



State of Utah

GARY R. HERBERT
Governor

GREG BELL
Lieutenant Governor

Department of
Environmental Quality

Amanda Smith
Executive Director

DIVISION OF RADIATION CONTROL
Dane L. Finerfrock
Director

April 6, 2010

Terrence Reis, Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington, D.C. 20555-0001

Dear Mr. Reis:

Enclosed is a copy of the revisions to the proposed Utah Division of Radiation Control Rules R313-19-13 and 30, and R313-21-22. The proposed revisions will be made available for public comment on May 1, 2010 with a request for comments by May 31, 2010. We request NRC's comments by May 31, 2010. The proposed regulations are identified by underline/strike-out text and correspond to the following equivalent amendment to NRC's regulations.

| <u>Rats ID</u> | <u>Title</u> | <u>State Section</u> |
|----------------|---|--------------------------------|
| 2007-2 | Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements | R313-19-13 & 30; R313-21-22 |

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact Philip Griffin of my staff at (801) 536-4250 or pgriffin@utah.gov.

Sincerely,

Dane L. Finerfrock, Director
Utah Division of Radiation Control

Enclosures

R313. Environmental Quality, Radiation Control.

R313-19. Requirements of General Applicability to Licensing of Radioactive Material.

R313-19-13. Exemptions.

(1) Source material.

(a) A person is exempt from Rules R313-19, R313-21, and R313-22 to the extent that the person receives, possesses, uses, owns, or transfers source material in a chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of one percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) A person is exempt from Rules R313-19, R313-21, and R313-22 to the extent that the 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 the ore.

(c) A person is exempt from Rules R313-19, R313-21, and R313-22 to the extent that the person receives, possesses, uses or transfers:

(i) any quantities of thorium contained in:

(A) incandescent gas mantles,

(B) vacuum tubes,

(C) welding rods,

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

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

(F) rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent 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;

(ii) source material contained in the following products:

(A) glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

(B) piezoelectric ceramic containing not more than two percent by weight source material, or

(C) glassware containing not more than ten percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

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

(iv) a finished product or part fabricated of, or containing, tungsten-thorium 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 the product or part;

(v) uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of the counterweights,

provided that:

(A) the counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission authorizing distribution by the licensee pursuant to 10 CFR Part 40,

(B) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM",

(C) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED",

(D) The requirements specified in Subsections R313-19-13(1)(c)(v)(B) and (C) 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", as previously required by the rules, and

(E) the exemption contained in Subsection R313-19-13(1)(c)(v) shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of counterweights other than repair or restoration of any plating or other covering;

(vi) natural or depleted uranium metal used as shielding constituting part of a 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 inch (3.2 mm);

(vii) thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

(A) the shaping, grinding, or polishing of a lens or manufacturing processes other than the assembly of such lens into optical systems and devices without alteration of the lens, or

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

(viii) uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie (185.0 Bq) of uranium; or

(ix) thorium contained in a 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) The exemptions in Subsection R313-19-13(1)(c) do not authorize the manufacture of any of the products described.

(2) Radioactive material other than source material.

(a) Exempt concentrations.

(i) Except as provided in Subsection R313-19-13(2)(a)(ii) a person is exempt from Rules R313-19, R313-21 and R313-22 to the extent that the person receives, possesses, uses, transfers, owns

or acquires products or materials containing:

(A) radioactive material introduced in concentrations not in excess of those listed in Section R313-19-70, or

(B) natural occurring radioactive materials containing less than 15 picocuries per gram radium-226.

(ii) A person may not introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under Subsection R313-19-13(2)(a)(i) or equivalent regulations of a Licensing State, the U.S. Nuclear Regulatory Commission or an Agreement State, except in accordance with a specific license issued pursuant to Subsection R313-22-75(1) [~~or the general license provided in Section R313-19-30~~].

(b) Exempt quantities.

(i) Except as provided in Subsections R313-19-13(2)(b)(ii) [~~and (iii)~~] through (iv) a person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities which do not exceed the applicable quantity set forth in Section R313-19-71.

(ii) Subsection R313-19-13(2)(b) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(iii) A person may not, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Section R313-19-71, knowing or having reason to believe that the quantities of radioactive material will be transferred to persons exempt under Subsection R313-19-13(2)(b) or equivalent regulations of a Licensing State, the U.S. Nuclear Regulatory Commission or an Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, pursuant to 10 [~~C.F.R.~~]CFR Part 32 or by the Executive Secretary pursuant to Subsection R313-22-75(2), which license states that the radioactive material may be transferred by the licensee to persons exempt under Subsection R313-19-13(2)(b) or the equivalent regulations of a Licensing State, the U.S. Nuclear Regulatory Commission or an Agreement State.

(iv) A person who possesses radioactive material received or acquired prior to September 25, 1971, under the general license formerly provided in 10 [~~C.F.R.~~]CFR Part 31. ~~5~~⁴ is exempt from the requirements for a license set forth in Rule R313-19 to the extent that the person possesses, uses, transfers or owns the radioactive material. This exemption does not apply for radium-226.

(v) 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 exceeds the limits set forth in R313-19-71, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise provided by these rules.

(c) Exempt items.

(i) Certain items containing radioactive material. Except

for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, a person is exempt from these rules to the extent that 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 (925.0 MBq) of tritium per timepiece;

(II) five millicuries (185.0 MBq) of tritium per hand;

(III) 15 millicuries (555.0 MBq) of tritium per dial. Bezels when used shall be considered as part of the dial;

(IV) 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece;

(V) 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of promethium-147 per other timepiece hand;

(VI) 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of promethium-147 per other timepiece dial. Bezels when used shall be considered as part of the dial;

(VII) the radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

for wrist watches, 0.1 millirad (1.0 uGy) per hour at ten centimeters from any surface;

for pocket watches, 0.1 millirad (1.0 uGy) per hour at one centimeter from any surface;

for other timepieces, 0.2 millirad (2.0 uGy) per hour at ten centimeters from any surface;

(VIII) one microcurie (37.0 kBq) of radium-226 per timepiece in timepieces manufactured prior to the effective date of these rules.

~~(B) [Lock illuminators containing not more than 15 millicuries (555.0 MBq) of tritium or not more than two millicuries (74.0 MBq) of promethium 147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium 147 will not exceed one millirad (10 uGy) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.~~

~~—(C)] Precision balances containing not more than one millicurie (37.0 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part manufactured before June 9, 2010.~~

~~[(D) Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.~~

~~—(E)](C) Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured before June 9, 2010.~~

~~[(F) Thermostat dials and pointers containing not more than 25 millicuries (925.0 MBq) of tritium per thermostat.~~

~~—(G)]~~

(D) Ionization chamber smoke detectors containing not more than 1 microcurie (37 kBq) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(E) Electron tubes, including spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and other completely sealed tubes that are designed to conduct or control electrical currents; provided that each tube does not contain more than one of the following specified quantities of radioactive material:

(I) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or ten millicuries (370.0 MBq) of tritium per any other electron tube;

(II) one microcurie (37.0 kBq) of cobalt-60;

(III) five microcuries (185.0 kBq) of nickel-63;

(IV) 30 microcuries (1.11 MBq) of krypton-85;

(V) five microcuries (185.0 kBq) of cesium-137;

(VI) 30 microcuries (1.11 MBq) of promethium-147;

(VII) one microcurie (37.0 kBq) of radium-226;

and provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed one millirad (10.0 uGy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber.

~~[(H)]~~ (F) 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 Section R313-19-71; and

(II) each instrument contains no more than ten exempt quantities. For purposes of 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 exempt quantities in Section R313-19-71, provided that the sum of the fractions shall not exceed unity;

(III) for purposes of Subsection R313-19-13(2)(c)(i)(H), 0.05 microcurie (1.85 kBq) of americium-241 is considered an exempt quantity under Section R313-19-71.

~~[(I) Spark gap irradiators containing not more than one microcurie (37.0 kBq) of cobalt 60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons (11.4 liters) per hour.~~

— (ii) Self-luminous products containing radioactive material.

(A) Tritium, krypton-85 or promethium-147. Except for persons who manufacture, process or produce self-luminous products containing tritium, krypton-85 or promethium-147, a person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a

specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 [C.F.R.]CFR Part 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in Subsection R313-19-13(2)(c)(ii) does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.

(B) Radium-226. A person is exempt from these rules, to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to the effective date of these rules.

(iii) Gas and aerosol detectors containing radioactive material.

(A) Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, a person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 [~~C.F.R.~~]CFR Part 32.26, or a Licensing State pursuant to Subsection R313-22-75(3) or equivalent requirements, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(B) Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under Subsection R313-19-13(2)(c)(iii)(A), provided that the device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and provided further that they meet the requirements of Subsection R313-22-75(3).

(C) Gas and aerosol detectors containing naturally occurring and accelerator-produced radioactive material (NARM) previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under Subsection R313-19-13(2)(c)(iii)(A), provided that the device is labeled in accordance with the specific license authorizing distribution, and provided further that they meet the requirements of Subsection R313-22-75(3).

(iv) Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

(A) Except as provided in Subsection R313-19-13(2)(c)(iv)(B), any person is exempt from the requirements in Rules R313-19 and R313-32 provided that the person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 uCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(B) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific

license pursuant to Rule R313-32.

(C) Nothing in Subsection R313-19-13(2)(c)(iv) relieves persons from complying with applicable United States Food and Drug Administration, other Federal, and State requirements governing receipt, administration, and use of drugs.

~~(v) [Resins containing scandium 46 and designed for sand consolidation in oil wells. A person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium 46 which are designed for sand consolidation in oil wells. The resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the Executive Secretary or an Agreement State to the manufacturer of resins pursuant to licensing requirements equivalent to those in 10 C.F.R. Part 32.16 and 32.17. This exemption does not authorize the manufacture of any resins containing scandium 46.~~

~~_____~~(vi) With respect to Subsections R313-19-13(2)(b)(iii), R313-19-13(2)(c)(i), (iii) and (iv), the authority to transfer possession or control by the manufacturer, processor, or producer of equipment, devices, commodities, or other products containing byproduct material whose subsequent possession, use, transfer, and disposal by other persons is exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

R313-19-30. Reciprocal Recognition of Licenses.

(1) Subject to these rules, a person who holds a specific license from the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State, and issued by the agency 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 the licensing document within this state, except in areas of exclusive federal jurisdiction, for a period not in excess of 180 days in a calendar year provided that:

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

(b) the out-of-state licensee notifies the Executive Secretary in writing at least three days prior to engaging in such activity. Notifications shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Executive Secretary, obtain permission to proceed sooner. The Executive Secretary may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the

general license provided in Subsection R313-19-30(1);

(c) the out-of-state licensee complies with all applicable rules of the Board and with the terms and conditions of the licensing document, except those terms and conditions which may be inconsistent with applicable rules of the Board;

(d) the out-of-state licensee supplies other information as the Executive Secretary may request; and

(e) the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in Subsection R313-19-30(1) except by transfer to a person[+

~~—(i)—] specifically licensed by the Executive Secretary or by the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State to receive the material[, or~~

~~—(ii)— exempt from the requirements for a license for material under Subsection R313-19-13(2)(a)].~~

(2) Notwithstanding the provisions of Subsection R313-19-30(1), a person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, a Licensing State, or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in Subsection R313-21-22(4) within the areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service a device in this state provided that:

(a) the person shall file a report with the Executive Secretary within thirty days after the end of a calendar quarter in which a device is transferred to or installed in this state. Reports shall identify each general licensee to whom a device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

(b) the device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to the person by the Nuclear Regulatory Commission, a Licensing State, or an Agreement State;

(c) the person shall assure that any labels required to be affixed to the device under rules of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

(d) the holder of the specific license shall furnish to the general licensee to whom the device is transferred or on whose premises a device is installed a copy of the general license contained in Subsection R313-21-22(4) or in equivalent rules of the agency having jurisdiction over the manufacture and distribution of the device.

(3) The Executive Secretary may withdraw, limit, or qualify his acceptance of a specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State, or a product distributed pursuant to the licensing document, upon determining that the action is necessary in order to prevent undue hazard to public health and safety or the environment.

KEY: license, reciprocity, transportation, exemptions

Date of Enactment or Last Substantive Amendment: [~~October 8,~~
~~2007~~] June 9, 2010

Notice of Continuation: October 5, 2006

Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-3-
108

R313. Environmental Quality, Radiation Control.

R313-21. General Licenses.

R313-21-22. General Licenses*--Radioactive Material Other Than Source Material.

NOTE: *Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

(1) Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the Executive Secretary, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of R313-12-51 through R313-12-70, R313-14, R313-15, R313-18 and R313-19 as applicable.

(a) Static Elimination Devices. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 megabecquerel (500 uCi) of polonium-210 per device.

(b) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 megabecquerel (500 uCi) of polonium-210 per device or a total of not more than 1.85 gigabecquerel (50 mCi) of hydrogen-3 (tritium) per device.

(2) RESERVED.

(3) RESERVED.

(4) Certain detecting, measuring, gauging or controlling devices and certain devices for producing light or an ionized atmosphere.*

NOTE: *Persons possessing radioactive material in devices under a general license in R313-21-22(4) before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of R313-21-22(4) in effect on January 14, 1975.

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of R313-21-22(4)(b), (c) and (d), radioactive material, excluding special nuclear 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.

(b)(i) The general license in R313-21-22(4)(a) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

(A) a specific license issued by the Executive Secretary pursuant to R313-22-75(4); or

(B) an equivalent specific license issued by the Nuclear

Regulatory Commission, an Agreement State or a Licensing State.*

NOTE: *Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(ii) The devices must have been received from one of the specific licensees described in R313-21-22(4)(b)(i) or through a transfer made under R313-21-22(4)(c)(ix).

(c) Any person who owns, acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in R313-21-22(4)(a):

(i) 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 the labels;

(ii) 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 other intervals as are specified in the label; however:

(A) Devices containing only krypton need not be tested for leakage of radioactive material, and

(B) Devices containing only tritium or not more than 3.7 megabecquerel (100 uCi) of other beta, gamma, or both, emitting material or 0.37 megabecquerel (10 uCi) 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;

(iii) shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

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

(B) by a person holding a specific license pursuant to R313-22 or from the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such activities;

(iv) shall maintain records showing compliance with the requirements of R313-21-22(4)(c)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from the installation the radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(A) Each record of a test for leakage ~~of~~ of radioactive material required by R313-21-22(4)(c)(ii) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;

(B) Each record of a test of the on-off mechanism and indicator required by R313-21-22(4)(c)(ii) 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;

(C) Each record that is required by R313-21-22(4)(c)(iii) shall be retained for three years from the date of the recorded event or until the device is transferred or disposed of;

(v) 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 185 becquerel (0.005 uCi) 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 the device that was issued by the Executive Secretary, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The device and any radioactive material from the device may 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 Executive Secretary, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 becquerel (0.005 uCi) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Executive Secretary within 30 days. Under these circumstances, the criteria set out in R313-15-402 may be applicable, as determined by the Executive Secretary on a case-by-case basis;

(vi) shall not abandon the device containing radioactive material;

(vii) shall not export the device containing radioactive materials except in accordance with 10 CFR 110;

(viii)(A) shall transfer or dispose of the device containing radioactive material only by export as provided by R313-21-22(4)(c)(vii), by transfer to another general licensee as authorized in R313-21-22(4)(c)(ix), to a person authorized to receive the device by a specific license issued under R313-22, to an authorized waste collector under R313-25, or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State, or as otherwise approved under R313-21-22(4)(c)(viii)(C);

(B) shall furnish a report to the Executive Secretary within 30 days after transfer of a device to a specific licensee or export. The report must contain:

(I) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(II) the name, address, and license number of the person receiving the device, the license number is not applicable if exported; and

(III) the date of the transfer;

(C) shall obtain written approval from the Executive Secretary before transferring the device to any other specific licensee not specifically identified in R313-21-22(4)(c)(viii)(A); 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:

(I) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(II) removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by R313-21-22(4)(c)(i)) so that the device is labeled in compliance with R313-15-904; however, the manufacturer, model number, and serial number must be retained;

(III) 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

(IV) reports the transfer under R313-21-22(4)(c)(viii)(B);

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

(A) the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of R313-21-22(4), R313-12-51, R313-15-1201, and R313-15-1202, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Executive Secretary:

(I) the manufacturer's or initial transferor's name;

(II) the model number and serial number of the device transferred;

(III) the transferee's name and mailing address for the location of use; and

(IV) the name, title, and phone number of the responsible individual identified by the transferee in accordance with R313-21-22(4)(c)(xiii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(B) 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;

(x) shall comply with the provisions of R313-15-1201 and R313-15-1202 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of R313-15 and R313-18;

(xi) shall respond to written requests from the Executive Secretary 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 submitting a letter to the Executive Secretary and provide written justification as to why it cannot comply;

(xii) 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;

(xiii)(A) shall register, in accordance with R313-21-22(4)(c)(xiii)(B) and (C), devices containing at least 370 megabecquerel (ten mCi) of cesium-137, 3.7 megabecquerel (0.1 mCi) of strontium-90, 37 megabecquerel (one mCi) of cobalt-60, 3.7

megabecquerel (0.1 mCi) of radium-226, or 37 megabecquerel (one mCi) of americium-241 or any other transuranic, (elements with atomic number greater than uranium-92), based on the activity indicated on the label. Each address for a location of use, as described under R313-21-22(4)(c)(xiii)(C)(IV) represents a separate general licensee and requires a separate registration and fee;

(B) if in possession of a device meeting the criteria of R313-21-22(4)(c)(xiii)(A), shall register these devices annually with the Executive Secretary and shall pay the fee required by R313-70. Registration shall include verifying, correcting, or adding, as appropriate, to the information provided in a request for registration received from the Executive Secretary. The registration information must be submitted to the Executive Secretary 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 R313-21-22(4)(c)(xiii)(A) is subject to the bankruptcy notification requirement in R313-19-34(5) and (6);

(C) in registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Executive Secretary:

(I) name and mailing address of the general licensee;

(II) information about each device: the manufacturer or initial transferor, model number, serial number, the radioisotope and activity as indicated on the label;

(III) name, title, and telephone number of the responsible person designated as a representative of the general licensee under R313-21-22(4)(c)(xii);

(IV) address or location at which the device(s) are used, stored, or both. For portable devices, the address of the primary place of storage;

(V) 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

(VI) certification by the responsible representative of the general licensee that they are aware of the requirements of the general license; and

(D) persons generally licensed by the Nuclear Regulatory Commission, an Agreement State, or Licensing State with respect to devices meeting the criteria in R313-21-22(4)(c)(xiii)(A) are not subject to registration requirements if the devices are used in areas subject to Division jurisdiction for a period less than 180 days in any calendar year. The Executive Secretary will not request registration information from such licensees;

(xiv) shall report changes to the mailing address for the location of use, including changes in the name of a general licensee, to the Executive Secretary 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; and

(xv) may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the

shutter must be locked in the closed position. The testing required by R313-21-22(4)(c)(ii) 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 must 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.

(d) The general license in R313-21-22(4)(a) does not authorize the manufacture or import of devices containing radioactive material.

(e) The general license provided in R313-21-22(4)(a) is subject to the provisions of R313-12-51 through R313-12-53, R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100.

(5) Luminous safety devices for aircraft.

(a) 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:

(i) each device contains not more than 370.0 gigabecquerel (10 Ci) of tritium or 11.1 gigabecquerel (300 mCi) of promethium-147; and

(ii) each device has been manufactured, assembled or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission or an Agreement State, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Executive Secretary or an Agreement State to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in R313-22-75(5).

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in R313-21-22(5) are exempt from the requirements of R313-15 and R313-18, except that they shall comply with the provisions of R313-15-1201 and R313-15-1202.

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

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

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

(f) This general license is subject to the provisions of R313-12-51 through R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100.

(6) Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of R313-21, this general license does not authorize the manufacture, production, transfer, receipt, possession, use, import, or export of radioactive material except as authorized in a specific license.

(7) Calibration and reference sources.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer, in the form of calibration or reference sources, americium-241, plutonium or radium-226 in accordance with the provisions of R313-21-22(7)(b) and (c), to a person who holds a specific license issued by the Executive Secretary which authorizes that person to receive, possess, use and transfer radioactive material.

(b) The general license in R313-21-22(7)(a) applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the Nuclear Regulatory Commission pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Executive Secretary, a Licensing State, or an Agreement State in accordance with requirements equivalent to 10 CFR 32.57 or 10 CFR 70.39.

(c) The general license provided in R313-21-22(7)(a) is subject to the provisions of R313-12-51 through R313-12-53, R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, R313-19-100, R313-15 and R313-18. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to these general licenses:

(i) shall not possess at any one time, at any one location of storage or use, more than 185.0 kilobecquerel (5 uCi) of americium-241, 185.0 kilobecquerel (5 uCi) of plutonium, or 185.0 kilobecquerel (5 uCi) of radium-226 in such source;

(ii) shall not receive, possess, use or transfer a source unless the source, or the storage container, bears a label which includes one of the following statements 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 No., Serial No., 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 (AMERICIUM-241) (PLUTONIUM) (RADIUM-226)*
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

.....
Typed or printed name of the manufacturer or initial transferor

NOTE: *Show the name of the appropriate material.

(iii) shall not transfer, abandon, or dispose of a source except by transfer to a person authorized by a license from the Executive Secretary, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to receive the source;

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

(v) shall not use a source for any purpose other than the

calibration of radiation detectors or the standardization of other sources.

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

(8) RESERVED.

(9) General license for use of radioactive material for certain in vitro clinical or laboratory testing.*

NOTE: *The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drug in interstate commerce.

(a) 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 the following stated tests, in accordance with the provisions of R313-21-22(9) (b), (c), (d), (e), and (f) the following radioactive materials in prepackaged units for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) iodine-125, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(ii) iodine-131, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(iii) carbon-14, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(iv) hydrogen-3 (tritium), in units not exceeding 1.85 megabecquerel (50 uCi) each;

(v) iron-59, in units not exceeding 740.0 kilobecquerel (20 uCi) each;

(vi) cobalt-57, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(vii) selenium-75, in units not to exceed 370.0 kilobecquerel (10 uCi) each; or

(viii) mock iodine-125, reference or calibration sources, in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 185.0 becquerel (0.005 uCi) of americium-241 each.

(b) A person shall not receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by R313-21-22(9)(a) until that person has filed form DRC-07, "Registration Form-In Vitro Testing with Radioactive Material Under General License," with the Executive Secretary and received a Certificate of Registration signed by the Executive Secretary, or until that person has been authorized pursuant to R313-32 to use radioactive material under the general license in R313-21-22(9). The physician, veterinarian, clinical laboratory or hospital shall furnish on form DRC-07 the following information and other information as may be required by that form:

(i) name and address of the physician, veterinarian, 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 R313-21-22(9)(a) and that the tests will be performed only by personnel competent in the use of radiation measuring instruments and in the handling of the radioactive material.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by R313-21-22(9)(a) shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in R313-21-22(9)(a) at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, cobalt-57, or any combination, in excess of 7.4 megabecquerel (200 uCi).

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

(iii) The general licensee shall use the radioactive material only for the uses authorized by R313-21-22(9)(a).

(iv) The general licensee shall not transfer the radioactive material except to a person authorized to receive it pursuant to a license issued by the Executive Secretary, the Nuclear Regulatory Commission, an Agreement State or Licensing State, nor transfer the radioactive material in a manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in R313-21-22(9)(a)(viii) as required by R313-15-1001.

(vi) The general licensee shall pay annual fees pursuant to R313-70.

(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to R313-21-22(9)(a):

(i) Except as prepackaged units which are labeled in accordance with the provision of a specific license issued pursuant to R313-22-75([&]7) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3(tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under R313-22(9) or its equivalent, and

(ii) 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 United States 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"

(e) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license in R313-21-22(9)(a) shall report in writing to the Executive Secretary, changes in the information previously furnished in the "Registration Form-In Vitro Testing with Radioactive Material Under General License", form DRC -07. The report shall be furnished within 30 days after the effective date of the change.

(f) Any person using radioactive material pursuant to the general license of R313-21-22(9)(a) is exempt from the requirements of R313-15 and R313-18 with respect to radioactive material covered by that general license, except that persons using the Mock Iodine-125 described in R313-21-22(9)(a)(viii) shall comply with the provisions of R313-15-1001, R313-15-1201 and R313-15-1202.

(10) Ice Detection Devices.

(a) 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 1.85 megabecquerel (50 uCi) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Executive Secretary, an Agreement State, or a Licensing State to the manufacturer of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

(b) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in R313-21-22(10)(a):

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from over-heating 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 Executive Secretary, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to manufacture or service the device; or shall dispose of the device pursuant to the provisions of R313-15-1001;

(ii) 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 thereon; and

(iii) are exempt from the requirements of R313-15 and R313-18 except that the persons shall comply with the provisions of R313-15-1001, R313-15-1201 and R313-15-1202.

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

(d) This general license is subject to the provision of R313-12-51 through R313-12-53, R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100 of these rules.

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