection K of 20.3.3.315 NMAC or equivalent requirements of NRC or an agreement state;

(2) sealed sources or devices non-commercially transferred from a 20.3.7 NMAC licensee, a NRC or agreement state licensee; or

(3) teletherapy sources manufactured and distributed in accordance with a license issued under 20.3.3 NMAC or the equivalent requirements of NRC or an agreement state.

[20.3.7.702 NMAC - Rp, 20 NMAC 3.1.7.702, 04/30/2009; A XX/XX/2022]

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 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 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 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 six months before transfer to the licensee; and

(b) test the source for leakage at intervals not to exceed 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 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 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 (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 (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, 4/30/2009; A, 6/13/2017]

20.3.7.704 USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION AND EXCRETION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED: Except for quantities that require a written directive under Paragraph (3) of Subsection G of Section 20.3.7.702 NMAC, a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution or excretion studies that is:

A. obtained from:

(1) a manufacturer or preparer licensed under Subsection J of 20.3.3.315 NMAC, or equivalent NRC or agreement state requirements; or

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

B. excluding production of PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in either Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290, or Subsection H of 20.3.7.714 NMAC, incorporating 10 CFR 35.390, and Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290(c)(1)(ii)(G); or

(3) an individual under the supervision, as specified in Subsection F of 20.3.7.702 NMAC, of the authorized nuclear pharmacist in Paragraph (1) of this subsection or the physician who is an authorized user in Paragraph (2) of this subsection; or

C. obtained from and prepared by 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 protocol accepted by FDA; or

D. prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by FDA.

[20.3.7.704 NMAC - Rp, 20 NMAC 3.1.7.704, 4/30/2009]

20.3.7.705 USE OF UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES FOR WHICH A WRITTEN DIRECTIVE IS NOT REQUIRED: Except for quantities that require a written directive under Paragraph (3) of Subsection G of 20.3.7.702 NMAC, a licensee may use any unsealed radioactive material prepared for medical for imaging and localization studies use that is:

A. obtained from:

(1) a manufacturer or preparer licensed pursuant to Subsection J of 20.3.3.315 NMAC or equivalent NRC or agreement state requirements; or

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

B. excluding production of PET radionuclides, prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in either Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290, or Subsection H of 20.3.7.714 NMAC, incorporating 10 CFR 35.390, and Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290(c)(1)(ii)(G); or

(3) an individual under the supervision, as specified in Subsection F of 20.3.7.702 NMAC, of the authorized nuclear pharmacist in Paragraph (1) of this subsection or the physician who is an authorized user in Paragraph (2) of this subsection; or

C. obtained from and prepared by 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 protocol accepted by FDA; or

D. prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new drug protocol accepted by FDA.

[20.3.7.705 NMAC - Rp, 20 NMAC 3.1.7.705, 4/30/2009]

20.3.7.706 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82 AND STRONTIUM-85 CONCENTRATIONS:

A. Maximum concentrations. A licensee may not administer to humans a radiopharmaceutical containing:

(1) more than 0.15 microcurie of molybdenum-99 per each millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per each megabecquerel of technetium-99m); or

(2) more than 0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride injection (0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride); or more than 0.2 microcurie of strontium-85 per millicurie of rubidium-82 chloride injection (0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82).

B. Measurement.

(1) A licensee preparing technetium-99m radiopharmaceutical from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration [~~of the first eluate after the receipt of the generator to demonstrate compliance with Subsection A of this section~~] in each eluate from a generator to demonstrate compliance with Subsection A of this section.

(2) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with Subsection A of this section.

C. Record keeping. If a licensee is required to measure the molybdenum-99 concentration or strontium-85 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with Subsection M of 20.3.7.715 NMAC.

D. Reporting. The licensee shall report any measurement that exceeds the limits in Subsection A of this section at the time of generator elution, in accordance with subsection D of 20.3.7.716 NMAC and 10 CFR § 35.3204.

[20.3.7.706 NMAC - Rp, 20 NMAC 3.1.7.706, 04/30/2009, A, XX/XX/2022]

20.3.7.707 CONTROL OF AEROSOLS AND GASES:

A. System Requirements.

(1) A licensee who administers radioactive aerosols or gases shall do so with a system that shall keep airborne concentrations of the radioactive material, including releases to the environment, within the limits prescribed by 20.3.4 NMAC.

(2) The delivery or control system for the radioactive aerosols or gases shall either be directly vented to the atmosphere though an air exhaust or shall provide collection and decay or disposal of the aerosol or gas in a shielded container. Other federal, state or local regulatory requirements shall be met.

(3) The licensee shall perform check of the operation of reusable gas collection systems monthly or at other frequency approved by the department.

B. Room Requirements.

(1) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

(2) The licensee shall perform measurements of ventilation rate at least semiannually or other frequency approved by the department for those areas of use required to operate under a negative pressure.

C. Clearance Time.

(1) Before receiving, using or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the limits in 20.3.4.461 NMAC. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(2) A licensee shall post the time calculated in Paragraph (1) of this subsection in the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed or the concentration in the area of use is reduced below the limits in 20.3.4.461 NMAC.

D. Record keeping. A copy of the calculations required in Paragraph (1) of Subsection C of this section shall be retained in accordance with Subsection N of 20.3.7.715 NMAC.

[20.3.7.707 NMAC - Rp, 20 NMAC 3.1.7.707, 4/30/2009]

20.3.7.708 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: A licensee may use any unsealed [~~radioactive~~] byproduct material identified in 10 CFR 35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is [~~either~~]:

A. Obtained from a manufacturer or preparer licensed under Subsection J of 20.3.3.315 NMAC or equivalent agreement state or NRC requirements; or

B. Prepared by:

(1) an authorized nuclear pharmacist;

(2) a physician who is an authorized user and who meets the requirements specified in either Subsection G of 20.3.7.714 NMAC, incorporating 10 CFR 35.290, or Subsection H of 20.3.7.714 NMAC, incorporating 10 CFR 35.390; or

(3) an individual under the supervision, as specified in Subsection F of 20.3.7.702 NMAC, of the authorized nuclear pharmacist in Paragraph (1) of this subsection or the physician who is an authorized user in Paragraph (2) of this subsection; or

C. Obtained from and prepared by 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 protocol accepted by FDA; or

D. Prepared by the licensee for use in research in accordance with a radioactive drug research committee-approved application or an investigational new protocol accepted by FDA.

[20.3.7.708 NMAC - Rp, 20 NMAC 3.1.7.708, 04/30/2009, A, XX/XX/2022]

20.3.7.709 SAFETY INSTRUCTIONS AND PRECAUTIONS FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: In addition to the requirements in 20.3.10.1002 NMAC, the licensee shall provide the following.

A. Safety Instructions. A licensee shall provide radiation safety instructions initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under Subsection I of 20.3.7.703 NMAC. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) patient or human research subject control;

(2) visitor control, including:

(a) routine visitation to hospitalized individuals in accordance with Paragraph (1) of Subsection A of 20.3.4.413 NMAC; and

(b) visitation authorized in accordance with Subsection F of 20.3.4.413 NMAC;

(3) contamination control;

(4) waste control; and

(5) notification of the radiation safety officer, or their designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

B. Record Keeping. A licensee shall retain a record of individuals receiving safety instructions, as specified in Subsection A of this section, in accordance with Subsection O of 20.3.7.715 NMAC.

C. Safety Precautions. For each patient or human research subject who cannot be released under Subsection I of 20.3.7.703 NMAC, a licensee shall:

(1) quarter the patient or the human research subject either in:

(a) a private room with a private sanitary facility; or

(b) a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under Subsection I of 20.3.7.703 NMAC;

(2) visibly post the patient's or human research subject's room with a “Radioactive Materials” sign;

(3) note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(4) either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste; and

(5) a licensee shall notify the radiation safety officer, or their designee, and an authorized user, as soon as possible if the patient or human research subject has a medical emergency or dies.

[20.3.7.709 NMAC - Rp, 20 NMAC 3.1.7.708, 4/30/2009]

20.3.7.710 MANUAL BRACHYTHERAPY:

A. Use of sources for manual brachytherapy. [~~A licensee shall use only brachytherapy sources for therapeutic medical uses.~~] The regulations of the NRC set forth in 10 CFR 35.400 are hereby incorporated by reference:

~~[(1) as approved in the sealed source and device registry; or~~

~~(2) in research in accordance with an active investigational device exemption application accepted by the FDA provided the requirements of Paragraph (1) of Section I of 20.3.7.702 NMAC are met.~~]

B. Surveys after source implant and removal.

(1) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

(2) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(3) A licensee shall retain a record of the surveys required by Paragraphs (1) and (2) of this subsection in accordance with Subsection P of 20.3.7.715 NMAC.

C. Brachytherapy sources accountability.

(1) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(2) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(3) A licensee shall maintain a record of the brachytherapy source accountability in accordance with Subsection Q of 20.3.7.715 NMAC.

D. Safety instructions. In addition to the requirements in 20.3.10.1002 NMAC:

(1) the licensee shall provide radiation safety instructions, initially and at least annually, to personnel caring for patients or the human research subjects who are receiving brachytherapy and cannot be released under Subsection I of 20.3.7.703 NMAC; to satisfy this requirement, the instructions must be commensurate with the duties of the personnel and include:

(a) the size and appearance of the brachytherapy sources;

(b) safe handling of the brachytherapy sources and shielding instructions;

(c) a patient or human research subject control;

(d) visitor control, including both routine visitation of hospitalized individuals in accordance with Paragraph (1) of Subsection A of 20.3.4.413 NMAC, and visitation authorized in accordance with Subsection F of 20.3.4.413 NMAC; and

(e) notification of the radiation safety officer, or their designee, and an authorized user if the patient or human research subject has a medical emergency or dies;

(2) a licensee shall retain a record of individuals receiving safety instructions in accordance with Subsection O of 20.3.7.715 NMAC.

E. Safety precautions.

(1) For each patient or human research subject receiving brachytherapy and cannot be released under Subsection I of 20.3.7.703 NMAC a licensee shall:

(a) not quarter the patient or the human research subject in the same room with an individual who is not receiving brachytherapy;

(b) visibly post the patient's or human research subject's door with a “Radioactive Materials” sign; and

(c) note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(2) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

(a) dislodged from the patient; and

(b) lodged within the patient following removal of the source applicators.

(3) A licensee shall notify the radiation safety officer, or their designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

F. Calibration measurements of brachytherapy sources.

(1) Before the first medical use of a brachytherapy source, a licensee shall have:

(a) determined the source output or activity using a dosimetry system that meets the requirements of Paragraph (1) of Subsection F of 20.3.7.711 NMAC;

(b) determined source positioning accuracy within applicators; and

(c) used published protocols currently accepted by nationally recognized bodies to meet the requirements of Subparagraphs (a) and (b) of this paragraph.

(2) Instead of a licensee making its own measurements as required in Paragraph (1) of this subsection, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American association of physicists in medicine that are made in accordance with Paragraph (1) of this subsection.

(3) A licensee shall mathematically correct the outputs or activities determined in Paragraph (1) of this subsection for physical decay at intervals consistent with one percent physical decay.

(4) A licensee shall retain a record of each calibration in accordance with Subsection R of 20.3.7.715 NMAC.

G. Decay of strontium-90 sources for ophthalmic treatments.

[~~(1) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Subsection F of 20.3.7.710 NMAC.~~

~~(2) A licensee shall retain a record of the activity of each strontium-90 source in accordance with Subsection S of 20.3.7.715 NMAC.~~] The regulations of the NRC set forth in 10 CFR 35.433 are hereby incorporated by reference.

H. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(1) the source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays; and

(4) the accuracy of the software used to determine sealed source positions from radiographic images.

[20.3.7.710 NMAC - Rp, 20 NMAC 3.1.7.709, 04/30/2009; A, XX/XX/2022]

20.3.7.711 PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS:

A. Use of a sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit. A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units for therapeutic medical uses:

(1) as approved in the sealed source and device registry; or

(2) in research in accordance with an active investigational device exemption application accepted by the FDA provided the requirements of Paragraph (1) of Subsection I of 20.3.7.702 NMAC are met.

B. Surveys of patients and human research subjects treated with a remote afterloader unit.

(1) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

(2) A licensee shall retain a record of these surveys in accordance with Subsection P of 20.3.7.715 NMAC.

C. Installation, maintenance, adjustment and repair.

(1) Only a person specifically licensed by the department, NRC or an agreement state shall install, maintain, adjust or repair a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s) or compromise the radiation safety of the unit or the source(s).

(2) Except for low dose-rate remote afterloader units, only a person specifically licensed by the department, NRC or an agreement state shall install, replace, relocate or remove a sealed source or source contained in other remote afterloader units, teletherapy units or gamma stereotactic radiosurgery units.

(3) For a low dose-rate remote afterloader unit, only a person specifically licensed by the department, NRC, an agreement state or an authorized medical physicist shall install, replace, relocate or remove a sealed source(s) contained in the unit.

(4) A licensee shall retain a record of the installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units in accordance with Subsection T of 20.3.7.715 NMAC.

D. Safety procedures and instructions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

(1) A licensee shall:

(a) secure the unit, the console, the console keys and the treatment room when not in use or unattended;

(b) permit only individuals approved by the authorized user, radiation safety officer or authorized medical physicist to be present in the treatment room during treatment with the source(s);

(c) prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

(d) develop, implement and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

(i) instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) the names and telephone numbers of the authorized users, the authorized medical physicist and the radiation safety officer to be contacted if the unit or console operates abnormally.

(2) A copy of the procedures required by Subparagraph (d) of Paragraph (1) of this subsection must be physically located at the unit console.

(3) A licensee shall post instructions at the unit console to inform the operator of:

(a) the location of the procedures required by Subparagraph (d) of Paragraph (1) of this subsection; and

(b) the names and telephone numbers of the authorized users, the authorized medical physicist and the radiation safety officer to be contacted if the unit or console operates abnormally.

(4) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

[~~**(4)**~~] **(5)** A licensee shall provide operational and safety instruction, initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, in:

(a) the procedures identified in Subparagraph (d) of Paragraph (1) of this subsection; and

(b) the operating procedures for the unit.

[~~**(5)**~~] **(6)** A licensee shall ensure that operators, authorized medical physicists and authorized users participate in drills of the emergency procedures, initially and at least annually.

[~~**(6)**~~] **(7)** A licensee shall retain a record of individuals receiving instruction required by Paragraph (5) of this subsection, in accordance with Subsection O of 20.3.7.715 NMAC.

[~~**(7)**~~] **(8)** A licensee shall retain a copy of the procedures required by Subparagraph (d) of Paragraph (1) and Subparagraph (b) of Paragraph (4) of this subsection in accordance with Subsection U of 20.3.7.715 NMAC.

E. Safety precautions for remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

(1) A licensee shall control access to the treatment room by a door at each entrance.

(2) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

(a) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(b) cause the source(s) to be shielded when an entrance door is opened; and

(c) prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(3) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(4) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(5) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(6) In addition to the requirements specified in Paragraphs (1) through (5) of this subsection, a licensee shall:

(a) for medium dose-rate and pulsed dose-rate remote afterloader units, require:

(i) an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) an authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit;

(b) for high dose-rate remote afterloader units, require:

(i) an authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) an authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit;

(c) for gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit;

(d) notify the radiation safety officer, or their designee and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(7) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source which:

(a) remains in the unshielded position; or

(b) is lodged within the patient following completion of the treatment.

F. Dosimetry equipment.

(1) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(a) The system must have been calibrated using a system or source traceable to the NIST and published protocols accepted by nationally recognized bodies, or by a calibration laboratory accredited by the American association of physicists in medicine. The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration.

(b) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been inter-compared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the American association of physicists in medicine. The results of the inter-comparison must indicate that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the inter-comparison result to change the calibration factor. When inter-comparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

(2) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with Paragraph (1) of this subsection. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in Paragraph (1) of this subsection.

(3) The licensee shall retain a record of each calibration, inter-comparison and comparison in accordance with Subsection V of 20.3.7.715 NMAC.

G. Full calibration measurements on teletherapy units.

(1) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(a) before the first medical use of the unit;

(b) before medical use under the following conditions:

(i) whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(c) at intervals not exceeding one year.

(2) To satisfy the requirement of Paragraph (1) of this subsection, full calibration measurements must include determination of:

(a) the output within plus or minus three percent for the range of field sizes and for the distance or range of distances used for medical use;

(b) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(c) the uniformity of the radiation field and its dependence on the orientation of the useful beam;

(d) timer accuracy and linearity over the range of use;

(e) on-off error; and

(f) the accuracy of all distance measuring and localization devices in medical use.

(3) A licensee shall use the dosimetry system described in Paragraph (1) of Subsection F of 20.3.7.711 NMAC to measure the output for one set of exposure conditions. The remaining radiation measurements required in Subparagraph (a) of Paragraph (2) of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by Paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in Subparagraph (a) of Paragraph (2) of this subsection for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with one percent decay for all other nuclides.

(6) Full calibration measurements required by Paragraph (1) of this subsection and physical decay corrections required by Paragraph (5) of this subsection must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with Subsection W of 20.3.7.715 NMAC.

H. Full calibration measurements on remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

(a) before the first medical use of the unit;

(b) before medical use under the following conditions:

(i) following replacement of the source or following reinstallation of the unit in a new location; and

(ii) following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;

(c) at intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(d) at intervals not exceeding one year for low dose-rate remote afterloader units.

(2) To satisfy the requirement of Paragraph (1) of this subsection, full calibration measurements must include, as applicable, determination of:

(a) the output within plus or minus five percent;

(b) source positioning accuracy to within plus or minus 1 millimeter;

(c) source retraction with backup battery upon power failure;
(d) length of the source transfer tubes;
(e) timer accuracy and linearity over the typical range of use;
(f) length of the applicators; and
(g) function of the source transfer tubes, applicators and transfer tube-applicator interfaces.

(3) A licensee shall use the dosimetry system described in Paragraph (1) of Subsection F of 20.3.7.711 NMAC to measure the output.

(4) A licensee shall make full calibration measurements required by Paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in Paragraph (2) of this subsection, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(6) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with Paragraphs (1) through (5) of this subsection.

(7) A licensee shall mathematically correct the outputs determined in Subparagraph (a) of Paragraph (2) of this subsection for physical decay at intervals consistent with one percent physical decay.

(8) Full calibration measurements required by Paragraph (1) of this subsection and physical decay corrections required by Paragraph (7) of this subsection must be performed by the authorized medical physicist.

(9) A licensee shall retain a record of each calibration in accordance with Subsection W of 20.3.7.715 NMAC.

I. Full calibration measurements on gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:
(a) before the first medical use of the unit;
(b) before medical use under the following conditions:
(i) whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
(ii) following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
(iii) following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
(c) at intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(2) To satisfy the requirement of Paragraph (1) of this subsection, full calibration measurements must include determination of:
(a) the output within plus or minus three percent;
(b) relative helmet factors;
(c) isocenter coincidence;
(d) timer accuracy and linearity over the range of use;
(e) on-off error;
(f) trunnion centricity;
(g) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
(h) helmet microswitches;
(i) emergency timing circuits; and
(j) stereotactic frames and localizing devices (trunnions).

(3) A licensee shall use the dosimetry system described in Paragraph (1) of Subsection F of 20.3.7.711 NMAC to measure the output for one set of exposure conditions. The remaining radiation measurements required in Subparagraph (a) of Paragraph (2) of this subsection of this subsection may be made using a dosimetry system that indicates relative dose rates.

(4) A licensee shall make full calibration measurements required by Paragraph (1) of this subsection in accordance with published protocols accepted by nationally recognized bodies.

(5) A licensee shall mathematically correct the outputs determined in Subparagraph (a) of Paragraph (2) of this subsection at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with one percent physical decay for all other radionuclides.

(6) Full calibration measurements required by Paragraph (1) of this subsection and physical decay corrections required by Paragraph (5) of this subsection must be performed by the authorized medical physicist.

(7) A licensee shall retain a record of each calibration in accordance with Subsection W of 20.3.7.715 NMAC.

J. Periodic spot-checks for teletherapy units.

(1) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(a) timer accuracy and timer linearity over the range of use;

(b) on-off error;

(c) the coincidence of the radiation field and the field indicated by the light beam localizing device;

(d) the accuracy of all distance measuring and localization devices used for medical use;

(e) the output for one typical set of operating conditions measured with the dosimetry system described in Paragraph (2) of Subsection F of 20.3.7.711 NMAC; and

(f) the difference between the measurement made in Subparagraph (e) of this paragraph and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(2) A licensee shall perform measurements required by Paragraph (1) of this subsection in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

(a) electrical interlocks at each teletherapy room entrance;

(b) electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(c) source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

(d) viewing and intercom systems;

(e) treatment room doors from inside and outside the treatment room; and

(f) electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(5) If the results of the checks required in Paragraph (4) of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.

(6) A licensee shall retain a record of each spot-check required by Paragraphs (1) and (4) of this subsection, and a copy of the procedures required by Paragraph (2), in accordance with Subsection X of 20.3.7.715 NMAC.

K. Periodic spot-checks for remote afterloader units.

(1) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

(a) before the first use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit on a given day;

(b) before each patient treatment with a low dose-rate remote afterloader unit; and

(c) after each source installation.

(2) A licensee shall perform the measurements required by Paragraph (1) of this subsection in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(3) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(4) To satisfy the requirements of Paragraph (1) of this subsection, spot-checks must, at a minimum, assure proper operation of:

(a) electrical interlocks at each remote afterloader unit room entrance;

(b) source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;

(d) emergency response equipment;

(e) radiation monitors used to indicate the source position;

(f) timer accuracy;

(g) clock (date and time) in the unit's computer; and

(h) decayed source(s) activity in the unit's computer.

(5) If the results of the checks required in Paragraph (4) of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.

(6) A licensee shall retain a record of each check required by Paragraph (4) of this subsection and a copy of the procedures required by Paragraph (2) of this subsection in accordance with Subsection Y of 20.3.7.715 NMAC.

L. Periodic spot-checks for gamma stereotactic radiosurgery units.

(1) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

(a) monthly;

(b) before the first use of the unit on a given day; and

(c) after each source installation.

(2) A licensee shall:

(a) perform the measurements required by Paragraph (1) of this subsection in accordance with written procedures established by the authorized medical physicist; that individual need not actually perform the spot check measurements;

(b) have the authorized medical physicist review the results of each spot-check within 15 days; the authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(3) To satisfy the requirements of Subparagraph (a) of Paragraph (1) of this subsection, spot-checks must, at a minimum:

(a) assure proper operation of:

(i) treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) helmet microswitches;

(iii) emergency timing circuits; and

(iv) stereotactic frames and localizing devices (trunnions); and

(b) determine:

(i) the output for one typical set of operating conditions measured with the dosimetry system described in Paragraph (2) of Subsection F of 20.3.7.711 NMAC;

(ii) the difference between the measurement made above (Item (i) of Subparagraph (b) of Paragraph (3) of Subsection L of 20.3.7.711 NMAC) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) source output against computer calculation;

(iv) timer accuracy and linearity over the range of use;

(v) on-off error; and

(vi) trunnion centricity.

(4) To satisfy the requirements of Subparagraphs (b) and (c) of Paragraphs (1) of this subsection, spot-checks must assure proper operation of:

(a) electrical interlocks at each gamma stereotactic radiosurgery room entrance;

(b) source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

(c) viewing and intercom systems;

(d) timer termination;

(e) radiation monitors used to indicate room exposures; and

(f) emergency off buttons.

(5) A licensee shall arrange for the repair of any system identified in Paragraph (3) of this subsection that is not operating properly as soon as possible.

(6) If the results of the checks required in Paragraph (4) of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.

(7) A licensee shall retain a record of each check required by Paragraphs (3) and (4) and a copy of the procedures required by Paragraph (2) of this subsection in accordance with Subsection Z of 20.3.7.715 NMAC.

M. Additional technical requirements for mobile remote afterloader units.

(1) A licensee providing mobile remote afterloader service shall:

(a) check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and

(b) account for all sources before departure from a client's address of use.

(2) In addition to the periodic spot-checks required by Subsection K of 20.3.7.711 NMAC, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

(a) electrical interlocks on treatment area access points;

(b) source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(c) viewing and intercom systems;

(d) applicators, source transfer tubes and transfer tube-applicator interfaces;

(e) radiation monitors used to indicate room exposures;

(f) source positioning (accuracy); and

(g) radiation monitors used to indicate whether the source has returned to a safe shielded position.

(3) In addition to the requirements for checks in Paragraph (2) of this subsection, a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(4) If the results of the checks required in Paragraph (2) of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace or check the malfunctioning system.

(5) A licensee shall retain a record of each check required by Paragraph (2) of this subsection in accordance with Subsection AA of 20.3.7.715 NMAC.

N. Radiation surveys.

(1) In addition to the survey requirements in Subsection H of 20.3.7.703 NMAC and 20.3.4.416 NMAC, a person subject to this section shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the sealed source and device registry.

(2) The licensee shall make the survey required by Paragraph (1) of this subsection at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s) or compromise the radiation safety of the unit or the source(s).

(3) A licensee shall retain a record of the radiation surveys required by Paragraph (1) of this subsection in accordance with Subsection BB of 20.3.7.715 NMAC.

O. Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(1) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement [~~or at intervals not to exceed 5 years, whichever comes first,~~] to

assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

(2) This inspection and servicing may only be performed by persons specifically licensed to do so by the department, NRC or an agreement state.

(3) A licensee shall keep a record of the inspection and servicing in accordance with Subsection CC of 20.3.7.715 NMAC.

P. Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(1) the source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays;

(4) the accuracy of the software used to determine sealed source positions from radiographic images; and

(5) the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

[20.3.7.711 NMAC - Rp, 20 NMAC 3.1.7.710, 04/30/2009; A, XX/XX/2022]

20.3.7.712 SEALED SOURCES FOR DIAGNOSIS:

A. Use of sealed sources for diagnosis. A licensee shall use only sealed sources for diagnostic medical uses [~~as approved in the sealed source and device registry~~] if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 10 CFR § 35.49(a) are met.

[~~**B**~~] **D.** Survey instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation survey meter capable of detecting dose rates ranging from 0.1 millirem (1 millisievert) per hour to 1000 millirems (10 millisieverts) per hour. The instrument shall be operable and calibrated in accordance with section Subsection C of 20.3.7.703 NMAC.

[20.3.7.712 NMAC - Rp, 20 NMAC 3.1.7.711, 04/30/2009; A, XX/XX/2022]

20.3.7.713 OTHER MEDICAL USES OF RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL: A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in 20.3.7.704 NMAC through 20.3.7.712 NMAC of this part if:

A. the applicant or licensee has submitted the information required by Paragraph (2) through (4) of Subsection E of 20.3.7.700 NMAC; and

B. the applicant or licensee has received written approval from the department in a license or license amendment and uses the material in accordance with the requirements and specific conditions the department considers necessary for the medical use of the material.

[20.3.7.713 NMAC - N, 4/30/2009]

20.3.7.714 TRAINING REQUIREMENTS:

A. Radiation safety officer and Associate Radiation Safety Officer. The regulations of the NRC set forth in 10 CFR 35.50 are hereby incorporated by reference.

B. Training for an authorized medical physicist. The regulations of the NRC set forth in 10 CFR 35.51 are hereby incorporated by reference.

C. Training for an authorized nuclear pharmacist. The regulations of the NRC set forth in 10 CFR 35.55 are hereby incorporated by reference.

D. Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist and authorized nuclear pharmacist. The regulations of the NRC set forth in 10 CFR 35.57 are hereby incorporated by reference.

E. Recentness of training. The training and experience specified in Subsections A, B, C, F, G, H, I, J, K, L, M, N and O of this section must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

F. Training for uptake, dilution, and excretion studies. (For use of unsealed radioactive material under 20.3.7.704 NMAC) The regulations of the NRC set forth in 10 CFR 35.190 are hereby incorporated by reference.

G. Training for imaging and localization studies. (For use of unsealed radioactive material under 20.3.7.705 NMAC) The regulations of the NRC set forth in 10 CFR 35.290 are hereby incorporated by reference.

H. Training for use of unsealed radioactive material for which a written directive is required. (For use of unsealed radioactive material under 20.3.7.708 NMAC) The regulations of the NRC set forth in 10 CFR 35.390 are hereby incorporated by reference.

I. Training for the oral administration of sodium iodide i-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels). The regulations of the NRC set forth in 10 CFR 35.392 are hereby incorporated by reference.

J. Training for the oral administration of sodium iodide i-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels). The regulations of the NRC set forth in 10 CFR 35.394 are hereby incorporated by reference.

K. Training for the parenteral administration of unsealed byproduct material requiring a written directive. The regulations of the NRC set forth in 10 CFR 35.396 are hereby incorporated by reference.

L. Training for use of manual brachytherapy sources. (For use of radioactive material under 20.3.7.710 NMAC) The regulations of the NRC set forth in 10 CFR 35.490 are hereby incorporated by reference.

M. Training for ophthalmic use of strontium-90. (For use of radioactive material under 20.3.7.710 NMAC) The regulations of the NRC set forth in 10 CFR 35.491 are hereby incorporated by reference.

N. Training for use of sealed sources for diagnosis: (For use of radioactive material under 20.3.7.712 NMAC) The regulations of the NRC set forth in 10 CFR 35.590 are hereby incorporated by reference.

O. Training for use of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units (For use of radioactive material under 20.3.7.711 NMAC). The regulations of the NRC set forth in 10 CFR 35.690 are hereby incorporated by reference.

P. Modifications. The following modifications are made to the incorporated federal regulations in this section.

(1) "Commission" means the *department or NRC*.

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

(3) "Byproduct material" means *radioactive material* as defined in this chapter.

(4) "10 CFR 35.100" means 20.3.7.704 NMAC.

(5) "10 CFR 35.200" means 20.3.7.705 NMAC.

(6) "10 CFR 35.300" means 20.3.7.708 NMAC.

(7) "10 CFR 35.400" means 20.3.7.710 NMAC.

(8) "10 CFR 35.500" means 20.3.7.712 NMAC.

(9) "10 CFR 35.600" means 20.3.7.711 NMAC.

(10) "At all other locations of use" in Subsection D of this section, incorporating 10 CFR 35.57 means *at all other locations of use in non-licensing state*, as defined in 20.3.1.7 NMAC.

[20.3.7.714 NMAC - Rp, 20 NMAC 3.1.7.712; A, XX/XX/2022]

20.3.7.715 RECORDS:

A. Records of Authority and Responsibilities for Radiation Protection Programs.

(1) A licensee shall retain a record of actions taken by the licensee's management in accordance with Subsection C of 20.3.7.702 NMAC for five years. The record must include a summary of the actions taken and a signature of licensee management.

(2) The licensee shall retain a copy of both authority, duties and responsibilities of the radiation safety officer as required by Paragraph (2) of Subsection A of 20.3.7.702 NMAC, and a signed copy of each radiation safety officer's agreement to be responsible for implementing the radiation safety program, as

required by Paragraph (1) of Subsection A of 20.3.7.702 NMAC, for the duration of the license. The records must include the signature of the radiation safety officer and licensee management.

B. Records of Radiation Protection Program Changes. A licensee shall retain a record of each radiation protection program change made in accordance with Subsection E of 20.3.7.702 NMAC for five years. The record must include a copy of the old and new procedures, the effective date of the change and the signature of the licensee management that reviewed and approved the change.

C. Records of Written Directives. A licensee shall retain a copy of each written directive as required by Subsection G of 20.3.7.702 NMAC for three years.

D. Records for Procedures for Administrations Requiring a Written Directive. A licensee shall retain a copy of the procedures required by Subsection H of 20.3.7.702 NMAC for the duration of the license.

E. Records of Calibrations, Test or Checks of Instruments Used to Measure the Activity of Unsealed Radioactive Material. A licensee shall maintain a record of instrument checks, tests and calibrations required by Subsection A of 20.3.7.703 NMAC for three years. The records must include the model and serial number of the instrument, the date of the check, test or calibration, the activity and serial number of the calibration source(s) used for the check, test or calibration, whichever applicable, the results of the check, test or calibration and the name of the individual who performed the check, test or calibration.

F. Records of Radiation Survey Instrument Calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by Subsection C of 20.3.7.703 NMAC for three years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration and the name of the individual who performed the calibration.

G. Records of Dosages of Unsealed Radioactive Material for Medical Use.

(1) A licensee shall maintain a record of dosage determinations required by Subsection B of 20.3.7.703 NMAC for three years.

(2) The record must contain:

(a) the radiopharmaceutical;

(b) the patient's or human research subject's name or identification number if one has been assigned;

(c) the prescribed dosage, the determined dosage or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);

(d) the date and time of the dosage determination; and

(e) the name of the individual who determined the dosage.

H. Records of Leaks Tests and Inventory of Sealed Sources and Brachytherapy Sources.

(1) A licensee shall retain records of leak tests required by Paragraph (2) of Subsection F of 20.3.7.703 NMAC for three years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test and the name of the individual who performed the test.

(2) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by Paragraph (7) of Subsection F of 20.3.7.703 NMAC for three years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source and the name of the individual who performed the inventory.

I. Records of Surveys. A licensee shall retain a record of each survey required by Subsection H of 20.3.7.703 NMAC for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey and the name of the individual who performed the survey.

J. Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

(1) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with Subsection I of 20.3.7.703 NMAC, if the total effective dose equivalent is calculated by:

(a) using the retained activity rather than the activity administered;

(b) using an occupancy factor less than 0.25 at one meter;

(c) using the biological or effective half-life; or

(d) considering the shielding by tissue.

(2) A licensee shall retain a record that the instructions required by Paragraph (2) of Subsection I of 20.3.7.703 NMAC were provided to a breast-feeding female if the radiation dose to the infant or child from continued breastfeeding could result in a total effective dose equivalent exceeding 0.5 rem (five millisieverts).

(3) The records required by Paragraphs (1) and (2) of this section must be retained for three years after the date of release of the individual.

K. Records of Mobile Medical Services.

(1) A licensee shall retain a copy of each letter that permits the use of radioactive material at a client's address, as required by Subparagraph (a) of Paragraph (1) of Subsection J of 20.3.7.703 NMAC. Each letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for three years after the last provision of service.

(2) A licensee shall retain the record of each survey required by Subparagraph (d) of Paragraph (1) of Subsection J of 20.3.7.703 NMAC for three years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey and the name of the individual who performed the survey.

L. Records of Decay-In-Storage. A licensee shall maintain records of the disposal of licensed materials, as required by Subsection L of 20.3.7.703 NMAC, for three years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container and the name of the individual who performed the survey.

M. Records of Molybdenum-99, Strontium-82 and Strontium-85 Concentrations. A licensee shall maintain a record of the molybdenum-99, strontium-82 and strontium-85 concentration tests required by 20.3.7.706 NMAC for three years. The record must include:

(1) for each measured elution of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum-99 per each millicurie of technetium-99m (or kilobecquerel of molybdenum-99 per each megabecquerel of technetium-99m), the time and date of the measurement and the name of the individual who made the measurement; or

(2) for each measured elution of rubidium-82, the ratio of the measures expressed as microcuries of strontium-82 per millicurie of rubidium-82 (or kilobecquerel of strontium-82 per megabecquerel of rubidium), microcurie of strontium-85 per millicurie of rubidium-82 (or kilobecquerel of strontium-85 per megabecquerel of rubidium), the time and date of the measurement and the name of the individual who made the measurement.

N. Records of Gas Controls. A licensee shall maintain the records specified in Subsection D of 20.3.7.707 NMAC for 3 years.

O. Records of Safety Instructions. A licensee shall maintain a record of safety instructions required by Subsection A of 20.3.7.709 NMAC, Subsection D of 20.3.7.710 NMAC and Subsection D of 20.3.7.711 NMAC for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s) and the name(s) of the individual(s) who provided the instruction.

P. Records of Surveys after Source Implant and Removal. A licensee shall maintain a record of the surveys required by Subsection B of 20.3.7.710 NMAC and Subsection B of 20.3.7.711 NMAC for three years. Each record must include the date and results of the survey, the survey instrument used and the name of the individual who made the survey.

Q. Records of Brachytherapy Source Accountability.

(1) A licensee shall maintain a record of brachytherapy source accountability required by Subsection B of 20.3.7.710 NMAC for three years.

(2) For temporary implants, the record must include:

(a) the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage and the location of use; and

(b) the number and activity of sources returned to storage, the time and date they were returned to storage and the name of the individual who returned them to storage.

(3) For permanent implants, the record must include:

(a) the number and activity of sources removed from storage, the date they were removed from storage and the name of the individual who removed them from storage;

(b) the number and activity of sources not implanted, the date they were returned to storage and the name of the individual who returned them to storage; and

(c) the number and activity of sources permanently implanted in the patient or human research subject.

R. Records of Calibration Measurements of Brachytherapy Sources.

(1) A licensee shall maintain a record of the calibrations of brachytherapy sources required by Subsection F of 20.3.7.710 NMAC for three years after the last use of the source.

(2) The record must include:

(a) the date of the calibration;

(b) the manufacturer's name, model number and serial number for the source and the instruments used to calibrate the source;

(c) the source output or activity;

(d) the source positioning accuracy within the applicators; and

(e) the name of the individual, the source manufacturer or the calibration laboratory that performed the calibration.

S. Records of Decay of Strontium- 90 Sources for Ophthalmic Treatments.

(1) A licensee shall maintain a record of the activity of a strontium-90 source required by Subsection G of 20.3.7.710 NMAC for the life of the source.

(2) The record must include:

(a) the date and initial activity of the source as determined under Subsection F of 20.3.7.710 NMAC; and

(b) for each decay calculation, the date and the source activity as determined under Subsection G of 20.3.7.710 NMAC.

T. Records of Installation, Maintenance, Adjustment and Repair of Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units. A licensee shall retain a record of the installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units as required by Subsection C of 20.3.7.711 NMAC for three years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service and name(s) of the individual(s) who performed the work.

U. Records of Safety Procedures. A licensee shall retain a copy of the procedures required by Subparagraph (d) of Paragraph (1) of Subsection D of 20.3.7.711 NMAC and Subparagraph (b) of Paragraph (4) of Subsection D of 20.3.7.711 NMAC until the licensee no longer possesses the remote afterloader, teletherapy unit or gamma stereotactic radiosurgery unit.

V. Records of Dosimetry Equipment Used with Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall retain a record of the calibration, inter-comparison and comparisons of its dosimetry equipment done in accordance with Subsection F of 20.3.7.711 NMAC for the duration of the license.

(2) For each calibration, inter-comparison or comparison, the record must include:

(a) the date;

(b) the manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, inter-compared or compared as required by Paragraphs (1) and (2) of Subsection F of 20.3.7.711 NMAC;

(c) the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an inter-comparison; and

(d) the names of the individuals who performed the calibration, inter-comparison or comparison.

W. Records of Teletherapy, Remote Afterloader and Gamma Stereotactic Radiosurgery Full Calibrations.

(1) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit and gamma stereotactic radiosurgery unit full calibrations required by Subsection G of 20.3.7.711 NMAC, Subsection H of 20.3.7.711 NMAC and Subsection I of 20.3.7.711 NMAC for three years, respectively.

(2) The record must include:

(a) the date of the calibration;

(b) the manufacturer's name, model number and serial number of the teletherapy, remote afterloader and gamma stereotactic radiosurgery unit(s), the source(s) and the instruments used to calibrate the unit(s);

(c) the results and an assessment of the full calibrations;

(d) the results of the autoradiograph required for low dose-rate remote afterloader units; and

(e) the signature of the authorized medical physicist who performed the full calibration.

X. Records of Periodic Spot Checks for Teletherapy Units.

(1) A licensee shall retain a record of each periodic spot-check for teletherapy units required by Subsection J of 20.3.7.711 NMAC for three years.

(2) The record must include:

(a) the date of the spot-check;

(b) the manufacturer's name, model number and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(c) an assessment of timer linearity and constancy;

(d) the calculated on-off error;

(e) a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(f) the determined accuracy of each distance measuring and localization device;

(g) the difference between the anticipated output and the measured output;

(h) notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light and the viewing and intercom system and doors; and

(i) the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(3) A licensee shall retain a copy of the procedures required by Paragraph (2) of Subsection J of 20.3.7.711 NMAC until the licensee no longer possesses the teletherapy unit.

Y. Records of Periodic Spot-checks for Remote Afterloader Units.

(1) A licensee shall retain a record of each spot-check for remote afterloader units required by Subsection K of 20.3.7.711 NMAC for three years.

(2) The record must include, as applicable:

(a) the date of the spot-check;

(b) the manufacturer's name, model number and serial number for the remote afterloader unit and source;

(c) an assessment of timer accuracy;

(d) notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems and clock and decayed source activity in the unit's computer; and

(e) the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(3) A licensee shall retain a copy of the procedures required by Paragraph (2) of Subsection K of 20.3.7.711 NMAC until the licensee no longer possesses the remote afterloader unit.

Z. Records of Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by Subsection L of 20.3.7.711 NMAC for three years.

(2) The record must include:

(a) the date of the spot-check;

(b) the manufacturer's name, model number and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

(c) an assessment of timer linearity and accuracy;

(d) the calculated on-off error;

(e) a determination of trunnion centricity;

(f) the difference between the anticipated output and the measured output;

(g) an assessment of source output against computer calculations;

(h) notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism and stereotactic frames and localizing devices (trunnions); and

(i) the name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(3) A licensee shall retain a copy of the procedures required by Paragraph (2) of Subsection L of 20.3.7.711 NMAC until the licensee no longer possesses the gamma stereotactic radiosurgery unit.

AA. Records of Additional Technical Requirements for Mobile Remote Afterloader Units.

(1) A licensee shall retain a record of each check for mobile remote afterloader units required by Subsection M of 20.3.7.711 NMAC for three years.

(2) The record must include:

(a) the date of the check;

(b) the manufacturer's name, model number and serial number of the remote afterloader unit;

(c) notations accounting for all sources before the licensee departs from a facility;

(d) notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes and transfer tube applicator interfaces and source positioning accuracy; and

(e) the signature of the individual who performed the check.

BB. Records of Surveys of Therapeutic Treatment Units.

(1) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Subsection N of 20.3.7.711 NMAC for the duration of use of the unit.

(2) The record must include:

(a) the date of the measurements;

(b) the manufacturer's name, model number and serial number of the treatment unit, source and instrument used to measure radiation levels;

(c) each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

(d) the signature of the individual who performed the test.

CC. Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery units required by Subsection O of 20.3.7.711 NMAC for the duration of use of the unit.

(2) The record must contain:

(a) the inspector's radioactive materials license number;

(b) the date of inspection;

(c) the manufacturer's name, model number and serial number of both the treatment unit and source;

(d) a list of components inspected and serviced and the type of service; and

(e) the signature of the inspector.

[20.3.7.715 NMAC - N, 4/30/2009]

20.3.7.716 REPORTS:

A. Report and notification of a medical event.

(1) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of [~~radioactive~~] byproduct material or radiation from [~~radioactive~~] byproduct material, except permanent implant brachytherapy, results in:

(a) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rems (50 millisieverts) effective dose equivalent, 50 rems (0.5 sievert) to an organ or tissue or 50 rems (0.5 sievert) shallow dose equivalent to the skin; and:

(i) the total dose delivered differs from the prescribed dose by twenty percent or more;

(ii) the total dosage delivered differs from the prescribed dosage by twenty percent or more or falls outside the prescribed dosage range; or

(iii) the fractionated dose delivered differs from the prescribed dose, for a single fraction, by fifty percent or more;

(b) a dose that exceeds 5 rems (50 millisieverts) effective dose equivalent, 50 rems (0.5 sievert) to an organ or tissue, or 50 rems (0.5 sievert) shallow dose equivalent to the skin from any of the following:

(i) an administration of a wrong radioactive drug containing byproduct [~~radioactive~~] material;

(ii) an administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) an administration of a dose or dosage to the wrong individual or human research subject;

(iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) a leaking sealed source; and

(c) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rems (0.5 sievert) to an organ or tissue and fifty percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(d) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following: the wrong radionuclide; the wrong individual or human research subject; sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

(2) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(3) The licensee shall notify by telephone the department no later than the next calendar day after discovery of the medical event.

(4) The licensee shall submit a written report to the department within 15 days after discovery of the medical event.

(a) The written report must include:

(i) the licensee's name;

(ii) the name of the prescribing physician;

(iii) a brief description of the event;

(iv) why the event occurred;

(v) the effect, if any, on the individual(s) who received the administration;

(vi) what actions, if any, have been taken or are planned to prevent recurrence; and

(vii) certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(b) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(5) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event or to that individual's responsible relatives or guardians.

(7) A licensee shall:

(a) annotate a copy of the report provided to the department with the:

(i) name of the individual who is the subject of the event; and

(ii) social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(b) provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

B. Report and notification of a dose to an embryo, fetus or a nursing child.

(1) A licensee shall report any dose to an embryo or fetus that is greater than 5 rems (50 millisieverts) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo or fetus was specifically approved, in advance, by the authorized user.

(2) A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

(a) is greater than 5 rems (50 millisieverts) total effective dose equivalent; or

(b) has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(3) The licensee shall notify by telephone the department no later than the next calendar day after discovery of a dose to the embryo, fetus or nursing child that requires a report in Paragraphs (1) or (2) in this subsection.

(4) The licensee shall submit a written report to the department within 15 days after discovery of a dose to the embryo, fetus or nursing child that requires a report in Paragraphs (1) or (2) in this subsection.

(a) The written report must include:

(i) the licensee's name;

(ii) the name of the prescribing physician;

(iii) a brief description of the event;

(iv) why the event occurred;

(v) the effect, if any, on the embryo, fetus or the nursing child;

(vi) what actions, if any, have been taken or are planned to prevent recurrence; and

(vii) certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

(b) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

(5) The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under Paragraph (1) or (2) of this subsection, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo, fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(6) A licensee shall:

(a) annotate a copy of the report provided to the NRC with the:

(i) name of the pregnant individual or the nursing child who is the subject of the event; and

(ii) social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

(b) provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

C. Report of a leaking source. A licensee shall file a report within five days if a leak test required by Subsection F of 20.3.7.703 NMAC reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination. The report must be filed with the department and it must include the model number and serial number, if assigned, of the leaking source, the radionuclide and its estimated activity, the results of the test, the date of the test and the action taken.

D. Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations:

(1) The licensee shall notify by telephone the department and NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 10 CFR § 35.204(a) at the time of generator elution. The telephone report to the department and NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

(2) By an appropriate method listed in 10 CFR § 30.6(a) of this chapter, the licensee shall submit a written report to the department and appropriate NRC Regional Office listed in 10 CFR § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (1) of this section.

[20.3.7.716 NMAC - N, 04/30/2009; A, XX/XX/2022]

HISTORY OF 20.3.7 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the commission of public records - state records center and archives.

EIB 73-2, Regulations for Governing the Health and Environmental Aspects of Radiation filed 7/9/1973; EIB 73-2, Amendment 1, Regulations for Governing the Health and Environmental Aspects of Radiation filed on 4/17/1978; EIB RPR-1, Radiation Protection Regulations filed on 4-21-80; EIB RPR-1, Amendment 1, Radiation Protection Regulations filed on 10/13/1981; EIB RPR-1, Amendment 2, Radiation Protection Regulations filed on 12/15/1982; and EIB RPR-1, Radiation Protection Regulations filed on 3/10/1989.

History of Repealed Material: 20 NMAC 3.1 Subpart 7, Radiation Materials And Radiation Machines, Medical Use Of Radionuclides (filed 6/17/1999) repealed 4/30/2009.

Other History: EIB RPR 1, Radiation Protection Regulations (filed 3/10/1989) was renumbered and reformatted to 20 NMAC 3.1, Radiation Materials and Radiation Machines, effective 5/3/1995.

20 NMAC 3.1, Radiation Materials and Radiation Machines (filed 4/3/1995) was internally renumbered, reformatted and replaced by 20 NMAC 3.1, Radiation Materials And Radiation Machines, effective 7/30/1999.

20 NMAC 3.1 Subpart 7, Radiation Materials And Radiation Machines, Medical Use Of Radionuclides (filed 6/17/1999) was reformatted, renumbered and replaced by 20.3.7 NMAC, Medical Use Of Radionuclides, effective 4/30/2009.

TITLE 20 ENVIRONMENTAL PROTECTION
CHAPTER 3 RADIATION PROTECTION
PART 12 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WELL LOGGING

20.3.12.1 ISSUING AGENCY: Environmental Improvement Board.
[20.3.12.1 NMAC - Rp, 20.3.12.1 NMAC, 6/30/2011]

20.3.12.2 SCOPE: The regulations in this part apply to all licensees who use sources of radiation for well logging service operations, radioactive markers or subsurface tracer studies in oil, gas, mineral, groundwater or geological exploration.
[20.3.12.2 NMAC - Rp, 20.3.12.2 NMAC, 6/30/2011]

20.3.12.3 STATUTORY AUTHORITY: Sections 74-1-9, 74-3-5, and 74-3-9 NMSA 1978.
[20.3.12.3 NMAC - Rp, 20.3.12.3 NMAC, 6/30/2011]

20.3.12.4 DURATION: Permanent.
[20.3.12.4 NMAC - Rp, 20.3.12.4 NMAC, 6/30/2011]

20.3.12.5 EFFECTIVE DATE: June 30, 2011, unless a later date is cited at the end of a section.
[20.3.12.5 NMAC - Rp, 20.3.12.5 NMAC, 6/30/2011]

20.3.12.6 OBJECTIVE:

A. This part prescribes requirements for the issuance of a license authorizing the use of licensed materials including sealed sources, radioactive tracers, radioactive markers and uranium sinker bars in well logging in a single well. This part also prescribes radiation safety requirements for persons using licensed materials in these operations. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of 20.3.1 NMAC, 20.3.3 NMAC, 20.3.4 NMAC and 20.3.10 NMAC apply to applicants and licensees subject to this part.

B. The requirements set out in this part do not apply to the issuance of a license authorizing the use of licensed material in tracer studies involving multiple wells, such as field flooding studies, or to the use of sealed sources auxiliary to well logging but not lowered into wells.
[20.3.12.6 NMAC- Rp, 20.3.12.6 NMAC, 6/30/2011]

20.3.12.7 DEFINITIONS: As used in this part, the following definitions apply.

A. "Energy compensation source" (ECS) means a small sealed source, with an activity not exceeding 100 microcuries (3.7 megabecquerels), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

B. "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

C. "Fresh water aquifer" means a geologic formation that is capable of yielding fresh water to a well or spring.

D. "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

E. "Irretrievable well logging source" means any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

F. "Licensed material" means byproduct, source, or special nuclear material received, processed, used or transferred under a license issued by the department under this chapter.

G. "Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 20.3.12.14 NMAC.

H. "Logging supervisor" means the individual who uses licensed material or provides personal supervision in the use of licensed material at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the department's regulations and the conditions of the license.

I. "Logging tool" means a device used subsurface to perform well logging.

J. "Personal supervision" means guidance and instruction by a logging supervisor, who is physically present at a temporary job site, who is in personal contact with logging assistants and who can give immediate assistance.

K. "Radioactive marker" means licensed material used for depth determination or direction orientation. For the purposes of this part, this term includes radioactive collar markers and radioactive iron nails.

L. "Safety review" means a periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed and opportunities for employees to ask safety questions.

M. "Sealed source" means any licensed material that is encased in a capsule designed to present leakage or escape of the licensed material.

N. "Source holder" means a housing or assembly into which a sealed source is placed for the purpose of facilitating the handling and use of the source in well logging operations.

O. "Subsurface tracer study" means the release of unsealed licensed material or a substance labeled with licensed material in a single well for the purpose of tracing the movement or position of the material or substance in the well or adjacent formation.

P. "Surface casing for protecting fresh water aquifers" means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

Q. "Temporary job site" means a location where licensed materials are present for the purpose of performing well logging or subsurface tracer studies.

R. "Tritium neutron generator target source" means a tritium source used within a neutron generator tube to produce neutrons for use in well logging applications.

S. "Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

T. "Well" means a drilled hole, in which well logging may be performed. As used in this part, "well" includes drilled holes for the purpose of oil, gas, mineral, groundwater or geological exploration.

U. "Well logging" means all operations involving the lowering and raising of measuring devices or tools which may contain licensed material or are used to detect licensed materials in wells for the purpose of obtaining information about the well or adjacent formations which may be used in oil, gas, mineral, groundwater or geological exploration.

[20.3.12.7 NMAC - Rp, 20.3.12.7 NMAC, 6/30/2011]

20.3.12.8 APPLICATION FOR A SPECIAL LICENSE: A person, as defined in 20.3.1.7 NMAC, shall file an application in duplicate for a specific license authorizing the use of licensed material in well logging on a department prescribed form pursuant to 20.3.3.307 NMAC. The application must be sent to the department for review and approval.

[20.3.12.8 NMAC - N, 6/30/2011]

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

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

(1) initial training;

(2) on-the-job training;

(3) annual safety reviews provided by the licensee;

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

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

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

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

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

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

(1) instruments to be used;

(2) methods of performing the analysis; and

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

[20.3.12.9 NMAC- N, 6/30/2011; A, 06/13/2017; A, XX/XX/2022]

20.3.12.10 RETRIEVAL OR ABANDONMENT OF SEALED SOURCES:

A. Agreement with well owner or operator.

(1) A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement shall identify who will meet the requirements of Subsections B and C of this section and who will meet the following requirements:

(a) the radiation monitoring requirements of Subsection A of 20.3.12.15 NMAC shall be performed; and

(b) if the environment, any equipment or personnel are contaminated with licensed material, they shall be decontaminated before release from the site or release for unrestricted use.

(2) Recordkeeping. The licensee shall retain a copy of the written agreement for three[3] years after the completion of the well logging operation.

(3) A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements of Subsections B and C of this section.

B. Retrieval of lodged sealed sources.

(1) If a sealed source becomes lodged in the well, a reasonable effort shall be made to recover it.

(2) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.

C. Irretrievable sealed sources. If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the licensee shall implement the requirements of this subsection within 30 days.

(1) Each irretrievable well logging source shall be immobilized and sealed in place with a cement plug.

(2) The licensee shall implement means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations.

(3) The licensee shall install a permanent identification plaque, constructed of long lasting material such as stainless steel, brass, bronze or monel, shall be mounted at the surface of the well, unless the

mounting of the plaque is not practical. The size of the plaque shall be at least 17 centimeters (seven inches) square and three millimeters (one-eighth inch) thick. The plaque shall contain:

(a) the word "caution";

(b) the radiation symbol (the color requirement in Subsection A of 20.3.4.427 NMAC need not be met);

(c) the date the source was abandoned;

(d) the name of the well owner or well operator, as appropriate;

(e) the well name and well identification number(s) or other designation;

(f) an identification of the sealed source(s) by radionuclide and quantity;

(g) the depth of the source and depth to the top of the plug; and

(h) an appropriate warning, such as, "do not re-enter this well."

D. A licensee may apply, pursuant to Subsection A of 20.3.1.107 NMAC, for department approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in this subsection.

[20.3.12.10 NMAC - Rp, 20.3.12.1203 NMAC, 6/30/2011]

20.3.12.11 TRAINING:

A. Logging supervisor. The licensee may not permit an individual to act as a logging supervisor until that person has met all of the following requirements:

(1) the person has completed training in the subjects outlined in Subsection E of this section;

(2) the person has received copies of, and instruction in:

(a) the department rules contained in the applicable sections of 20.3.4 NMAC, 20.3.10 NMAC and 20.3.12 NMAC;

(b) the department license under which the logging supervisor will perform well logging; and

(c) the licensee's operating and emergency procedures required by 20.3.12.12 NMAC;

(3) the person has completed on-the-job training and demonstrated competence in the use of licensed materials, remote handling tools and radiation survey instruments by a field evaluation; and

(4) the person has demonstrated understanding of the requirements in Paragraphs (1) and (2) of this subsection by successfully completing a written test.

B. Logging assistant. The licensee may not permit an individual to act as a logging assistant until that person has met the following requirements:

(1) the person has received instruction in applicable sections of 20.3.4 NMAC, 20.3.10 NMAC and 20.3.12 NMAC;

(2) the person has received copies of, and instruction in, the licensee's operating and emergency procedures required by 20.3.12.12 NMAC;

(3) the person has demonstrated understanding of the materials listed in Paragraphs (1) and (2) of this subsection by successfully completing a written or oral test; and

(4) the person has received instruction in the use of licensed materials, remote handling tools and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.

C. The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

D. Recordkeeping. The licensee shall maintain a record on each logging supervisor's and logging assistant's training and annual safety review. The training records must include copies of written tests and dates of oral tests. The training records must be retained until three years following the termination of employment. Records of annual safety reviews must list the topics discussed and be retained for 3 years.

E. The licensee shall include the following subjects in the training required in Paragraph (1) of Subsection A of this section.

(1) Fundamentals of radiation safety including:

(a) characteristics of radiation;

(b) units of radiation dose and quantity of radioactivity;

(c) hazards of exposure to radiation;

(d) levels of radiation from licensed material;

(e) methods of controlling radiation dose (time, distance, and shielding); and

(f) radiation safety practices, including prevention of contamination, and methods of decontamination.

(2) Radiation detection instruments including:

(a) use, operation, calibration and limitations of radiation survey instruments;

(b) survey techniques; and

(c) use of personnel monitoring equipment.

(3) Equipment to be used including:

(a) operation of equipment, including source handling equipment and remote handling tools;

(b) storage, control and disposal of licensed material; and

(c) maintenance of equipment.

(4) The requirements of pertinent department regulations.

(5) Case histories of accidents in well logging.

[20.3.12.11 NMAC - Rp, 20.3.12.1214 and 20.3.12.1225 NMAC, 6/30/2011]

20.3.12.12 OPERATING AND EMERGENCY PROCEDURES: Each licensee shall develop and follow written operating and emergency procedures that cover the following topics:

A. the handling and use of licensed materials including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;

B. the use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

C. methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by Subsections C through E of 20.3.12.14 NMAC;

D. minimizing personnel exposure including exposures from inhalation and ingestion of licensed tracer materials;

E. methods and occasions for locking and securing stored licensed materials;

F. personnel monitoring and the use of personnel monitoring equipment;

G. transportation of licensed materials to field stations or temporary jobsites, packaging of licensed materials for transport in vehicles, placarding of vehicles when needed, and physically securing licensed materials in transport vehicles during transportation to prevent accidental loss, tampering or unauthorized removal;

H. picking up, receiving and opening packages containing licensed materials, in accordance with 20.3.4.432 NMAC;

I. for the use of tracers, decontamination of the environment, equipment, and personnel;

J. maintenance of records generated by logging personnel at temporary jobsites;

K. the inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers and uranium sinker bars as required by 20.3.12.22 NMAC;

L. actions to be taken if a sealed source is lodged in a well;

M. notifying proper persons in the event of an accident; and

N. actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of licensed materials and actions to obtain suitable radiation survey instruments as required by Subsection B of 20.3.12.17 NMAC.

[20.3.12.12 NMAC - Rp, 20.3.12.1215 and 20.3.12.1218 NMAC, 6/30/2011]

20.3.12.13 PERSONNEL MONITORING:

A. The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of licensed radioactive materials, a personnel dosimeter that is processed and evaluated by an accredited national voluntary laboratory accreditation program (NVLAP) processor. Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be replaced at least monthly and other personnel dosimeters replaced at least quarterly. After replacement, each personnel dosimeter shall be promptly processed.

B. The licensee shall provide bioassay services to individuals using licensed radioactive materials in subsurface tracer studies if required by the license.

C. Recordkeeping. The licensee shall retain records of personnel dosimeters required by Subsection A of this section and bioassay results for inspection until the department authorizes disposition of the records.

[20.3.12.13 NMAC - Rp, 20.3.12.1216 NMAC, 6/30/2011]

20.3.12.14 RADIATION SURVEYS:

A. The licensee shall make radiation surveys, including but not limited to the surveys required under Subsections B through E of this section, of each area where licensed materials are used and stored.

B. Before transporting licensed materials, the licensee shall make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the licensed materials.

C. If the sealed source assembly is removed from the logging tool before departure from the temporary jobsite, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.

D. If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

E. The licensee shall make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

F. Recordkeeping. The results of surveys required under Subsections A through E of this section must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey instrument used, and the location of the survey. The licensee shall retain records of surveys for inspection by the department for 3 years after they are made.

[20.3.12.14 NMAC - Rp, 20.3.12.1221 NMAC, 6/30/2011]

20.3.12.15 RADIOACTIVE CONTAMINATION CONTROL:

A. If the licensee detects evidence that a sealed source has ruptured or licensed materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by 20.3.12.12 NMAC.

B. If contamination results from the use of licensed material in well logging, the licensee shall decontaminate all work areas, equipment and unrestricted areas.

C. During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

[20.3.12.15 NMAC - N, 6/30/2011]

20.3.12.16 LABELS, SECURITY AND TRANSPORT PRECAUTIONS:

A. Labels.

(1) The licensee may not use a source, source holder or logging tool that contains licensed material unless the smallest component that is transported as a separate piece of equipment with the licensed material inside bears a durable, legible and clearly visible marking or label. The marking or label must contain the radiation symbol specified in 20.3.4.427 NMAC, without the conventional color requirements, and the wording "Danger (or Caution) radioactive material."

(2) The licensee may not use a container to store licensed material unless the container has securely attached to it a durable, legible and clearly visible label. The label must contain the radiation symbol specified in 20.3.4.427 NMAC and the wording "Danger (or Caution), radioactive material, notify civil authorities (or name of company)."

(3) The licensee may not transport licensed material unless the material is packaged, labeled, marked and accompanied with appropriate shipping papers in accordance with regulations set out in 20.3.3.306 NMAC, incorporating 10 CFR Part 71.

B. Security precautions during storage and transportation.

(1) The licensee shall store each source containing licensed material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of licensed material from storage by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.

(2) The licensee shall lock and physically secure the transport package containing licensed material in the transporting vehicle to prevent accidental loss, tampering or unauthorized removal of the licensed material from the vehicle.

[20.3.12.16 NMAC - Rp, 20.3.12.1205, 20.3.12.1206, and 20.3.12.1212 NMAC, 6/30/2011]

20.3.12.17 RADIATION SURVEY INSTRUMENTS:

A. The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by this part and by 20.3.4 NMAC. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.001 millisievert (0.1 millirem) per hour through at least 0.5 millisievert (50 millirems) per hour.

B. The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party.

C. The licensee shall have each radiation survey instrument required under this section calibrated:

(1) at intervals not to exceed six months and after each instrument servicing;

(2) for linear scale instruments, at two points located approximately one-third and two-third of full-scale on each scale; for logarithmic scale instruments, and mid-range of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

(3) so that an accuracy within plus or minus 20 percent of the calibration standard can be demonstrated on each scale.

D. Recordkeeping. The licensee shall retain calibration records for a period of three years after the date of calibration for inspection by the department.

[20.3.12.17 NMAC - Rp, 20.3.12.1207 NMAC, 6/30/2011]

20.3.12.18 LEAK TESTING OF SEALED SOURCES:

A. Testing and recordkeeping requirements. Each licensee who uses a sealed source of radioactive material shall have the source tested for leakage periodically. Records of leak tests results shall be kept in units of microcuries and maintained for inspection by the department for three years after the leak test is performed.

B. Method of testing. The wipe of a sealed source shall be performed using a leak test kit or method approved by the department, NRC or an agreement state. The wipe sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample shall be analyzed for radioactive contamination. The analysis shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample and shall be performed by a person approved by the department, NRC or an agreement state to perform the analysis.

C. Test frequency.

(1) Each sealed source (except an energy compensation source (ECS)) shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested.

(2) Each energy compensation source (ECS) that is not exempt from testing in accordance with Subsection E of this section shall be tested at intervals not to exceed three[3] years. In the absence of a certificate from a transferor that a test has been made within the three years before the transfer, the energy compensation source (ECS) may not be used until tested.

D. Removal of leaking source from service.

(1) If the test conducted pursuant to Subsections A and B of this section reveals the presence of 0.005 microcurie (185 becquerels) or more of removable radioactive material, the licensee shall remove the sealed source from service immediately and have it decontaminated, repaired or disposed of by a department, NRC or an agreement state licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by a department, NRC or an agreement state licensee that is authorized to perform these functions.

(2) The licensee shall submit a report to the department within five days of receiving the test result. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source and the corrective actions taken up to the time the report was made.

E. Exemptions. The following sealed sources are exempt from the periodic leak test requirements set out in Subsections A through D of this section:

(1) hydrogen-3 (tritium) sources;

(2) sources containing licensed material with a half-life of 30 days or less;

(3) sealed sources containing licensed material in gaseous form;

(4) sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 megabecquerels) or less; and

(5) sources of alpha- or neutron-emitting radioactive material with an activity of 10 microcuries (0.370 megabecquerel) or less.

[20.3.12.18 NMAC - Rp, 20.3.12.1208 NMAC, 6/30/2011]

20.3.12.19 PHYSICAL INVENTORY: Each licensee shall conduct a semi-annual physical inventory to account for all licensed material received and possessed under the license. The licensee shall retain records of the inventory for 3 years from the date of the inventory for inspection by the department. The inventory must indicate the quantity and kind of licensed material, the location of the licensed material, the date of the inventory and the name of the individual conducting the inventory. Physical inventory records may be combined with leak test records.

[20.3.12.19 NMAC - Rp, 20.3.12.1209 NMAC, 6/30/2011]

20.3.12.20 RECORDS OF MATERIAL USE:

A. Each licensee shall maintain records for each use of licensed material showing:

(1) the make, model number and serial number or a description of each sealed source used;

(2) in the case of unsealed licensed material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer materials;

(3) the identity of the logging supervisor who is responsible for the licensed material and the identity of logging assistants present; and

(4) the location and date of use of the licensed material.

B. Recordkeeping. The licensee shall make the records required by Subsection A of this section available for inspection by the department. The licensee shall retain the records for 3 years from the date of the recorded event.

[20.3.12.20 NMAC - Rp, 20.3.12.1210 NMAC, 6/30/2011]

20.3.12.21 DESIGN AND PERFORMANCE CRITERIA FOR SEALED SOURCES:

A. A licensee may use a sealed source for use in well logging applications if:

(1) the sealed source is doubly encapsulated;

(2) the sealed source contains licensed material whose chemical and physical forms are as insoluble and nondispersible as practical; and

(3) meets the requirements of Subsections B, C and D of this section.

B. For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the requirements of USASI N5.10-1968, classification of sealed radioactive sources, or the requirements in Subsections C and D of this section.

C. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications if it meets the oil well logging requirements of ANSI/HPS N43.6-1997, sealed radioactive sources - classification.

D. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well logging applications, if the sealed source's prototype has been tested and found to maintain its integrity after each of the tests in Paragraphs (1) through (5) of this subsection.

(1) Temperature. The test source shall be held at -40 degrees celsius for 20 minutes, 600 degrees celsius for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600 degrees celsius to 20 degrees celsius within 15 seconds.

(2) Impact test. A 5-kilogram steel hammer, 2.5 centimeters in diameter, shall be dropped from a height of 1 meter onto the test source.

(3) Vibration test. The test source shall be subject to a vibration from 25 hertz to 500 hertz at 5 g (g meaning the acceleration due to gravity) amplitude for 30 minutes.

(4) Puncture test. A 1 gram hammer and pin, 0.3 centimeter pin diameter, shall be dropped from a height of 1 meter onto the test source.

(5) Pressure test. The test source shall be subject to an external pressure of 1.695x107 pascals (24,600 pounds per square inch absolute).

E. The requirements in Subsections A, B, C and D of this section do not apply to sealed sources that contain licensed material in gaseous form.

F. The requirements in Subsections A, B, C and D of this section do not apply to energy compensation sources (ECS). ECSs shall be registered with the sealed source and device registry (see definition in 20.3.1.7 NMAC) upon an approval by the NRC under 10 CFR 32.210 or an agreement state equivalent regulations.

[20.3.12.21 NMAC - Rp, 20.3.12.1211 NMAC, 6/30/2011]

20.3.12.22 INSPECTION, MAINTENANCE AND OPENING OF A SOURCE OR SOURCE HOLDER:

A. Each licensee shall visually check source holders, logging tools and source handling tools, for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: the date of check, name of inspector, equipment involved, defects found and repairs made. These records must be retained for three years after the defect is found.

B. Each licensee shall have a program for semiannual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: date, equipment involved, inspection and maintenance operations performed, any defects found and any actions taken to correct the defects. These records must be retained for three years after the defect is found.

C. Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written operating procedure is developed and has been approved either by the department, NRC or an agreement state.

D. If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting or chiseling, on the source holder unless the licensee is specifically approved by the department, NRC or an agreement state to perform this operation.

E. The opening, repair or modification of any sealed source must be performed by persons specifically approved to do so by the department, NRC or an agreement state.

[20.3.12.22 NMAC - Rp, 20.3.12.1213 NMAC, 6/30/2011]

20.3.12.23 SUBSURFACE TRACER STUDIES:

A. The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other protective clothing and equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

B. A licensee shall not knowingly inject licensed material into fresh water aquifers unless specifically authorized to do so by the department.

[20.3.12.23 NMAC - Rp, 20.3.12.1219 NMAC, 6/30/2011]

20.3.12.24 RADIOACTIVE MARKERS: The licensee may use radioactive markers in wells only if the individual markers contain quantities of licensed material not exceeding the exempt quantities specified in 20.3.3.330 NMAC. The use of markers is subject only to the requirements of physical inventory in 20.3.12.19 NMAC.

[20.3.12.24 NMAC - N, 6/30/2011]

20.3.12.25 URANIUM SINKER BARS: The licensee may use a uranium sinker bar in well logging applications only if it is legibly impressed with the words ”Caution - radioactive - depleted uranium” and “Notify civil authorities (or name of company) if found.”

[20.3.12.25 NMAC - Rp, 20.3.12.1200 NMAC, 6/30/2011]

20.3.12.26 USE OF A SEALED SOURCE IN A WELL WITHOUT A SURFACE CASING: The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the department pursuant to Subsection C of 20.3.12.9 NMAC, the NRC or an agreement state.

[20.3.12.26 NMAC - N, 6/30/2011]

20.3.12.27 ENERGY COMPENSATION SOURCE:

A. The licensee may use an energy compensation source (ECS) which is contained within a logging tool or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 megabecquerels).

B. For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 20.3.12.18 NMAC, 20.3.12.19 NMAC and 20.3.12.20 NMAC.

C. For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of 20.3.12.10 NMAC, 20.3.12.18 NMAC, 20.3.12.19 NMAC, 20.3.12.20 NMAC, 20.3.12.26 NMAC and 20.3.12.32 NMAC.
[20.3.12.27 NMAC - Rp, 20.3.12.1201 NMAC, 6/30/2011]

20.3.12.28 TRITIUM NEUTRON GENERATOR TARGET SOURCE:

A. Use of a tritium neutron generator target source, containing quantities not exceeding 30 curies (1,110 megabecquerels) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this part except 20.3.12.10 NMAC, 20.3.12.21 NMAC and 20.3.12.32 NMAC.

B. Use of a tritium neutron generator target source, containing quantities exceeding 30 curies (1,110 megabecquerels) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this part except 20.3.12.21 NMAC.
[20.3.12.28 NMAC - Rp, 20.3.12.1202 NMAC, 6/30/2011]

20.3.12.29 SECURITY DURING USE OF LICENSED MATERIAL:

A. A logging supervisor must be physically present at a temporary jobsite whenever licensed materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

B. During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in 20.3.4.7 NMAC.
[20.3.12.29 NMAC - Rp, 20.3.12.1217 NMAC, 6/30/2011]

20.3.12.30 DOCUMENTS AND RECORDS REQUIRED AT FIELD STATIONS: Each licensee shall maintain the following documents and records at the field station:

A. a copy of 20.3.4 NMAC, 20.3.10 NMAC and 20.3.12 NMAC;

B. the license authorizing the use of licensed material;

C. operating and emergency procedures required by 20.3.12.12 NMAC;

D. the record of radiation survey instrument calibrations required by 20.3.12.17 NMAC;

E. the record of leak test results required by 20.3.12.18 NMAC;

F. physical inventory records required by 20.3.12.19 NMAC;

G. utilization records required by 20.3.12.20 NMAC;

H. records of inspection and maintenance required by 20.3.12.22 NMAC;

I. training records required by 20.3.12.11 NMAC; and

J. survey records required by 20.3.12.14 NMAC.
[20.3.12.30 NMAC - Rp, 20.3.12.1222 NMAC, 6/30/2011]

20.3.12.31 DOCUMENTS AND RECORDS REQUIRED AT TEMPORARY JOBSITES: Each licensee conducting operations at a temporary jobsite shall maintain the following documents and records at the temporary jobsite until the well logging operation is completed:

A. operating and emergency procedures required by 20.3.12.12 NMAC;

B. evidence of latest calibration of the radiation survey instruments in use at the site required by 20.3.12.17 NMAC;

C. latest survey records required by 20.3.12.14 NMAC;

D. the shipping papers for the transportation of radioactive materials required by 20.3.3.306 NMAC, incorporating 10 CFR 71.5; and

E. when operating under reciprocity pursuant to 20.3.3.324 NMAC, a copy of the NRC or agreement state license authorizing use of licensed materials.
[20.3.12.31 NMAC - Rp, 20.3.12.1223 NMAC, 6/30/2011]

20.3.12.32 NOTIFICATION OF INCIDENTS AND LOST SOURCES; ABANDONMENT PROCEDURES FOR IRRETRIEVABLE SOURCES:

A. The licensee shall immediately notify the department by telephone and subsequently, within 30 days, by confirmation in writing, if the licensee knows or has reason to believe that a sealed source has been ruptured. The written confirmation must designate the well or other location, describe the magnitude and extent of

the escape of licensed materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

B. The licensee shall notify the department of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation and certain other accidents as required by 20.3.4.451 NMAC, 20.3.4.452 NMAC, 20.3.4.453 NMAC and 20.3.3.325 NMAC.

C. If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee shall:

(1) notify the department by telephone of the circumstances that resulted in the inability to retrieve the source; and

(a) obtain department approval to implement abandonment procedures; or

(b) that the licensee implemented abandonment before department approval because the licensee believed there was an immediate threat to public health and safety; and

(2) advise the well owner or operator, as appropriate, of the abandonment procedures under Subsection A or D of 20.3.12.10 NMAC; and

(3) either ensure that abandonment procedures are implemented within 30 days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures.

D. The licensee shall, within 30 days after a sealed source has been classified as irretrievable, make a report in writing to the department. The licensee shall send a copy of the report to each appropriate local, state or federal agency that issued permits or otherwise approved of the drilling operation. The report must contain the following information:

(1) date of occurrence;

(2) a description of the irretrievable well logging source involved including the radionuclide and its quantity, chemical and physical form;

(3) surface location and identification of the well;

(4) results of efforts to immobilize and seal the source in place;

(5) a brief description of the attempted recovery effort;

(6) depth of the source;

(7) depth of the top of the cement plug;

(8) depth of the well;

(9) the immediate threat to public health and safety justification for implementing abandonment if prior department approval was not obtained in accordance with Subparagraph (b) of Paragraph (1) of Subsection C of this section;

(10) any other information, such as a warning statement, contained on the permanent identification plaque; and

(11) local, state and federal agencies receiving copy of this report.

[20.3.12.32 NMAC - Rp, 20.3.12.1224 NMAC, 6/30/2011]

HISTORY OF 20.3.12 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed as follows:
EIB 73-2, Regulations for Governing the Health and Environmental Aspects of Radiation filed on 7/9/1973;
EIB 73-2, Amendment 1, Regulations for Governing the Health and Environmental Aspects of Radiation filed on 4-17-78;
EIB RPR-1, Radiation Protection Regulations filed on 4/21/1980;
EIB RPR-1, Amendment 1, Radiation Protection Regulations filed on 10/13/1981;
EIB RPR-1, Amendment 2, Radiation Protection Regulations filed on 12/15/1982; and
EIB RPR-1, Radiation Protection Regulations filed on 3/10/1989.

History of Repealed Material: 20.3.12 NMAC, Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies, filed 3/15/2004 is repealed effective 6/30/2011 and replaced by 20.3.12 NMAC, Licenses and Radiation Safety Requirements for Well Logging, effective 6/30/2011.

Other History: EIB RPR 1, Radiation Protection Regulations, filed 3/10/1989 renumbered and reformatted to 20 NMAC 3.1; Radioactive Materials and Radiation Machines, effective 5/3/1995;
20 NMAC 3.1; Radioactive Materials and Radiation Machines (filed 4/3/1995) internally renumbered, reformatted and replaced by 20 NMAC 3.1, Radioactive Materials and Radiation Machines, effective 7/30/1999.

20 NMAC 3.1.Subpart 12, Radiation Safety Requirements For Wireline Service Operations And Subsurface Tracer Studies (filed 6/17/1999) reformatted, amended and replaced by 20.3.12 NMAC, Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies, effective 4/15/2004.

20.3.12 NMAC, Radiation Safety Requirements for Wireline Service Operations and Subsurface Tracer Studies, filed 3/15/2004 is repealed effective 6/30/2011 and replaced by 20.3.12 NMAC, Licenses and Radiation Safety Requirements for Well Logging, effective 6/30/2011.

TITLE 20 ENVIRONMENTAL PROTECTION
CHAPTER 3 RADIATION PROTECTION
PART 15 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

20.3.15.1 ISSUING AGENCY: Environmental Improvement Board.
[5/3/1995; 20.3.15.1 NMAC - Rn, 20 NMAC 3.1.1.100, 4/15/2004]

20.3.15.2 SCOPE:

A. The requirements of this part (20.3.15 NMAC) are in addition to other requirements in these regulations. In particular, the provisions of Parts 3, 4 and 10 (20.3.3 NMAC, 20.3.4 NMAC, and 20.3.10 NMAC) apply to applications and licenses subject to this part (20.3.15 NMAC). Nothing in this part (20.3.15 NMAC) relieves the licensee from complying with other applicable federal, state and local regulations governing the siting, zoning, land use and building code requirements for industrial facilities.

B. The regulations in this part (20.3.15 NMAC) apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to under water irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed five grays (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part (20.3.15 NMAC).

C. The regulations in this part (20.3.15 NMAC) do not apply to self-contained dry-source storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.
[5/3/1995; 20.3.15.2 NMAC - Rn, 20 NMAC 3.1.15.1500, 4/15/2004]

20.3.15.3 STATUTORY AUTHORITY: Sections 74-1-9, 74-3-5, and 74-3-9 NMSA 1978.
[5/3/1995; 20.3.15.3 NMAC - Rn, 20 NMAC 3.1.1.102, 4/15/2004]

20.3.15.4 DURATION: Permanent.
[5/3/1995; 20.3.15.4 NMAC - Rn, 20 NMAC 3.1.1.103, 4/15/2004]

20.3.15.5 EFFECTIVE DATE: May 3, 1995, unless a later date is cited at the end of a section.
[5/3/1995, 8-2-95, A, 7-30-99; 20.3.3.5 NMAC - Rn, 20 NMAC 3.1.1.104, 4/15/2004]

20.3.15.6 OBJECTIVE: This part (20.3.15 NMAC) contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part (20.3.15 NMAC) also contains radiation safety requirements for operating irradiators.
[5/3/1995; 20.3.15.2 NMAC - Rn, 20 NMAC 3.1.15.1500.A, 4/15/2004]
[Refer to the purpose and scope promulgated by the board as specified in 20.3.15.2 NMAC.]

20.3.15.7 DEFINITIONS:

A. **"Annually"** means either:

(1) at intervals not to exceed one year; or

(2) once per year, at about the same time each year (plus or minus 1 month).

B. **"Doubly encapsulated sealed source"** means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

C. **"Irradiator"** means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding five grays (500 rads) per hour exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

D. **"Irradiator operator"** means an individual who has successfully completed the training and testing described in 20.3.15.1517 NMAC and is authorized by the terms of the license to operate the irradiator without a supervisor present.

E. **"Panoramic dry-source-storage irradiator"** means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid

materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

F. "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

G. "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

H. "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water, including panoramic wet-source-storage irradiators and under water irradiators.

I. "Product conveyor system" means a system for moving the product to be irradiated to, from and within the area where irradiation takes place.

J. "Radiation room" means a shielded room in which irradiations take place. Under water irradiators do not have radiation rooms.

K. "Radiation safety officer" means an individual with responsibility for the overall radiation safety program at the facility.

L. "Sealed source" means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

M. "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. geological survey.

N. "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

[5/3/1995; 20.3.15.7 NMAC - Rn, 20 NMAC 3.1.15.1500, 4/15/2004]

20.3.15.8 through 20.3.15.1500 [RESERVED]

20.3.15.1501 APPLICATION FOR A SPECIFIC LICENSE. A person, as defined in 20.3.1 NMAC of these regulations, may file an application for a specific license authorizing the use of sealed sources in an irradiator on forms provided by the department, in accordance with 20.3.3.307 NMAC.

[5/3/1995; 20.3.15.1501 NMAC - Rn, 20 NMAC 3.1.15.1501, 4/15/2004]

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

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

(1) classroom training;

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

(3) safety reviews;

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

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

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

E. The application must describe the organizational structure for managing the irradiator, specifically

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

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

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

(1) instruments to be used;

(2) methods of performing the analysis; and

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

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

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

[05/03/95; 20.3.15.1502 NMAC - Rn, 20 NMAC 3.1.15.1502, 04/15/2004; A, 06/13/2017; A, XX/XX/2022]

20.3.15.1503 START OF CONSTRUCTION: The applicant may not begin construction of a new irradiator prior to the submission to the department an application for a license for the irradiator. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site, but does not include engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license.

[5/3/1995; 20.3.15.1503 NMAC - Rn, 20 NMAC 3.1.15.1503, 4/15/2004]

20.3.15.1504 APPLICATIONS FOR EXEMPTIONS:

A. The department may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this part (20.3.15 NMAC) that it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

B. Any application for a license or for amendment of a license authorizing use of teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part (20.3.15 NMAC). The department will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

[5/3/1995; 20.3.15.1504 NMAC - Rn, 20 NMAC 3.1.15.1504, 4/15/2004]

20.3.15.1505 REQUEST FOR WRITTEN STATEMENTS:

A. After the filing of the original application, the department may request further information necessary to enable the department to determine whether the application should be granted or denied.

B. Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the department's request, submit written statements to enable the department to determine whether the license should be modified, suspended or revoked.

[5/3/1995; 20.3.15.1505 NMAC - Rn, 20 NMAC 3.1.15.1505, 4/15/2004]

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 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 three 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.

[5/3/1995; 20.3.15.1506 NMAC - Rn, 20 NMAC 3.1.15.1506, 4/15/2004; A, 6/13/2017]

20.3.15.1507 ACCESS CONTROL:

A. Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyer systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the source. The doors and barriers must not prevent any individual in the radiation room from leaving.

B. In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position, and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is on-site of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

C. A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in Subsection B of 20.3.15.1507 NMAC. The monitor may be located in the entrance (normally referred to as the maze), but not in the direct radiation beam.

D. Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

E. Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

F. Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position, unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

G. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by 20.3.4.428 NMAC. Radiation postings for panoramic irradiators must comply with the posting requirements of 20.3.4.428 NMAC, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

H. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring

inspection of shielding before operating.

I. Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

[5/3/1995; 20.3.15.1507 NMAC - Rn, 20 NMAC 3.1.15.1507 & A, 4/15/2004]

20.3.15.1508 SHIELDING:

A. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (two millirems) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 0.02 millisievert (two millirems) per hour must be locked, roped off or posted.

B. The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (two millirems) per hour when the sources are in the fully shielded position.

C. The radiation dose rate at one meter from the shield of a dry-source-storage panoramic irradiator when the source in shielded may not exceed 0.02 millisievert (two millirems) per hour and at five centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

[5/3/1995; 20.3.15.1508 NMAC - Rn, 20 NMAC 3.1.15.1508, 4/15/2004]

20.3.15.1509 FIRE PROTECTION:

A. The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

B. The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

[5/3/1995; 20.3.15.1509 NMAC - Rn, 20 NMAC 3.1.15.1509, 4/15/2004]

20.3.15.1510 RADIATION MONITORS:

A. Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound, and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this subsection.

B. Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

[5/3/1995; 20.3.15.1510 NMAC - Rn, 20 NMAC 3.1.15.1510, 4/15/2004]

20.3.15.1511 CONTROL OF SOURCE MOVEMENT:

A. The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

B. The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit and when the sources are exposed.

C. The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

D. Each control for a panoramic irradiator must be clearly marked as to its function.

[5/3/1995; 20.3.15.1511 NMAC - Rn, 20 NMAC 3.1.15.1511, 4/15/2004]

20.3.1512 IRRADIATOR POOLS:

A. For licenses initially issued after July 1, 1993, irradiator pools must either:

(1) have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(2) be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination; and

(3) in either case, the licensee shall have a method to safely store the sources during repairs of the pool.

B. For licenses initially issued after July 1, 1993, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

C. A means must be provided to replenish water losses from the pool.

D. A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

E. Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

F. A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection and service operations.

G. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (two millirems) per hour.

[5/3/1995; 20.3.15.1512 NMAC - Rn, 20 NMAC 3.1.15.1512, 4/15/2004]

20.3.15.1513 SOURCE RACK PROTECTION: If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

[5/3/1995; 20.3.15.1513 NMAC - Rn, 20 NMAC 3.1.15.1513. 4/15/2004]

20.3.15.1514 POWER FAILURES:

A. If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the source must automatically return to the shielded position.

B. The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

C. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

[5/3/1995; 20.3.15.1514 NMAC - Rn, 20 NMAC 3.1.15.1514, 4/15/2004]

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 x 10^{17} becquerels (five 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 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.

[5/3/1995; 20.3.15.1515 NMAC - Rn, 20 NMAC 3.1.15.1515, 4/15/2004; A, 6/13/2017]

20.3.15.1516 CONSTRUCTION MONITORING AND ACCEPTANCE TESTING: The requirements of this section must be met for irradiators whose construction begins after July 1, 1993. The requirements must be met prior to loading sources.

A. Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

B. Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

C. Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of Subsection B of 20.3.15.1512 NMAC.

D. Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter and the water level indicators operate properly.

E. Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system, and the related alarms and interlocks required by Subsection A of 20.3.15.1510 NMAC. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm, if used, to meet Subsection B of 20.3.15.1521 NMAC. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms and interlocks required by Subsection B of 20.3.15.1510 NMAC.

F. Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation conveyor system to assure that the requirements in 20.3.15.1513 NMAC are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

G. Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed, and that all alarms, controls and interlocks work properly.

H. Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

I. Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

J. Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost, and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

K. Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

[5/3/1995; 20.3.15.1516 NMAC - Rn, 20 NMAC 3.1.15.1516, 4/15/2004]

20.3.15.1517 TRAINING:

A. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

(1) the fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses must be avoided, how shielding and access controls as provided in these regulations prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

(2) the requirements of 20.3.10 NMAC and 20.3.15 NMAC that are relevant to the irradiator;

(3) the operation of the irradiator;

(4) those operating and emergency procedures listed in 20.3.15.1518 NMAC that the individual is responsible for performing; and

(5) case histories of accidents or problems involving irradiators.

B. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received, consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

C. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that the individual is to perform.

D. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

(1) changes in operating and emergency procedures since the last review, if any;

(2) changes in regulations and license conditions since the last review, if any;

(3) reports on recent accidents, mistakes or problems that have occurred at irradiators, if any;

(4) relevant results of inspections of operator safety performance;

(5) relevant results of the facility's inspection and maintenance checks; and

(6) a drill to practice an emergency or abnormal event procedure.

E. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator, and shall instruct the operator on how to correct any mistakes or deficiencies observed.

F. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in 20.3.15.1518 NMAC that they are expected to perform or comply with, and their proper response to alarms required in this part (20.3.15 NMAC). Tests may be oral.

G. Individuals who must be prepared to respond to alarms required by Subsection B of 20.3.15.1507

NMAC, Subsection I of 20.3.15.1507 NMAC, Subsection A of 20.3.15.1509 NMAC, Subsections A and B of 20.3.15.1510 NMAC, and Subsection B of 20.3.15.1521 NMAC shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.
[5/3/1995; 20.3.15.1517 NMAC - Rn, 20 NMAC 3.1.15.1517, 4/15/2004]

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 20.3.15.1507 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.

[5/3/1995; 20.3.15.1518 NMAC - Rn, 20 NMAC 3.1.15.1518, 4/15/2004; A, 6/13/2017]

20.3.15.1519 PERSONNEL MONITORING:

A. Irradiator operators shall wear a personnel dosimeter that is processed and evaluated by an accredited national voluntary laboratory accreditation program (NVLAP) processor while operating a panoramic irradiator, or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited for high-energy photons in the normal and accident dose ranges (see Subsection C of 20.3.4.416 NMAC). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly.

B. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

[5/3/1995; 20.3.15.1519 NMAC - Rn, 20 NMAC 3.1.15.1519, 4/15/2004; A, 8/31/2005]

20.3.15.1520 RADIATION SURVEYS:

A. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded, but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

B. If the radiation levels specified in 20.3.15.1508 NMAC are exceeded, the facility must be modified to comply with the requirements in 20.3.15.1508 NMAC.

C. Portable radiation survey meters must be calibrated at least annually to an accuracy of +20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale, or for digital instruments at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

D. Water from the irradiator pool, other potentially contaminated liquids and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 20.3.4 NMAC, column 2 of table II, or table III of 20.3.4.461 NMAC, "annual limits on intake (ALIs) and derived air concentrations (DACs) of radionuclides for occupational exposure; effluent concentration; concentrations for release to sewerage".

E. Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

[5/3/1995; 20.3.15.1520 NMAC - Rn, 20 NMAC 3.1.15.1520, 4/15/2004]

20.3.15.1521 DETECTION OF LEAKING SOURCES:

A. Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the department. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the department to perform the test.

B. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set point to a higher level if necessary, to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

C. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired or disposed of by a department licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities or products are found, the licensee shall arrange to have them decontaminated or disposed of by a department licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in column 2 of table II, 20.3.4.461 NMAC. (See 20.3.3.325 NMAC for reporting requirements.)

[5/3/1995; 20.3.15.1521 NMAC - Rn, 20 NMAC 3.1.15.1521, 4/15/2004; A, 4/30/2009]

20.3.15.1522 INSPECTION AND MAINTENANCE:

A. The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(1) operability of each aspect of the access control system required by 20.3.15.1507 NMAC;

(2) functioning of the source position indicator required by Subsection B of 20.3.15.1511 NMAC;

(3) operability of the radiation monitor for radioactive contamination in pool water required by Subsection B of 20.3.15.1521 NMAC, using a radiation check source, if applicable;

(4) operability of the over-pool radiation monitor at underwater irradiator as required by Subsection B of 20.3.15.1510 NMAC;

(5) operability of the product exit monitor required by Subsection A of 20.3.15.1510 NMAC;

(6) operability of the emergency source return control required by Subsection C of 20.3.15.1511 NMAC;

(7) leak-tightness of systems through which pool water circulates (visual inspection);

(8) operability of the heat and smoke detectors and extinguisher system required by 20.3.15.1509 NMAC, but without turning extinguishers on;

(9) operability of the means of pool water replenishment required by Subsection C of 20.3.15.1512 NMAC;

(10) operability of the indicators of high and low pool water levels required by Subsection D of 20.3.15.1512 NMAC;

(11) operability of the intrusion alarm required by Subsection I of 20.3.15.1507 NMAC;

(12) functioning and wear of the system, mechanisms, and cables used to raise and lower sources;

(13) condition of the barrier to prevent products from hitting the sources or source mechanism as required by 20.3.15.1513 NMAC;

(14) amount of water added to the pool to determine if the pool is leaking;

(15) electrical wiring on required safety systems for radiation damage; and

(16) pool water conductivity measurements and analysis as required by Subsection B of 20.3.15.1523 NMAC.

B. Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

[5/3/1995; 20.3.15.1522 NMAC - Rn, 20 NMAC 3.1.15.1522, 4/15/2004]

20.3.15.1523 POOL WATER PURITY:

A. Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

B. The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

[5/3/1995; 20.3.15.1523 NMAC - Rn, 20 NMAC 3.1.15.1523, 4/15/2004]

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.

[5/3/1995; 20.3.15.1524 NMAC - Rn, 20 NMAC 3.1.15.1524, 4/15/2004; A, 6/13/2017]

20.3.15.1525 ENTERING AND LEAVING THE RADIATION ROOM:

A. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

B. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(1) visually inspect the entire radiation room to verify that no one else is in it; and

(2) activate a control in the radiation room that permits the sources to be moved from the shielded position, only if the door to the radiation room is locked within a preset time after setting the control.

C. During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter, unless the over-the-pool monitor required by Subsection B of 20.3.15.1510 NMAC is operating with backup power.

[5/3/1995; 20.3.15.1525 NMAC - Rn, 20 NMAC 3.1.15.1525, 4/15/2004]

20.3.15.1526 IRRADIATION OF EXPLOSIVE OR FLAMMABLE MATERIALS:

A. Irradiation of explosive material is prohibited, unless the licensee has received prior written authorization from the department. Authorization will not be granted, unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems or cause radiation overexposures of personnel.

B. Irradiation of more than small quantities of flammable material (flash point below 140 degrees F) is prohibited in panoramic irradiators, unless the licensee has received prior written authorization from the department. Authorization will not be granted, unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

[5/3/1995; 20.3.15.1526 NMAC - Rn, 20 NMAC 3.1.15.1526, 4/15/2004]

20.3.15.1527 RECORDS AND RETENTION PERIODS: The licensee shall maintain the following records at the irradiator for the periods specified.

A. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the department terminates the license for documents not superseded.

B. Records of each individual's training, tests and safety reviews provided to meet the requirements of Subsections A, B, C, D, F and G of 20.3.15.1517 NMAC, until three years after the individual terminates work.

C. Records of the annual evaluations of the safety performance of irradiator operators required by Subsection E of 20.3.15.1517 NMAC for three years after the evaluation.

D. A copy of the current operating and emergency procedures required by 20.3.15.1518 NMAC, until superseded or the department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by Paragraph (3) of Subsection C of 20.3.15.1518 NMAC retained for three years from the date of the change.

E. Evaluations of personnel dosimeters required by 20.3.15.1519 NMAC until the department terminates the license.

F. Records of radiation surveys required by 20.3.15.1520 NMAC for three years from the date of the survey.

G. Records of radiation survey meter calibrations required by 20.3.15.1520 NMAC, and pool water conductivity meter calibrations required by Subsection B of 20.3.15.1523 NMAC until three years from the date of calibration.

H. Records of the results of leak tests required by Subsection A of 20.3.15.1521 NMAC, and the results of contamination checks required by Subsection B of 20.3.15.1521 NMAC for three years from the date of each test.

I. Records of the results of leak tests required by 20.3.15.1522 NMAC for three years.

J. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

K. Records of the receipt, transfer and disposal of all licensed sealed sources as required by

20.3.1.108 NMAC.

L. Records on the design checks required by 20.3.15.1515 NMAC, and the construction control checks as required by 20.3.15.1516 NMAC until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

M. Records related to decommissioning of the irradiator as required by 20.3.3.311 NMAC.

[5/3/1995; 20.3.15.1527 NMAC - Rn, 20 NMAC 3.1.15.1527, 4/15/2004; A, 8/31/2005]

20.3.15.1528 REPORTS:

A. In addition to the reporting requirements in other parts these regulations (20.3 NMAC), the licensee shall report the following events, if not reported under other parts these regulations (20.3 NMAC):

(1) source stuck in an unshielded position;

(2) any fire or explosion in a radiation room;

(3) damage to the source racks;

(4) failure of the cable or drive mechanism used to move the source racks;

(5) inoperability of the access control system;

(6) detection of radiation source by the product exit monitor;

(7) detection of radioactive contamination attributable to licensed radioactive material;

(8) structural damage to the pool liner or walls;

(9) abnormal water loss or leakage from the source storage pool; and

(10) pool water conductivity exceeding 100 microsiemens (mS) per centimeter.

B. The report must include a telephone report within 24 hours as described in Paragraph (1) of Subsection C of 20.3.3.325 NMAC, and a written report within 30 days as described in Paragraph (2) of Subsection C of 20.3.3.325 NMAC.

[5/3/1995; 20.3.15.1528 NMAC - Rn, 20 NMAC 3.1.15.1528, 4/15/2004; A, 4/30/2009]

HISTORY OF 20.3.15 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed as follows:
EIB 73-2, Regulations for Governing the Health and Environmental Aspects of Radiation filed on 7/9/1973;
EIB 73-2, Amendment 1, Regulations for Governing the Health and Environmental Aspects of Radiation filed on 4-17-78;
EIB RPR-1, Radiation Protection Regulations filed on 4/21/1980;
EIB RPR-1, Amendment 1, Radiation Protection Regulations filed on 10/13/1981;
EIB RPR-1, Amendment 2, Radiation Protection Regulations filed on 12/15/1982; and
EIB RPR-1, Radiation Protection Regulations filed on 3/10/1989.

History of Repealed Material: [**RESERVED**]

Other History: EIB RPR 1, Radiation Protection Regulations, filed 3/10/1989 renumbered and reformatted to 20 NMAC 3.1; Radioactive Materials and Radiation Machines, effective 5/3/1995;
20 NMAC 3.1; Radioactive Materials and Radiation Machines (filed 4/3/1995) internally renumbered, reformatted and replaced by 20 NMAC 3.1, Radioactive Materials and Radiation Machines, effective 7/30/1999.
20 NMAC 3.1.Subpart 15, Licenses and Radiation Safety Requirements for Irradiators (filed 6/17/1999) reformatted, amended and replaced by 20.3.15 NMAC, Licenses and Radiation Safety Requirements for Irradiators, effective 4/15/2004.

State Regulation, 20.3 NMAC	Federal Regulation 10 CFR	Comments
20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL: J.(1) (d) The applicant commits to [~~satisfies~~] the following labeling requirements.	*RATS 2018-1 category - B* **§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35** (a)(4) The applicant commits to the following labeling requirements:	**In § 32.72:** **(a)Revise the introductory text of (a)(4);** The applicant commits to the following labeling requirements: Based on RATS 2018-1 letter dated July 16, 2018
20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL: (J)(2) (f)shall provide to the Commission [~~department~~] a copy of (i)each individual's certification by a specialty board whose certification process has been recognized by the Commission [~~department, NRC~~] or agreement state as specified in 10 CFR 35.55(a)[~~Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(a), with the written attestation signed by a preceptor as required by Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(b)(2)~~]; or	*RATS 2018-1 category - B* **§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35** (5) Shall provide to the Commission: (i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or	**In § 32.72:** **(b)Revise (b)(5)(i);** A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or Based on RATS 2018-1 letter dated July 16, 2018

20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL: **(f)** ii) the Commission [~~department, NRC~~] or agreement state license, or (iii) Commission [~~the permit issued by a NRC~~] master material licensee permit, or (iv)the permit issued by a licensee or Commission [~~department, NRC or agreement state licensee, or NRC~~] master materials permittee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or	*none* **§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35** **(5)** (ii) The Commission or Agreement State license, or (iii) Commission master materials licensee permit, or (iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or	**RCB Correction** To align with current federal regulation
20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL: **(f)** (4) A licensee shall satisfy the labeling requirements in paragraph J(1)(d) of this section [~~Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs~~]. (5)Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.	RATS 2018-1 category - B **§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35** **(c)(2)** (d) A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section. (e) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.	**(c)Redesignate paragraph (d) as paragraph (e); and (d) Add new paragraph (d). to read as follows:** A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section. Based on RATS 2018-1 letter dated July 16, 2018

20.3.3.317 TERMS AND CONDITIONS OF LICENSES: A. Each license issued pursuant to the requirements in this part shall be subject to all the provisions of the act, now or hereafter in effect, and to all rules, regulations and orders of the board or department. (1) No right to the special nuclear material shall be conferred by the license except as defined by the license; (2) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of 20.3.3.317 NMAC; (3) The license shall be subject to and the licensee shall observe, all applicable rules, regulations and orders of the department.	*RATS 2018-2 category - C* **§ 70.32 Conditions of licenses.** (a) Each license shall contain and be subject to the following conditions: (2) No right to the special nuclear material shall be conferred by the license except as defined by the license; (3) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act; (8) The license shall be subject to and the licensee shall observe, all applicable rules, regulations and orders of the Commission.	**C: 70.32(a)(2), (a)(3), & (a)(8).** (a) Each license shall contain and be subject to the following conditions: (2) No right to the special nuclear material shall be conferred by the license except as defined by the license; (3) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act; (8) The license shall be subject to and the licensee shall observe, all applicable rules, regulations and orders of the Commission. Based on RATS 2018-2 letter dated November 21, 2018
20.3.3.317 TERMS AND CONDITIONS OF LICENSES: **E.Filing for bankruptcy.** (1)Each general licensee that is required to register by Paragraph (m) of Subsection B of 20.3.3.305 NMAC and each specific licensee shall notify the department and appropriate NRC Regional Administrator in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (bankruptcy) of the United States Code by or against:	RATS 2018-2 category - H&S **§ 70.32 Conditions of licenses.** (a) Each license shall contain and be subject to the following conditions: (9)(i) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:	**H&S: 70.32(a)(9)** § 70.32 Conditions of licenses. (a) Each license shall contain and be subject to the following conditions: (9)(i) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against: Based on RATS 2018-2 letter dated November 21, 2018

20.3.3.317 TERMS AND CONDITIONS OF LICENSES: I. Generators. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 20.3.7.706 NMAC of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 10 CFR 35.204(a) at the time of generator elution, in accordance with 10 CFR 35.3204.	*RATS 2018-1 category - B* **§ 30.34 Terms and conditions of licenses** (g) 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 § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a) of this chapter at the time of generator elution, in accordance with § 35.3204 of this chapter.	**In § 30.34, add a third sentence to paragraph (g) to read as follows:** (g)The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a) of this chapter at the time of generator elution, in accordance with § 35.3204 of this chapter. Based on RATS 2018-1 letter dated July 16, 2018
20.3.7.7 DEFINITIONS: C."Associate Radiation Safety Officer (ARSO)" means an individual who— (1) Meets the requirements in §§ 35.50 and 35.59; and (2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on— (a) A specific medical use license issued by the Commission or an Agreement State; or (b) A medical use permit issued by a Commission master material licensee.	*RATS 2018-1 category - B* **§ 35.2 Definitions.** Associate Radiation Safety Officer means an individual who— (1) Meets the requirements in §§ 35.50 and 35.59; and (2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on— (i) A specific medical use license issued by the Commission or an Agreement State; or (ii) A medical use permit issued by a Commission master material licensee.	**In § 35.2, add, in alphabetical order, the definitions for Associate Radiation Safety Officer...** Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.7 DEFINITIONS: V. "Ophthalmic physicist" means an individual who— (1) Meets the requirements in § 35.433(a)(2) and § 35.59; and (2) Is identified as an ophthalmic physicist on a— (a) Specific medical use license issued by the Commission or an Agreement State; (b) Permit issued by a Commission or Agreement State broad scope medical use licensee; (c) Medical use permit issued by a Commission master material licensee; or (d) Permit issued by a Commission master material licensee broad scope medical use permittee.	*RATS 2018-1 category - B* **§ 35.2 Definitions.** *Ophthalmic physicist means an individual who—* *(1) Meets the requirements in §§ 35.433(a)(2) and 35.59; and* *(2) Is identified as an ophthalmic physicist on a—* *(i) Specific medical use license issued by the Commission or an Agreement State;* *(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;* *(iii) Medical use permit issued by a Commission master material licensee; or* *(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.*	**In § 35.2, add, in alphabetical order, the definitions for.... Ophthalmic physicist….** Based on RATS 2018-1 letter dated July 16, 2018
20.3.7.7 DEFINITIONS: [~~AA~~]CC. "Preceptor" means an individual who provides, directs or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, [~~or a~~] R[~~r~~]adiation S[~~s~~]afety O[~~e~~]fficer, or a Associate Radiation Officer.	*RATS 2018-1 category - B* ***§ 35.2 Definitions.*** Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.	**In § 35.2, ... and revise the definition for Preceptor** … Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.702GENERAL ADMINISTRATIVE REQUIREMENTS: A.Radiation safety officer. (1)A licensee or licensee's management shall appoint a radiation safety officer, who agrees, in writing, to be responsible for implementing a radiation protection program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more	*RATS 2018-1 category - H&S* **§ 35.24 Authority and responsibilities for the radiation protection program.** (b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more.....	**In § 35.24, revise paragraphs (b) to read as follows:** (b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more .....
Continued Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.	**Continued** Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.	**Continued** Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation SafetyOfficer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.702GENERAL ADMINISTRATIVE REQUIREMENTS: G.Written directive. (3)(f)For permanent implant brachytherapy: (i) Before implantation: The treatment site, the radionuclide, and the total source strength; and (ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or [~~for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders, before implantation: treatment site, the radionuclide and dose; and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose).~~]	*RATS 2018-1 category - H & S* **§ 35.40 Written directives.** (6) For permanent implant brachytherapy: (i) Before implantation: The treatment site, the radionuclide, and the total source strength; and (ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or	**(b) revise paragraph (b)(6) to read as follows** (6) For permanent implant brachytherapy: (i) Before implantation: the treatment site, the radionuclide, and the total source strength; and (ii) After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.702GENERAL ADMINISTRATIVE REQUIREMENTS: G.Written directive. (3)(g) for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders: before implantation: the treatment site, [~~the~~] radionuclide and dose; and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose); and date.	*RATS 2018-1 category - H & S* **§ 35.40 Written directives.** *(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:* *(i) Before implantation: The treatment site, radionuclide, and dose; and* *(ii) After implantation but before completion of the procedure: The radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and date.*	**(b) revise paragraph (b)(6) to read as follows** (7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders: (i) Before implantation: the treatment site, radionuclide, and dose; and (ii) After implantation but before completion of the procedure: the radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and date. (c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.702 GENERAL ADMINISTRATIVE REQUIREMENTS: **G.Written directive.** (4) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.	*RATS 2018-1 category - H & S* **§ 35.40 Written directives.** *(c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.*	**Redesignate paragraph (c)(1) as paragraph (c)(2)** **to read as follows:** (c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

Continued If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.	**Continued** (2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.	**Continued** (2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.702 GENERAL ADMINISTRATIVE REQUIREMENTS: H.Procedures for administrations requiring a written directive. (2)(e) Determining if a medical event, as defined in 20.3.7.716 NMAC and 10 CFR 35.3045, has occurred; and (f) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.	*RATS 2018-1 category - H & S* **§ 35.41 Procedures for administrations requiring a written directive.** (5) Determining if a medical event, as defined in § 35.3045, has occurred; and (6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.	add new paragraphs (b)(5) and (b)(6) to read as follows: (5) Determining if a medical event, as defined in § 35.3045, has occurred; and (6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.706 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82 AND STRONTIUM-85 CONCENTRATIONS: B.Measurement. (1) A licensee preparing technetium-99m radiopharmaceutical from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration [~~of the first eluate after the receipt of the generator to demonstrate compliance with Subsection A of this section~~] in each eluate from a generator to demonstrate compliance with Subsection A of this section. D. Reporting. The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with subsection D of 20.3.7.716 NMAC and 10 CFR 35.3204.	*RATS 2018-1 category - H&S* **§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.** (b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (a) of this section. (e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with § 35.3204.	In § 35.204, revise paragraph (b) and add new paragraph (e) to read as follows: (b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (a) of this section. (e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with § 35.3204. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.708USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: A licensee may use any unsealed byproduct [~~radioactive~~] material identified in 10 CFR 35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is [~~either~~]:	*RATS 2018-1 category - B* **§ 35.300 Use of unsealed byproduct material for which a written directive is required.** A licensee may use any unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is—	revise the introductory text to read as follows: A licensee may use any unsealed byproduct material identified in §35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is— Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.710MANUAL BRACHYTHERAPY: A. Use of sources for manual brachytherapy. The regulations of the NRC set forth in 10 CFR 35.400 are hereby incorporated by reference. [~~A licensee shall use only brachytherapy sources for therapeutic medical uses:~~ ~~(1)as approved in the sealed source and device registry; or~~ ~~(2)in research in accordance with an active investigational device exemption application accepted by the FDA provided the requirements of Paragraph (1) of Section I of 20.3.7.702 NMAC are met.~~]	*RATS 2018-1 category - B* **§ 35.400 Use of sources for manual brachytherapy.** A licensee must use only brachytherapy sources: (a) Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or (b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.	In § 35.400 revise paragraphs (a) and (b) to read as follows: A licensee must use only brachytherapy sources: (a) Approved in the Sealed Source and Device Registry..... are met. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.710MANUAL BRACHYTHERAPY: G.Decay of strontium-90 sources for ophthalmic treatments. The regulations of the NRC set forth in 10 CFR 35.433 are hereby incorporated by reference. [~~(1)Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under Subsection F of 20.3.7.710 NMAC.~~ ~~(2)A licensee shall retain a record of the activity of each strontium-90 source in accordance with Subsection S of 20.3.7.715 NMAC.~~]	*RATS 2018-1 category - B* **§ 35.433 Strontium-90 sources for ophthalmic treatments.** (a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either: (1) An authorized medical physicist; or (2) An individual who: (i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and (ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and (iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and (iv) Has documented training in:	In § 35.433, revise paragraph (a), add new paragraphs (b), (b)(1) and (2), and redesignate paragraph (c) to read as follows: (a) Licensees who use strontium-90 for ophthalmic treatments must ensure that ..... Based on RATS 2018-1 letter dated July 16, 2018

Continued	Continued	Continued
	(A) The creation, modification, and completion of written directives; (B) Procedures for administrations requiring a written directive; and (C) Performing the calibration measurements of brachytherapy sources as detailed in § 35.432. (b) The individuals who are identified in paragraph (a) of this section must: (1) Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432; and (2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives. (c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433.	

20.3.7.711PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS: D(4) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training. (5[4])A licensee shall provide operational and safety instruction, initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, in: (a)the procedures identified in Subparagraph (d) of Paragraph (1) of this subsection; and (b)the operating procedures for the unit.	*RATS 2018-1 category - H&S* **§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.** (d)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training. (2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in— (i) The procedures identified in paragraph (a)(4) of this section; and (ii) The operating procedures for the unit.	**In § 35.610, add new paragraph (d)(1) and revise paragraphs (d) and (g) to read as follows:** ***** (d)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training. (2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as

Continued (8[~~7~~])A licensee shall retain a copy of the procedures required by Subparagraph (d) of Paragraph (1) and Subparagraph (b) of Paragraph (5[4]) of this subsection in accordance with Subsection U of 20.3.7.715 NMAC.	**Continued**	**Continued** appropriate to the individual's assigned duties. The instructions shall include instruction in— (i) The procedures identified in paragraph (a)(4) of this section; and (ii) The operating procedures for the unit. ***** (g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.711PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS: O.Five-year inspection for teletherapy and gamma stereotactic radiosurgery units. (1)A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement [~~or at intervals not to exceed 5 years, whichever comes first,~~] to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.	*RATS 2018-1 category - H&S* **§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.** (a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.	**In § 35.655, revise the section heading and paragraph (a) to read as follows:** (a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.712 SEALED SOURCES FOR DIAGNOSIS: A.Use of sealed sources for diagnosis. A licensee shall use only sealed sources for diagnostic medical uses [~~as approved in the sealed source and device registry~~] if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.	*RATS 2018-1 category - C* **§ 35.500 Use of sealed sources and medical devices for diagnosis.** (a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. (b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.	**In § 35.500 revise paragraph (a), and add new paragraphs (b) and (c) to read as follows:** (a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. (b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses.

Continued C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 10 CFR 35.49(a) are met.	**Continued** (c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.	**Continued** The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. (c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met. Based on RATS 2018-1 letter dated July 16, 2018
20.3.7.714 TRAINING REQUIREMENTS: A.Radiation safety officer and Associate Radiation Safety Officer. The regulations of the NRC set forth in 10 CFR 35.50 are hereby incorporated by reference.	*RATS 2018-1 category - B* **§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer.**	Revise § 35.50 to read as follows: incorporated by reference Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.716 REPORTS:

A.Report and notification of a medical event.

(1) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct [~~radioactive~~] material or radiation from byproduct [~~radioactive~~] material, except permanent implant brachytherapy, results in:

(a) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rems (50 millisieverts) effective dose equivalent, 50 rems (0.5 sievert) to an organ or tissue or 50 rems (0.5 sievert) shallow dose equivalent to the skin; and:

(i)the total dose delivered differs from the prescribed dose by twenty percent or more;

(ii)the total dosage delivered differs from the prescribed dosage by twenty percent or more or falls outside the prescribed dosage range; or

(iii)the fractionated dose delivered differs from the prescribed dose, for a single fraction, by fifty percent or more;

(b)a dose that exceeds 5 rems (50 millisieverts) effective dose equivalent, 50 rems (0.5 sievert) to an organ or tissue, or 50 rems (0.5 sievert) shallow dose equivalent to the skin from any of the following:

RATS 2018-1 category - C

Subpart M—Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which—

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in—

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

(ii) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

In § 35.3045, revise paragraph (a) to read as follows:

(a) A licensee shall report any event as a medical event, exceptfor an event that results from patient intervention, in which—

(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in—

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

Continued (i)an administration of a wrong radioactive drug containing byproduct[~~radioactive~~] material; (ii)an administration of a radioactive drug containing radioactive material by the wrong route of administration; (iii)an administration of a dose or dosage to the wrong individual or human research subject; (iv)an administration of a dose or dosage delivered by the wrong mode of treatment; or (v)a leaking sealed source; and	**Continued** A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure; (B) An administration of a radioactive drug containing byproduct material by the wrong route of administration; (C) An administration of a dose or dosage to the wrong individual or human research subject; (D) An administration of a dose or dosage delivered by the wrong mode of treatment; or (E) A leaking sealed source.	**Continued** (B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or (C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more20 percent of the total source strength documented in the post-implantation portion of the written directive; or
(c)a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rems (0.5 sievert) to an organ or tissue and fifty percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site). (d) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—	(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by: (A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and (B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration. (2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—	**Continued** (ii) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following— (A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure; (B) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

Continued (i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive; (ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or (iii) An administration that includes any of the following: the wrong radionuclide; the wrong individual or human research subject; sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.	**Continued** (i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive; (ii) The total source strength administered outside of thetreatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or (iii) An administration that includes any of the following: (A) The wrong radionuclide; (B) The wrong individual or human research subject; (C) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or (D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.	**Continued** (C) An administration of a dose or dosage to the wrong individual or human research subject; (D) An administration of a dose or dosage delivered by the wrong mode of treatment; or (E) A leaking sealed source. (iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by: (A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

Continued	**Continued**	**Continued** (B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration. (2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in— (i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;
Continued	**Continued**	**Continued** (ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or (iii) An administration that includes any of the following: (A) The wrong radionuclide; (B) The wrong individual or human research subject;

Continued	**Continued**	**Continued** (C) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or (D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue. Based on RATS 2018-1 letter dated July 16, 2018

20.3.7.716REPORTS: D. Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations: (1) The licensee shall notify by telephone the department and NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the department and NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.	*RATS 2018-1 category - C* **§ 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.** (a) The licensee shall notify by telephone the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.	**Add a new § 35.3204 to subpart M to read as follows:** (a) The licensee shall notify by telephone the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.

Continued (2) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the department and appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (1) of this section.	**Continued** (b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section.	Continued (b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects;
Continued	**Continued**	**Continued** and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section. Based on RATS 2018-1 letter dated July 16, 2018

RCB Corrections and Amendments		
20.3.3.307 FILING APPLICATION FOR SPECIFIC LICENSES: 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: (4)the license required report of events or notification in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 71, 10 CFR 37.77(a) through (d), and 10 CFR 37.81 shall use the following address when applicable: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469.	*none*	**RCB Correction to allign with NRC regulations.**
20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL: J.Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct [~~radioactive~~] material for medical use under 20.3.7 NMAC.	*None* PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL § 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35	**RCB Correction to align with current federal regulation**

20.3.5.10 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY: 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: (4)for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81 the licensee shall use the following address when applicable: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.	*none*	**RCB Correction to allign with NRC regulations.**
20.3.7.700 GENERAL REGULATORY REQUIREMENTS: E. Application for license, amendment or renewal. (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: (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 when applicable: New Mexico environment department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.	*none*	**RCB Correction to allign with NRC regulations.**

20.3.12.9 SPECIFIC LICENSES FOR WELL LOGGING: 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: (4) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81, the licensee shall use the following address when applicable: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.	*none*	**RCB Correction to allign with NRC regulations.**
20.3.15.1502 SPECIFIC LICENSES FOR IRRADIATORS: 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: (4) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), 10 CFR 37.81, the licensee shall use, when applicable, New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information.	*none*	**RCB Correction to allign with NRC regulations.**