State of Utah

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Department of
Environmental Quality

Alan Matheson
Executive Director

DIVISION OF WASTE MANAGEMENT
AND RADIATION CONTROL
Ty L. Howard
Director

June 19, 2019

Kevin Williams, Deputy Director
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
AgreementStateRegs.Resource@nrc.gov

Dear Mr. Williams:

Enclosed is a copy of the revisions to the proposed changes for R313-19-34, *Terms and Conditions of Licenses*, R313-22-75, *Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material.*, and R313-32, *Medical Use of Radioactive Material*, of the Utah Administrative Code. The proposed revisions will be made available for public comment on July 1, 2019, with a request for comments by July 31, 2019. We request NRC's comments by July 31, 2019. The proposed regulations are identified by line-in/line-out text (or similar identification) and correspond to the following equivalent amendments to NRC's regulations as modified in:

1. RATS ID # 2018-01, "Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments."; and

2. Additional requirements added in 10 CFR 35.92 to address decay in storage (DIS) for radiopharmaceuticals with half-lives greater than 120 days but less than 175 days. The requirements in 10 CFR 35.92 have been assigned a "Health & Safety" Compatibility Category by NRC; therefore, the State of Utah believes that the modification of 10 CFR 35.92 will still meet the NRC's compatibility requirements. Recently medical facilities in the State have begun to use Lutecium-177 (Lu-177), for the targeted radionuclide therapy for the treatment of certain tumors. The Lu-177 contains a small percentage of Lutetium-177m (Lu-177m) in the radiopharmaceutical used in these treatments. Lutetium-177m has a half-life of approximately 160.4 days which means that the waste from these treatments cannot be held for DIS in accordance with 10 CFR 35.92 if Lu-177m is present. Licensees would therefore be required to

(Over)

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dispose of this waste as low-level radioactive waste by sending the materials to the Northwest Compact disposal site in Hanford, Washington. The Commission may grant exceptions or exemptions to the requirements provided it determines they are authorized by law and will not result in undue hazard to public health and safety or the environment. Over the years, the Commission has granted licensees authorization to hold radioactive wastes with half-lives greater than 120 days provided certain conditions are met. The State of Utah has a Board that may grant the same exception or exemptions; however, the Board only meets once a month. In anticipation of the increased usage of Lu-177 for treatments and an increase in requests for exceptions or exemptions to the requirements in 10 CFR 35.92, the State is proactively attempting to address licensee requests for the ability to hold this waste for DIS without having to wait for the Board to meet. Utah is proposing a requirement in 10 CFR 35.92 in addition to the NRC requirements, that will allow the Director to address these requests through a license amendment providing certain criteria are met for storing, securing, and disposing of the waste. The approval for the storage of Lu-177m waste will be reviewed and approved on a case by case basis. The decision will be recorded in the radioactive materials license for ease of tracking those facilities who are authorized to store the Lu-177m waste for DIS and those that must dispose of the waste as low-level radioactive waste.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200.

If you have any questions, please feel free to contact Gwyn Galloway by email at ggalloway@utah.gov or by phone at 801-536-4258.

Sincerely,

Ty L. Howard, Director
Division of Waste Management and Radiation Control

TLH/GEG/kb

Enclosure: R313-19-34, *Terms and Conditions of Licenses* (DRC-2019-005682)
R313-22-75, *Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products* (DRC-2019-005683)
R313-32, *Medical Use of Radioactive Material* (DRC-2019-005684)
Regulation Crosswalk for RATS ID 2018-01 (DRC-2019-005685)

c: Michelle Beardsley, US NRC/NMSS/MSST/SLPB (Email)
Jacqueline "Jackie" D. Cook, US NRC Region IV/Regional Agreement States Officer (Email)

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-19. Requirements of General Applicability to Licensing of Radioactive Material.
R313-19-34. Terms and Conditions of Licenses.

(1) Licenses issued pursuant to Rule R313-19 shall be subject to provisions of the Act, now or hereafter in effect, and to all rules, and orders of the Director.

(2)(a) Licenses issued or granted under Rules R313-21 and R313-22 and rights to possess or utilize radioactive material granted by a license issued pursuant to Rules R313-21 and R313-22 shall not be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of a license to a person unless the Director shall, after securing full information find that the transfer is in accordance with the provisions of the Act now or hereafter in effect, and to all rules, and orders of the Director, and shall give his consent in writing.

(b) An application for transfer of license shall include:

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

(ii) Financial assurance for decommissioning information required by R313-22-35.

(3) Persons licensed by the Director pursuant to Rules R313-21 and R313-22 shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

(4) Licensees shall notify the Director in writing and request termination of the license when the licensee decides to terminate activities involving materials authorized under the license.

(5) Licensees shall notify the Director 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 USC 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 USC 101(2), of the licensee.

(6) The notification specified in Subsection R313-19-34(5) shall indicate:

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

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

(7) Licensees required to submit emergency plans pursuant to Subsection R313-22-32(8) shall follow the emergency plan approved by the Director. The licensee may change the approved plan without the Director's approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Director and to affected off-site response organizations within six months after the change is made. 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 Director.

(8) 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 Rule R313-32 (incorporating 10 CFR 35.204 by reference). The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of each test that exceeds the permissible concentration listed in R313-32 (incorporating 10 CFR 35.204(a)) at the time of generator elution, in accordance with R313-32 (incorporating 10 CFR 35.3204).

(9) 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.

(10)(a) Authorization under Subsection R313-22-32(9) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(b) A licensee authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in Subsection R313-22-75(9)(a)(iv) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in Subsection R313-22-75(9)(c).

(c) A licensee that is a pharmacy authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in Subsection R313-22-75(9)(b)(ii); or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in Rule R313-32 (incorporating 10 CFR 35.27 by reference).

(d) A pharmacy authorized under Subsection R313-22-32(9) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of Subsection R313-22-75(9)(b)(v).

KEY: licenses, reciprocity, transportation, exemptions
Date of Enactment or Last Substantive Amendment: [~~October 13, 2017~~]
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-22. Specific Licenses.
R313-22-75. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material.

(1) Licensing the introduction of radioactive material in exempt concentrations into products or materials, and transfer of ownership or possession of the products and materials.

(a) The authority to introduce radioactive material in exempt concentrations into equipment, devices, commodities or other products may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555; and

(b) The manufacturer, processor or producer of equipment, devices, commodities or other products containing exempt concentrations of radioactive materials may obtain the authority to transfer possession or control of the equipment, devices, commodities, or other products containing exempt concentrations to persons who are exempt from regulatory requirements only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(2) Licensing the distribution of radioactive material in exempt quantities. 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 who are exempted from regulatory requirements may be obtained only from the Nuclear Regulatory Commission, Washington, D.C. 20555.

(3) Reserved

(4) Licensing the manufacture and distribution of devices to persons generally licensed under Subsection R313-21-22(4).

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under Subsection R313-21-22(4) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State will be approved if:

(i) the applicant satisfies the general requirements of Section R313-22-33;

(ii) 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:

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

(B) 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 a person will receive in one year, a dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1), and

(C) under accident conditions, such as fire and explosion, associated with handling, storage and use of the device, it is unlikely that a person would receive an external radiation dose or dose

commitment in excess of the following organ doses:

TABLE

Whole body; head and trunk; gonads; or lens of eye	active blood-forming organs; 150.0 mSv (15 rems)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter	2.0 Sv (200 rems)
Other organs	500.0 mSv (50 rems); and

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

(A) 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,

(B) the requirement, or lack of requirement, for leak testing, or for testing an "on-off" mechanism and indicator, including the maximum time interval for testing, and the identification of radioactive material by radionuclide, quantity of radioactivity, and date of determination of the quantity, and

(C) the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

(I) "The receipt, possession, use and transfer of this device, Model No. ....., Serial No. ....., are subject to a general license or the equivalent, and the regulations of the 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 label shall be printed with the words "CAUTION -RADIOACTIVE MATERIAL" and the name of the manufacturer or distributor shall appear on the label. The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(II) "The receipt, possession, use and transfer of this device, Model No. ....., Serial No. ....., are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited." The label shall be printed with the words "CAUTION - RADIOACTIVE MATERIAL" and the name of the manufacturer or distributor shall appear on the label. The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

(iv) 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 Section R313-15-901, and the name of the manufacturer or initial distributor.

(v) Each device meeting the criteria of Subsection R313-21-22(4)(c)(xiii)(A), bears a permanent label, for example, embossed, etched, stamped, or engraved, 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 Section R313-15-901.

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

(b) In the event the applicant desires that the device be required to be tested at intervals longer 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 the application sufficient information to demonstrate that a 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 Director will consider information which includes, but is not limited to:

(i) primary containment, or source capsule;

(ii) protection of primary containment;

(iii) method of sealing containment;

(iv) containment construction materials;

(v) form of contained radioactive material;

(vi) maximum temperature withstood during prototype tests;

(vii) maximum pressure withstood during prototype tests;

(viii) maximum quantity of contained radioactive material;

(ix) radiotoxicity of contained radioactive material; and

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

(c) In the event the applicant desires that the general licensee under Subsection R313-21-22(4), or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing 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 the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with this activity or activities, and basis for these estimates. The submitted information shall demonstrate that performance of this 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 dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1).

(d)(i) If a device containing radioactive material is to be transferred for use under the general license contained in Subsection R313-21-22(4), each person that is licensed under Subsection

R313-22-75(4) shall provide the information specified in Subsections R313-22-75(4)(d)(i)(A) through (E) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) a copy of the general license contained in Subsection R313-21-22(4); if Subsections R313-21-22(4)(c)(ii) through (iv) or R313-21-22(4)(c)(xiii) do not apply to the particular device, those paragraphs may be omitted;

(B) a copy of Sections R313-12-51, R313-15-1201, and R313-15-1202;

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

(D) Information on acceptable disposal options including estimated costs of disposal; and

(E) An indication that the Director's policy is to issue civil penalties for improper disposal.

(ii) If radioactive material is to be transferred in a device for use under an equivalent general license of the Nuclear Regulatory Commission, an Agreement State, or Licensing State, each person that is licensed under Subsection R313-22-75(4) shall provide the information specified in Subsections R313-22-75(4)(d)(ii)(A) through (D) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(A) A copy of an Agreement State's or Licensing State's regulations equivalent to Sections R313-12-51, R313-15-1201, R313-15-1202, and Subsection R313-21-22(4) or a copy of 10 CFR 31.5, 10 CFR 31.2, 10 CFR 30.51, 10 CFR 20.2201, and 10 CFR 20.2202. If a copy of the Nuclear Regulatory Commission regulations is provided to a prospective general licensee in lieu of the Agreement State's or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;

(B) A list of services that can only be performed by a specific licensee;

(C) Information on acceptable disposal options including estimated costs of disposal; and

(D) The name or title, address, and phone number of the contact at the Nuclear Regulatory Commission, Agreement State, or Licensing State from which additional information may be obtained.

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

(iv) Each device that is transferred after February 19, 2002 must meet the labeling requirements in Subsection R313-22-75(4)(a)(iii).

(v) If a notification of bankruptcy has been made under Section R313-19-34 or the license is to be terminated, each person licensed

under Subsection R313-22-75(4) shall provide, upon request, to the Director, the Nuclear Regulatory Commission, or an appropriate Agreement State or Licensing State, records of final disposition required under Subsection R313-22-75(4)(d)(vii)(H).

(vi) Each person licensed under Subsection R313-22-75(4) to initially transfer devices to generally licensed persons shall comply with the requirements of Subsections R313-22-75(4)(d)(vi) and (vii).

(A) The person shall report all transfers of devices to persons for use under the general license under Subsection R313-21-22(4) and all receipts of devices from persons licensed under Subsection R313-21-22(4) to the Director. The report must be submitted on a quarterly basis on Form 653, "Transfers of Industrial Devices Report" as prescribed by the Nuclear Regulatory Commission, or in a clear and legible report containing all of the data required by the form.

(B) The required information for transfers to general licensees includes:

(I) 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 alternative address for the general licensee shall be submitted along with information on the actual location of use.

(II) 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;

(III) The date of transfer;

(IV) The type, model number, and serial number of device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(C) 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 must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate persons.

(D) For devices received from a Subsection R313-21-22(4) general licensee, the report must 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.

(E) If the licensee makes changes to a device possessed by a Subsection R313-21-22(4) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

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

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

(H) If no transfers have been made to or from persons generally licensed under Subsection R313-21-22(4) during the reporting period,

the report must so indicate.

(vii) The person shall report all transfers of devices to persons for use under a general license in the Nuclear Regulatory Commission's, an Agreement State's, or Licensing State's regulations that are equivalent to Subsection R313-21-22(4) and all receipts of devices from general licensees in the Nuclear Regulatory Commission's, Agreement State's, or Licensing State's jurisdiction to the Nuclear Regulatory Commission, or to the responsible Agreement State or Licensing State agency. The report must be submitted on Form 653, "Transfers of Industrial Devices Report" as prescribed by the Nuclear Regulatory Commission, or in a clear and legible report containing all of the data required by the form.

(A) The required information for transfers to general licensee includes:

(I) 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 alternative address for the general licensee shall be submitted along with information on the actual location of use.

(II) 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;

(III) The date of transfer;

(IV) The type, model number, and serial number of the device transferred; and

(V) The quantity and type of radioactive material contained in the device.

(B) 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 must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate persons.

(C) For devices received from a general licensee, the report must 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.

(D) 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 must identify the general licensee, the device, and the changes to information on the device label.

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

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

(G) If no transfers have been made to or from a Nuclear Regulatory Commission licensee, or to or from a particular Agreement State or Licensing State licensee during the reporting period, this information shall be reported to the Nuclear Regulatory Commission or the responsible Agreement State or Licensing State agency upon

request of the agency.

(H) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by Subsection R313-22-75(4)(d)(vii). Records required by Subsection R313-22-75(4)(d)(vii)(H) must be maintained for a period of three years following the date of the recorded event.

(5) Special requirements for the manufacture, assembly or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble or repair luminous safety devices containing tritium or promethium-147 for use in aircraft for distribution to persons generally licensed under Subsection R313-21-22(5) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the applicant satisfies the requirements of 10 CFR 32.53 through 32.56 (2015) or their equivalent.

(6) Special requirements for license to manufacture or initially transfer calibration sources containing americium-241, plutonium or radium-226 for distribution to persons generally licensed under Subsection R313-21-22(7). An application for a specific license to manufacture calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed under Subsection R313-21-22(7) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the applicant satisfies the requirements of 10 CFR 32.57 through 32.59, and 10 CFR 70.39 (2015), or their equivalent.

(7) 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 R313-21-22(9) will be approved if:

(a) the applicant satisfies the general requirements specified in Section R313-22-33;

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

(i) iodine-125 in units not exceeding 370 kilobecquerel (ten uCi) each;

(ii) iodine-131 in units not exceeding 370 kilobecquerel (ten uCi) each;

(iii) carbon-14 in units not exceeding 370 kilobecquerel (ten 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 kilobecquerel (ten uCi) each;

(vii) selenium-75 in units not exceeding 370 kilobecquerel (ten uCi) each; or

(viii) mock iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 1.85 kilobecquerel (0.05 uCi) of americium-241 each;

(c) prepackaged units bear a durable, clearly visible label:

(i) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kilobecquerel (ten uCi) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1.85 megabecquerel (50 uCi) of hydrogen-3 (tritium); 740.0 kilobecquerel (20 uCi) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 1.85 kilobecquerel (0.05 uCi) of americium-241 each; and

(ii) displaying the radiation caution symbol described in Section R313-15-901 and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals";

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

(i) "This radioactive material shall 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 Nuclear Regulatory Commission or of a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

.....

Name of Manufacturer"

(ii) "This radioactive material shall 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 a Licensing State.

.....

Name of Manufacturer"

(e) 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 and storing radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in Section R313-15-1001.

(8) 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 R313-21-22(10) will be approved if:

(a) the applicant satisfies the general requirements of Section R313-22-33; and

(b) the criteria of 10 CFR 32.61, 32.62, 2015 ed. are met.

(9) Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under R313-32.

(a) An application for a specific license to manufacture and

distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Rule R313-32 will be approved if:

(i) the applicant satisfies the general requirements specified in Section R313-22-33;

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

(A) registered with the U.S. Food and Drug Administration (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);

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

(C) licensed as a pharmacy by a State Board of Pharmacy; or

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

(E) registered with a State Agency as a Positron Emission Tomography (PET) drug production facility.

(iii) 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; and

(iv) the applicant [~~satisfies~~]commits to the following labeling requirements:

(A) 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.

(B) 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.

(b) A licensee described by Subsections R313-22-75(9)(a)(ii)(C) or (D):

(i) May prepare radioactive drugs for medical use, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in Subsections R313-22-75(9)(b)(ii) and (iv), or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule R313-32 (incorporating 10 CFR 35.27 by reference).

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(A) this individual qualifies as an authorized nuclear pharmacist as defined in Rule R313-32 (incorporating 10 CFR 35.2 by

reference);

(B) this individual meets the requirements specified in Rule R313-32 (incorporating 10 CFR 35.55(b) and 10 CFR 35.59 by reference) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(C) this individual is designated as an authorized nuclear pharmacist in accordance with Subsection R313-22-75(9)(b)(iv).

(iii) The actions authorized in Subsections R313-22-75(9)(b)(i) and (ii) are permitted in spite of more restrictive language in license conditions.

(iv) May designate a pharmacist, as defined in Rule R313-32 (incorporating 10 CFR 35.2 by reference), as an authorized nuclear pharmacist if:

(A) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator produced radioactive material, and

(B) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(v) Shall provide to the Director:

(A) a copy of each individual's certification by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or Agreement State as specified in Rule R313-32 (incorporating 10 CFR 35.55(a) by reference)[~~ with the written attestation signed by a preceptor as required by Rule R313-32 (incorporating 10 CFR 35.55(b)(2) by reference)~~]; or

(B) the Nuclear Regulatory Commission or Agreement State license; or

(C) 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

(D) the permit issued by a U.S. Nuclear Commission master materials licensee; or

(E) 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 locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(F) a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to Subsections R313-22-75(9)(b)(ii)(A) and R313-22-75(9)(b)(ii)(C), the individual to work as an authorized nuclear pharmacist.

(c) 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:

(i) 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

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

(d) A licensee shall satisfy the labeling requirements in R313-22-75(9)(a)(iv).

([~~d~~]e) Nothing in Subsection R313-22-75(9) relieves the licensee from complying with applicable FDA, or Federal, and State requirements governing radioactive drugs.

(10) 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 under Rule R313-32 for use as a calibration, transmission, or reference source or for the uses listed in Rule R313-32 (incorporating 10 CFR 35.400, 10 CFR 35.500, 10 CFR 35.600, and 35.1000 by reference) will be approved if:

(a) the applicant satisfies the general requirements in Section R313-22-33;

(b) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) the radioactive material contained, its chemical and physical form and amount,

(ii) details of design and construction of the source or device,

(iii) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

(iv) for devices containing radioactive material, the radiation profile of a prototype device,

(v) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

(vi) procedures and standards for calibrating sources and devices,

(vii) legend and methods for labeling sources and devices as to their radioactive content, and

(viii) instructions for handling and storing the source or device from the radiation safety standpoint, these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided that instructions which are too lengthy for a label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(c) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the source or device is licensed by the Director for distribution to persons licensed pursuant to Rule R313-32 (incorporating 10 CFR 35.18, 10 CFR 35.400, 10 CFR 35.500, and 10 CFR 35.600 by reference) or under equivalent regulations of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; provided that labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

(d) the source or device has been registered in the Sealed Source

and Device Registry.

(e) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that a longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(f) in determining the acceptable interval for test of leakage of radioactive material, the Director shall consider information that includes, but is not limited to:

(i) primary containment or source capsule,

(ii) protection of primary containment,

(iii) method of sealing containment,

(iv) containment construction materials,

(v) form of contained radioactive material,

(vi) maximum temperature withstood during prototype tests,

(vii) maximum pressure withstood during prototype tests,

(viii) maximum quantity of contained radioactive material,

(ix) radiotoxicity of contained radioactive material, and

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

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

(a) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to Subsection R313-21-21(7) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) the applicant satisfies the general requirements specified in Section R313-22-33;

(ii) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or 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 an individual to receive a radiation dose in excess of ten percent of the annual limits specified in Subsection R313-15-201(1); and

(iii) 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.

(b) In the case of an industrial product or device whose unique benefits are questionable, the Director will approve an application for a specific license under Subsection R313-22-75(11) 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.

(c) The Director may deny an application for a specific license under Subsection R313-22-75(11) if the end use of the industrial

product or device cannot be reasonably foreseen.

(d) Persons licensed pursuant to Subsection R313-22-75(11)(a) shall:

(i) 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;

(ii) label or mark each unit to:

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

(B) 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 Nuclear Regulatory Commission or an Agreement State;

(iii) assure that the uranium before being installed in each product or device has been impressed with the following legend clearly legible through a plating or other covering: "Depleted Uranium";

(iv) furnish to each person to whom depleted uranium in a product or device is transferred for use pursuant to the general license contained in Subsection R313-21-21(5) or its equivalent:

(A) a copy of the general license contained in Subsection R313-21-21(7) and a copy of form DWMRC-12; or

(B) a copy of the general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to Subsection R313-21-21(7) and a copy of the Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in Subsection R313-21-21(7) and a copy of form DWMRC-12 with a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in Subsection R313-21-21(7);

(v) report to the Director all transfers of industrial products or devices to persons for use under the general license in Subsection R313-21-21(7). The report shall identify each general licensee by name and address, an individual by name or position who may constitute a point of contact between the Director 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 thirty days after the end of the calendar quarter in which the product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under Subsection R313-21-21(7) during the reporting period, the report shall so indicate;

(vi) provide certain other reports as follows:

(A) report to the Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the Nuclear Regulatory Commission general license in 10 CFR 40.25 (2010);

(B) report to the responsible state agency all transfers of devices manufactured and distributed pursuant to Subsection R313-22-75(11) for use under a general license in that state's regulations equivalent to Subsection R313-21-21(7),

(C) reports shall identify each general licensee by name and

address, an individual by name or position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within thirty days after the end of each calendar quarter in which a product or device is transferred to the generally licensed person,

(D) if no transfers have been made to Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the Nuclear Regulatory Commission, and

(E) if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency; and

(vii) records shall be kept showing the name, address and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in Subsection R313-21-21(7) or equivalent regulations of the Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in the product or device transferred, and compliance with the report requirements of Subsection R313-22-75(11).

KEY: specific licenses, decommissioning, broad scope, radioactive materials
Date of Enactment or Last Substantive Amendment: [~~October 13, 2017~~]
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-104

R313. Environmental Quality, Waste Management and Radiation Control, Radiation.
R313-32. Medical Use of Radioactive Material.
R313-32-1. Purpose and Authority.

(1) The purpose of this rule is to prescribe requirements and provisions for the medical use of radioactive material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of Rule R313-32 are in addition to, and not in substitution for, other sections of Title R313.

(2) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-104(4) and 19-3-104(7).

R313-32-2. Clarifications or Exceptions.

For the purposes of Rule R313-32, 10 CFR 35.2 through 35.7; 35.10(d) through 35.10(f); 35.11(a) through 35.11(b); 35.12; and 35.13(b) through [~~35.3067~~]35.3204 ([~~2010~~]2019) are incorporated by reference with the following clarifications or exceptions:

(1) The exclusion of the following:

(a) In 10 CFR 35.2, exclude definitions for "Address of Use," "Agreement State," "Area of Use," "Dentist," "Pharmacist," "Physician," "Podiatrist," and "Sealed Source";[~~ and~~]

(b) In 10 CFR 35.19, exclude "or the common defense and security ";

[~~(b)~~](c) In 10 CFR 35.3067, exclude ", with a copy to the Director, Office of Nuclear Material Safety and Safeguards[~~.~~]";

(d) In 10 CFR 35.3045(d), 10 CFR 3047(d), 10 CFR 35.3067, and 10 CFR 35.3204(b), exclude "By an appropriate method listed in Sec. 30.6(a) of this chapter,".

(2) The substitution of the following date references:

(a) "May 13, 2005" for "October 24, 2002"; and

(b) [~~"May 10, 2006" for "April 29, 2005."~~]"December 31, 2019" for "January 14, 2019."

(3) The substitution of the following rule references:

(a) "Rules R313-32 and R313-15" for reference to "this part and 10 CFR Part 20" in 10 CFR 35.61(a);

(b) "Rule R313-15[~~or~~] for reference to "Part 20 of this chapter" in 10 CFR 35.70(a) and 10 CFR 35.80(a)(4);

[~~(b)~~](c) "Rules R313-19 and R313-22" for reference to "Part 30 of this chapter" in 10 CFR 35.18(a)(4);

(d) "Rules R313-19 and R313-22 or equivalent Nuclear Regulatory Commission or Agreement State requirements for reference to "10 CFR Part 30 or the equivalent requirements of an Agreement State" in 10 CFR 35.49(c)[~~ except for the reference to "Part 30 of this chapter" found in 10 CFR 35.65(d)~~];

[~~(c)~~](e) "10 CFR Part 30" for reference to "Part 30 of this chapter" as found in 10 CFR 35.65[~~(d)~~](a)(4);

[~~(d)~~](f) "Rules R313-15[~~ and~~], R313-19, and R313-22" for reference to "parts 20 and 30 of this chapter" as found in 10 CFR 35.63(e)(1);

[~~(e)~~](g) "Section R313-12-110" for reference to "Sec. 30.6 of this chapter" as found in 10 CFR 35.14(c).[~~or for reference to~~

~~"Sec. 30.6(a)" or for reference to "Sec. 30.6(a) of this chapter"~~];

[~~(f)~~](h) "Section R313-15-101" for reference to "Sec. 20.1101 of this chapter" as found in 10 CFR 35.24(a);

[~~(g)~~](i) "Subsection R313-15-301(1)(a)" for reference to "Sec. 20.1301(a)(1) of this chapter" as found in 10 CFR 35.310(a)(2)(i) and 10 CFR 35.410(a)(4)(i);

[~~(h)~~](j) "Subsection R313-15-301(1)(c)" for reference to "Sec. 20.1301(c) of this chapter" as found in 10 CFR 35.310(a)(2)(ii) and 10 CFR 35.410(a)(4)(ii);

[~~(i)~~](k) "Section R313-15-501" for reference to "Sec. 20.1501 of this chapter" as found in 10 CFR 35.652(a);

[~~(j)~~](l) "Section R313-18-12" for reference to "Sec. 19.12 of this chapter" as found in 10 CFR 35.27(a)(1), 10 CFR 35.27(b)(1), 10 CFR 35.310, and 10 CFR 35.410;

[~~(k)~~](m) "Rules R313-19, R313-22 and Subsection R313-22-75(10) or equivalent U.S. Nuclear Regulatory Commission or Agreement State [~~regulations~~]requirements" for reference to "10 CFR Part 30 and Sec. 32.74 of this chapter or equivalent requirements of an Agreement State[~~,~~]" as found in 10 CFR 35.[~~65(b)~~]49(a);

[~~(l)~~](n) "Subsection R313-22-75(10) or equivalent Nuclear Regulatory Commission or Agreement State requirements" [~~for reference to "10 CFR 32.74 of this chapter," or for reference to "Sec. 32.74 of this chapter" except for the reference to "Sec. 32.74 of this chapter" found in 10 CFR 35.65(b)~~]for references to "Sec. 32.74 of this chapter or equivalent Agreement State regulations found in 10 CFR 35.65(a)(1) and 10 CFR 35.65(a)(2);

[~~(m)~~](o) "Rule R313-70" for reference to "Part 170 of this chapter";

[~~(n)~~](p) "Subsection R313-19-34(2)" for reference to "Sec. 30.34(b) of this chapter" as found in 10 CFR 35.14(b)(4);

[~~(o)~~](q) "[~~Rule~~]Section R313-22-50" for reference to "Part 33 of this chapter" in 10 CFR 35.15;

[~~(p)~~](r) "Subsection R313-22-50(2)" for reference to "Sec. 33.13 of this chapter" in 10 CFR 35.12(e);

[~~(q)~~](s) "Subsection R313-22-75(9)(b)(iv)" for reference to "Sec. 32.72(b)(4)" in the definition of Authorized Nuclear Pharmacist in 10 CFR 35.2;

[~~(r)~~](t) "Subsection R313-22-75(9) or equivalent Nuclear Regulatory Commission or Agreement State requirements[~~, 10 CFR 32.72,~~]" for reference to "Sec. 32.72 of this chapter or equivalent Agreement State requirements" as found in 10 CFR 35.63(b)(2)(i), 10 CFR 35.63(c)(3)(i), 10 CFR 35.100(a)(1), 10 CFR 35.200(a)(1), and 10 CFR 35.300(a)(1);[

~~(s) "Subsection R313-22-75(9)(b)(v)" for reference to "Sec. 32.72(b)(5)"~~

~~(t) "(c)(1) or (c)(2)" for reference to "(c)(1)" in 10 CFR 35.50(d);~~

~~(u) "35.600 or 35.1000" for reference to "35.600" in 10 CFR 35.41(b)(1);~~] and

[~~(v)~~](u) "Subsection R313-22-32(9)[~~, 10 CFR 30.32(j),~~] or equivalent Nuclear Regulatory Commission or Agreement State requirements" for reference to "Sec. 30.32(j) of this chapter or equivalent Agreement State requirements" as found in 10 CFR

35.63(b)(2)(iii), 10 CFR 35.63(c)(3)(ii), 10 CFR 35.100(a)(2), 10 CFR 35.200(a)(2), or 10 CFR 35.300(a)(2).

(4) The substitution of the following terms:

(a) "radioactive material" for reference to "byproduct material";

(b) [~~"original" for "original and one copy";~~]"a Director, a Nuclear Regulatory Commission, or Agreement State" for reference to "an NRC or Agreement State" in 10 CFR 35.63(b)(2)(ii), 10 CFR 35.100(c), 10 CFR 35.200(c), or 10 CFR 35.300(c);

(c) "Director is (801) 536-0200 or after hours, (801) 536-4123" for "NRC Operations Center is (301) 816-5100[~~951-0550~~]" as found in the footnote included for 10 CFR 35.3045(c);

(d) "Form DWMRC-01, 'Application for Radioactive Material License[~~-Application~~]'" for reference to "NRC Form 313, 'Application for Material License'" as found in 10 CFR 35.12(b)(1), 10 CFR 35.12(c)(1)(i) and 10 CFR 35.18(a)(1);

(e) "Form DWMRC-01" for reference to "NRC Form 313" as found in 10 CFR 35.12(c)(1)(ii);

[~~(e)~~](f) "[~~State of Utah radioactive materials~~]medical use license issued by the Director" for reference to "NRC medical use license" in 10 CFR 35.6(c);

[~~(f)~~](g) "[~~the~~]Director, the U.S. Nuclear Regulatory Commission, or an Agreement State" for reference to "[~~the~~]Commission or Agreement State" in 10 CFR 35.2 in the definitions for Authorized Medical Physicist (2)(i), Authorized Nuclear Pharmacist (2)(iii), Radiation Safety Officer (2)(i), 10 CFR 35.57(b)(1) (first instance), 10 CFR 35.57(b)(2) (first instance), 10 CFR 35.433(a)(2)(i); or for references to "[~~the~~]Commission or an Agreement State" in 10 CFR 35.2 in the definitions for Associate Radiation Safety Officer (2)(i), Ophthalmic Physicist (2)(i), 10 CFR 35.11(a), 10 CFR 35.50(a), 10 CFR 35.50(a)(2)(ii)(A), 10 CFR 35.50(c)(1), 10 CFR 35.51(a), 10 CFR 35.51(a)(2)(i), 10 CFR 35.55(a), 10 CFR 35.190(a), 10 CFR 35.290(a), 10 CFR 35.390(a), 10 CFR 35.392(a), 10 CFR 35.394(a), 10 CFR 35.396(a)(3), 10 CFR 35.433(a)(2)(i), 10 CFR 35.490(a), 10 CFR 35.590(a), 10 CFR 35.605(a), 110 CFR 35.605(b), 10 CFR 35.605(c), 10 CFR 35.655(b) and 10 CFR 35.690(a);

[~~(g)~~](h) "[~~an~~]Director, [~~the~~]a U.S. Nuclear Regulatory Commission, or an Agreement State" for references to "[~~a~~]Commission or Agreement State" in 10 CFR 35.2 in the definitions for Authorized Medical Physicist (2)(iii), Authorized Nuclear Pharmacist (2)(i), Authorized User (2)(i), Authorized User (2)(iii), Ophthalmic Physicist (2)(ii), 10 CFR 13(b)(4)(ii), 10 CFR 35.14(a)(2)(second instance), 10 CFR 35.57(a)(1)(second instance), 10 CFR 35.57(b)(1)(second instance), 10 CFR 35.57(b)(2)(second instance), 10 CFR 35.433(a)(2)(ii)(second instance); or for references to "Commission or an Agreement State" in 10 CFR 35.50(c)(2)(second instance);

[~~(h)~~](i) [~~"Equivalent U.S. Nuclear Regulatory Commission or Agreement State~~]"license issued by the Director, the Nuclear Regulatory Commission, or the Agreement State" for reference to [~~"equivalent Agreement State~~]"Commission or Agreement State license" [~~- as found -~~]in 10 CFR 35.14(a)(2)(first instance)[~~63(b)(2)(i), 10 CFR 35.63(c)(3), 10 CFR 35.65(a), 10 CFR 35.100(a), 10 CFR 35.200(a),~~

~~and 10 CFR 35.300(a)~~];

[~~(i)~~](j) "Director" for reference to "NRC Operations Center" in 10 CFR 35.3045(c),[~~and~~] 10 CFR 35.3047(c), and 10 CFR 35.3204(a);

(k) "license issued by the Director, the Nuclear Regulatory Commission or an Agreement State" for reference to "Commission or Agreement State license" in 10 CFR 35.13(b)(4)(i), 10 CFR 35.14(a)(2)(first instance), 10 CFR 35.50(b)(1)(ii) or for reference to "Commission or an Agreement State license" in 10 CFR 35.50(b)(1)(ii), 10 CFR 35.50(c)(2), and 10 CFR 35.57(a)(2);

[~~(j) "Utah Division of Waste Management and Radiation Control" for reference to "NRC Operations Center" in Footnote 3 to 10 CFR 35.3045;~~

] [~~(k)~~](l) "Director at the address specified in Section R313-12-110" for reference to "appropriate NRC Regional Office listed in Sec. 30.6 of this chapter" in 10 CFR 35.3045(d), 10 CFR 35.3047(d), 10 CFR 35.3067, and 10 CFR 35.3204(b);

[~~(l)~~](m) "[~~Utah Waste Management and Radiation Control~~]Board" for reference to "Commission" in 10 CFR 35.18(a)(3)(second instance) and 10 CFR 35.19;

[~~(m)~~](n) "Director" for reference to "Commission" in [~~10 CFR 35.10(b),~~]10 CFR 35.[~~12(d)(2)~~]12(d)(4), 10 CFR 35.14(a)[~~(first instance)~~], 10 CFR 35.14(b), 10 CFR 35.18(a), 10 CFR 35.18(a)(3)(first instance), 10 CFR 35.18(b), 10 CFR 35.24(a)(1), 10 CFR 35.24(c), 10 CFR 35.26(a), and 10 CFR 35.1000(b);

[~~(n)~~](o) "[~~the~~]Director" for reference to "NRC" in [~~10 CFR 35.13(b)(4)(i),~~]10 CFR 35.3045(g)(1), [~~and~~]10 CFR 35.3047(f)(1), and 10 CFR 35.3204(a)(second instance);

[~~(o)~~](p) [~~"the U.S. Nuclear Regulatory Commission or an Agreement State" for reference to "an Agreement State" in 10 CFR 35.49(a) and 10 CFR 35.49(c)~~]"Nuclear Regulatory Commission" for reference to "Commission" in 10 CFR 35.67(b)(2);

[~~(p)~~](q) [~~"Director, a U.S. Nuclear Regulatory Commission, or Agreement State~~]"Director" for reference to [~~"NRC or Agreement State~~]"NRC" in 10 CFR 35.[~~63(b)(2)(ii)~~]3045(g)(1), 10 CFR 35.[~~100(c)~~]3047(f)(1), [~~10 CFR 5.200(c),~~]and 10 CFR 35.[~~300(c)~~]35.3204(a)(second instance); and

[~~(q)~~](r) [~~In 10 CFR 35.75(a) "Footnote 1", substitute "The current version of NUREG-1556, Vol. 9" for "NUREG-1556 Vol. 9,"~~]"the Director" for reference to "NRC" in 10 CFR 35.13(b)(4)(i);

(s) "licenses issued by the Director" for reference to "NRC licenses" in 10 CFR 35.57(c);

(t) "Director, the Nuclear Regulatory Commission, or an Agreement State" for reference to "NRC" in 10 CFR 35.13(b)(5), 10 CFR 35.14(a)(2), 10 CFR 35.57(b)(3), and 10 CFR 35.57(a)(4);

(u) "(c)" for reference to "(b)" in 10 CFR 35.92.

(5) The addition of the following to 10 CFR 35.92:

" (b) The Director may approve a radioactive material with a physical half-life of greater than 120 days but less than 175 days for decay-in-storage before disposal without regard to its radioactivity on a case by case basis if the licensee:

(1) Requests an amendment to the licensee's radioactive materials license for the approval;

(2) Can demonstrate that the radioactive waste will be safely

stored, and accounted for during the decay-in-storage period and that the additional radioactive waste will not exceed the licensee's radioactive waste storage capacity; and

(3) Commits to monitor the waste before disposal as stated in paragraphs (a)(1) and (a)(2) of this section before the waste is disposed."

KEY: radioactive materials, radiopharmaceutical, brachytherapy, nuclear medicine
Date of Enactment or Last Substantive Amendment: [~~October 13, 2010~~]
Notice of Continuation: July 1, 2016
Authorizing, and Implemented or Interpreted Law: 19-3-104; 19-6-107

Regulation Crosswalk for RATS ID # 2018-01

NRC Requirements	DWMRC Requirements
19.12	R313-18-12
20.1101	R313-15-101
20.1501	R313-15-501
30.6	R313-12-110
32.72	R313-22-75(9)
32.74	R313-22-75(10)
33.13	R313-22-50(2)
10 CFR 20	R313-15
10 CFR 32.74	R313-22-75(10)
10 CFR 35	R313-32
10 CFR Part 30	R313-19 and R313-22
20.1301(a)(1)	R313-15-301(1)(a)
20.1301(c)	R313-15-301(1)(c)
30.32(j)	R313-22-32(9)
30.34(b)	R313-19-34(2)
32.72(b)(4)	R313-22-75(9)(b)(iv)
Part 170	R313-70
Part 30	R313-19 and R313-22
Part 33	R313-22-50
Parts 20 and Parts 30	R313-15, R313-19, and R313-22